Region 4 U.S. Environmental Protection Agency Laboratory Services & Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Annual LSASD Management Review	**ID: LSASDPROC-1007-R2**
Issuing Authority: Deputy Director, LSASD	
Effective Date: September 10, 2021	**Next Review Date: September 10, 2025**
Method Reference: NA	**Author: Jeff Hendel**

Purpose

This Standard Operating Procedure (SOP) is specific to the Region 4 Laboratory Services & Applied Science Division (LSASD) to maintain conformance to technical and quality system requirements. This procedure describes the annual LSASD Management Review of the quality system and environmental testing activities.

Scope/Application

The LSASD Quality Management System (QMS) shall be internally reviewed, at least, annually to evaluate its continued suitability and effectiveness and to consider any necessary changes or improvements. Annual Management Review is a requirement of the ISO/IEC 17025:2017 Accreditation Standard and will be conducted as detailed in this SOP. 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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Procedural Section

1. Procedure

1.1. During the first quarter of each calendar year, the Division Quality Assurance Coordinator (QAC) or designee will meet with the Division Director, Deputy Division Director, Regional Quality Assurance Manager (RQAM), and Division Management (Branch Chiefs and Section Chiefs) to assess the LSASD Quality System and evaluate its continuing suitability and effectiveness. Additional staff, as requested, may also be in attendance. All changes or improvements to the quality system over the year will be introduced during this review. An agenda detailing the following discussion elements will be provided to all attendees:

- Other relevant factors, such as quality control activities, resources and staff training
- Suitability of Policy and Procedures
- Changes to Volume and/or Type of Work
- Summary of Internal Audit Conducted Over the Year
- Corrective Actions, Preventative Actions and Quality Improvements
- External Audits
- Staff Training
- Proficiency Tests
- Customer Feedback
- Complaints
- Results of Risk Identification
- Action Items from Previous Management Review
- Other relevant factors such as quality control activities and resources
- Recommendations for Improvement/Additional; Discussion Items

1.2. Any findings of nonconformance within the quality system that result from the Management Review will be handled as a corrective action according to the LSASD Procedure for Actions, Improvements, and Risk (LSASDPROC-1005). Management will review and/or act on proposed actions or improvements. Any corrective actions that result from the Management Review will be assigned an appropriate timeframe for completion as part of the Management Review meeting. The QAC will coordinate the tracking of these actions.

1.3. The Management Review agenda and any findings resulting from the Management Review will be recorded in the minutes of the meeting, which will be filed with records of assessments of the quality system. Records associated with corrective, preventive actions, quality improvements, or Risk will also be maintained by the QAC, as applicable.

2. Definitions

2.1. Management Review: Qualitative assessment of an organization's overall quality system and the effectiveness of its implementation.

2.2. Quality System: A system of quality assurance practices and operational procedures.

2.3. ISO/IEC 17025:2017: International standard that specifies the general requirements for the competency to carry out tests and/or calibrations.

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

2.5. Non-Conformance: Departure from or absence of a specified requirement.

2.6. Formal Corrective Action: Higher level corrective action that includes a multi-step process of describing the issue, performing a root cause analysis leading to a proposed action, acceptance, and closure.

2.7. Preventive Action (PA): A proactive process to identify opportunities for improvement or potential risks. PAs are identified as systematic and will be taken through the same multi-step process as formal corrective action, a root cause analysis may not be required for preventive actions.

2.8. Quality Assurance: All planned and systematic activities necessary to provide confidence that a product satisfies given acceptance criteria. Quality assurance activities are independent.

2.9. Quality System: Defined system of quality assurance practices and operational policies.

2.10. Risk: The laboratory shall consider the risks and opportunities associated with laboratory activities to give assurance that the management system achieves its intended results; enhance opportunities to achieve the purpose and objectives of the lab; prevent, or reduce, undesired impacts and potential failures in the lab; and achieve improvements.

2.11. For additional definitions, see the Laboratory Operations and Quality Assurance Manual (LOQAM), Section 5.2.

3. Management Review Meeting

3.1. A formal meeting will be scheduled and conducted by the QAC for presenting the key elements described above. Each meeting can be in an in-person setting or held remotely using an Internet based platform such as Microsoft Teams. A meeting attendance record should be created for each management review meeting that is conducted. The attendance list should be scanned and placed on the LAN for future reference.

3.2. For assistance during the meeting, the QAC should request an individual to take minutes/notes during the meeting. The meeting minutes are recorded on Form LSASDFORM-1023, which is located on the LAN. The meeting minutes form should be completed and submitted to the QAC within 30-days of the scheduled meeting conclusion.

3.3. As a curtesy and for efficiency, the RQAM may elect to present an update and activities associated with the Regional Quality Assurance System. The RQAM is responsible for the minutes/notes and action items that result from the management review meeting.

4. Records

4.1. It is the responsibility of the QAC to maintain the meeting minutes and resulting action items associated with each management meeting. Any corrective actions will follow the corrective action process defined in SOP LSASDPROC-1006. All documents related to the management meeting is kept on the LAN at:

M:\LSASD Quality System Documentation\Divisional Quality System Documentation\Management Review

4.1.1. Where possible, the QAC and RQAM should strive to use electronic files for record keeping for meeting the Agency's goal for going paperless.

4.1.2. The RQAM will be responsible for maintaining and record keeping about the Regional Quality System.

References

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

Laboratory Operations and Quality Assurance Manual, current version.

LSASD Operating Procedure for Internal Audits (LSASD PROC-1004), current version

LSASD Operating Procedure for Actions, Improvements, and Risk (LSASDPROC-1005), current version

Revision History

History	Effective Date
SESDPROC-1007-R0, Management Review	October 1, 2017
LSASDPROC-1007-R1, Management Review, replaces SESDPROC-1007-R0 Updated the document name to reflect the Division name post re-alignment. Replaced LQM and FQM with QAC throughout. Included the RQAM and Division Management as attendees to the Management Review meeting in Section1. Updated the review topics to be reflective of the requirements of ISO 17025:2017 standard. Updated ISO standard reference to the 2017 standard.	February 28, 2020
Document revised to include Risk Management in the presentation for the Management Review. Added a section for conducting the management review meeting and a section for records. Document revision number changed to R2.	September 2021