Region 4 U.S. Environmental Protection Agency Laboratory Services and Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Internal Audits	ID: LSASDPROC-1004-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 & Science Division (LSASD) to maintain conformance to technical and quality system requirements. This document defines the procedure used to conduct internal audits of the LSASD Quality Management System (QMS) and technical operations in order to identify areas requiring corrective action, areas that would benefit from quality improvements and commendable practices.

Scope/Application

The requirements of this procedure apply to all personnel who perform work under the LSASD QMS. 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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1.0 Procedure

1.1 Summary

The goal of the internal auditing program is to provide a means of evaluating the adequacy, implementation and effectiveness of the LSASD QMS. The adequacy of the QMS is evaluated by determining if the applicable policies, procedures, guidance documents, practices, facilities, equipment and materials are adequate for the task; implemented and utilized as intended; and are adequate for achieving intended results.

This procedure discusses how internal audits will be conducted in order to determine if quality management and technical operations within LSASD are in compliance with requirements of the LSASD QMS. Internal audits will be scheduled annually, at a minimum, by the Quality Assurance Coordinator (QAC). Internal audits will be conducted by trained staff who are, whenever possible, independent of the activity being audited. In the event that audit findings cast doubt on the correctness and/or validity of reported results, the QAC will initiate a corrective action to address those audit findings, including notifying the customer whose work has been affected in a timely manner.

1.2 Audit Schedule and Tracking

Annually, the System Managers will develop an audit schedule for the upcoming year using the LSASD Audit Schedule Form (LSASD FORM-1013). The schedule will address both internal and external audits. Once the audit schedule is developed it will be distributed to LSASD management and then posted on the LSASD Local Area Network (LAN). During a typical year, internal audits can be scheduled anytime throughout the year, however, it is desired that they conducted during the September to December time frame.

Based on work type or function, it may be necessary to conduct internal audits that focus on specific LSASD Branches or workgroups separately but regardless of the yearly audit program structure the focus of internal audits will be the components of the LSASD QMS and technical operations, previous internal and external audit findings and corrective action requests. All aspects of the QMS will be audited each year but may be conducted over several internal audits throughout the year. For accredited activities, the internal audit process shall cover all elements of the applicable ISO/IEC 17025 standard. Additional audits may be scheduled based on requests and/or recommendations of management. The QAC will update the audit schedule if audits are added during the year.

Audits will be uniquely identified with a to facilitate tracking. Prior to the audit the appropriate System Manager will create a project number in R4LIMS to be used as its unique identifier and tracking.

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1.3 Audit Plan

Prior to an internal audit, the QAC will prepare an audit plan that will describe:

1.3.1 the audit objectives;
1.3.2 the audit criteria;
1.3.3 the audit scope;
1.3.4 the dates and place where the audit activities will be conducted;
1.3.5 the expected time and duration of the audit; and
1.3.6 the roles and responsibilities of the audit team members.

The QAC will define the audit objectives, scope and criteria. The audit objectives define what is to be accomplished by the audit. The audit scope describes the extent and boundaries of the audit such as the activities and processes to be audited. The audit criteria are used as a reference against which conformity is determined and may include, but not limited to applicable policies, procedure, standards and management system requirements.

Prior to the Internal Audit, the Internal Audit Plan shall be approved by the appropriate management team. Once the plan has been approved the QAC will then notify staff that will be audited.

1.4 Audit Personnel Qualifications

Audits will be conducted by trained auditors. The QAC and management are responsible for identifying training opportunities for LSASD Internal Auditors. The training will address the basics needed to plan, conduct, record and report audits of the LSASD QMS. The QAC will keep a record for each auditor in their workgroup showing training and experience accumulated by conducting internal audits. Auditor training can also be provided by trained auditors during LSASD internal audits and a record of the training will be documented in the LSASD Training Evaluation Form (LSASD FORM-1022). Training records will be updated by the appropriate QAC on a yearly basis after the completion of that year's internal audit.

In order to maintain status as an internal auditor, an individual must participate in at least one internal audit within four years or attend auditor training.

1.5 Audit Team

The QAC in consultation with management will assemble an audit team and designate an audit team leader. The audit team may be sub-divided into several smaller teams depending on the scope of the audit. A team can consist of one or more individuals as needed. The audit team leader(s) will be responsible for facilitating the audit and preparing the audit report for his/her team. Audit team(s) will be, whenever possible, independent of the activity to be audited.

1.6 Audit Process

Prior to the start of audit activities, an opening meeting shall be conducted by the QAC with the appropriate staff and management. The System Manager shall review the schedule and responsibilities with the staff and management. Attendance shall be documented via a sign-in sheet at the opening and closing meetings and retained for the audit file.

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Internal audits will include interviews; examination of documents and records; and observation of pertinent facilities, equipment, and activities. Generally, internal audits will consist of a quality system review, project file review, and a method witness per discipline as outlined on LSASD scope of accreditation, which for field processes may be conducted during normal work activities during the year. For drinking water methods, a technical procedure review must also be conducted per year. Audits will be scheduled and announced in advance of the actual audit.

The audit team(s) will evaluate the adequacy, implementation and effectiveness of their assigned audit task. This evaluation will determine if the applicable policies, procedures and guidance documents are implemented as intended and are achieving intended results. Audit team(s) findings, including nonconformances and opportunities for improvements, and commendable practices will be documented utilizing the LSASD Audit Checklist (LSASD FORM-1015). In addition, the audit checklist addresses:

1.6.1. The subject to be evaluated.
1.6.2. The document(s)/activity upon which the audit is based.
1.6.3. The questions asked and responses received.
1.6.4. The information provided by the personnel that were audited

After the audit is conducted, the team(s) will brief the auditees, the QAC and affected management regarding the results. This discussion will include nonconformances, opportunities for improvement and commendable practices. This meeting provides an opportunity for reviewing, clarifying and verifying information gathered during the audit.

Upon conclusion of the internal audit, each audit team leader shall submit their completed forms and audit notes to the QAC by the designated timeframe listed in the audit plan. The QAC shall review the findings, providing clarification if needed, and compile a draft internal audit report. The QAC shall distribute the draft report to appropriate management for feedback on the nonconformances, opportunities for improvement and/or commendable practices. If there are any misunderstandings on behalf of the audit team, management shall clarify any issues within a week from when the draft report was distributed. Once all clarifications have been addressed the QAC will finalize the report and disseminate for the appropriate management signatures. When appropriate, a notification will be sent out to staff informing them that the Audit Report has been finalized and the location that it can be viewed.

Nonconformances will be remediated via the LSASD corrective action process described in the LSASD Operating Procedure for Actions and Improvements (LSASD PROC-1005). The QAC will monitor progress of the corrective actions and conduct follow-up audits as necessary to ensure the issue has been resolved. Opportunities for improvements which results from an audit, should be reviewed by the QAC as a candidate for preventive action or quality improvement. Preventive actions and quality improvements will be handled in accordance with the LSASD Operating Procedure for Actions and Improvements (LSASD PROC-1005).

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2 Definitions

Audit - Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Audit Criteria - Set of policies, procedures or requirements.

Objective Evidence - Records, statements of fact or other information, which are relevant to the audit criteria and verifiable

Auditee - Organization or individuals being audited.

Auditor - Person with the competence to conduct an audit.

Audit Team - One or more auditors conducting an audit.

Nonconformance - Departure from or absence of a specified requirement.

Opportunity for Improvement (OFI) - Observation which may help improve method performance or prevent non-conforming work from occurring in the future.

Method witness – consists of reviewing the written procedure and observing the analyst performing the analysis

Quality system review - review of processes to verify continual compliance to requirements of the LSASD QMS and the ISO/IEC 17025

Project file review – review of project file for content and accuracy against the appropriate operating procedures and additional requirements.

Technical Procedure Review - For drinking water methods, the ASB operating procedure being reviewed will be assessed against the appropriate method. For drinking water methods, they are prescriptive and cannot be altered.

3 References

LSASD Audit Schedule, LSASD FORM-1013, Most Recent Version

LSASD Internal Audit Checklist, LSASD FORM-1015, Most Recent Version

LSASD Internal Audit Report, LSASD FORM-1016, Most Recent Version

ISO 19011: 2002(E), Guidelines for quality and/or environmental management systems auditing

ISO/IEC 17025: 2017, Third edition 11/2017

LSASD Training Evaluation Form, LSASD FORM-1022, Most Recent Version

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LSASD Operating Procedure for Actions and Improvements, LSASD PROC-1005, Most Recent 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 Document Control Coordinator.

History	Effective Date
LSASDPROC-1004-R2, Internal Audit, replaces SESDPROC-1004-R1 Clarifying language added throughout. Updated references to the current ISO Standard	June 6, 2020
LSASDPROC-1004-R1, Internal Audits, replaces SESDPROC-1004-R0 Updated document name to reflect the new Division name post re-alignment. Replaced all references to the Systems Manager with Quality Assurance Coordinator (QAC). Added language to Section 1.3 to allow for additional audits throughout the year for newly developed procedures. Added note to Section 1.3.	February 28, 2020
SESDPROC-1004-R0, Internal Audits, Original Issue	October 1, 2017

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