Region 4 U.S. Environmental Protection Agency Laboratory Services and Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Actions, Improvements, and Risk	**ID: LSASDPROC-1005-R1**
Issuing Authority: LSASD Deputy Director	
Review Issue Date: July 21,2021	**Next Review Due: July 21, 2025**

Purpose

This Operating Procedure is specific to the Region 4 Laboratory Services and Applied Science Division (LSASD) to maintain conformance to technical and administrative quality system requirements. This procedure defines the process for handling Corrective Actions, Preventive Actions, Risk Assessments, Quality Improvements and Correction of Work associated with the LSASD Quality Management System.

Scope/Application

The requirements of this procedure apply to all personnel who perform work under the LSASD Quality Management System. 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.

Note: LSASD is currently migrating to a paperless organization. As a result, this SOP will allow for the use of electronic logbooks, checklists, and report forms as they are developed, which will also be housed in the LIMS and traceable to each project. LSASD is committed to maintaining its quality system by continued traceability of original observations in the final report as migration to an electronic system occurs.

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Procedural Section

1. Introduction

1.1. This procedure discusses how corrective action, preventive actions, quality improvements and correction, and risk assessments of work will be handled. Corrective actions will be implemented to address nonconforming work within the LSASD QMS that is systematic in nature. Preventive Actions will be taken to prevent potential nonconformances from occurring or when there is the potential for a nonconformance to recur. Quality improvements will be implemented to improve the effectiveness of the QMS and technical operations. A correction of work will be utilized for nonconformances that are onetime occurrences, nonsystematic in nature. Risk identification, evaluation, and actions with the implementation of corrective actions and opportunities for improvements will be assessed.

1.2. Any person within or outside of LSASD can identify an opportunity for actions or improvements. They may be identified through, but not limited to audits (internal and external), complaints (internal and external), customer feedback or quality assessments, and staff suggestions. Quality assessments include observations of work, internal/external reviews of quality system procedures, quality control checks, competency/proficiency test evaluations and management reviews. The Quality Assurance Manager will review the pertinent information and in consultation with affected management will make the determination if an action is needed.

2. Procedure

2.1. Corrective actions, preventive actions, quality improvements, and risk assessments will be uniquely identified to facilitate tracking. An eight-digit identification number will be assigned to each action or improvement by the Quality Assurance Manager (QAM) for actions and improvements. Tracking numbers will begin with L for the Laboratory Service Branch, F for the Field Services Branch, and Q for the Quality Assurance and Program Services Branch. The next two letters will identify its category, CA for corrective actions, PA for preventive actions, QI for quality improvements, and RA for risk assessments. The first four digits will represent the calendar year that the action was initiated. The last three digits will begin at 001 and increase sequentially with each additional action or improvement. The last three digits will start over at 001 at the beginning of each calendar year (Ex. LCA2021-001 for an Laboratory Service Branch corrective action). The QAM will track actions and improvements using the most recent version of the LSASD Action, Improvement, Risk Form (LSASDFORM-1001).

2.2. Each Corrective action, preventive action, quality improvement, and Risk assessment will be documented using the LSASD Action, Improvement, Risk Form (LSASDFORM-1001). Upon identification or notification of the need for an action or improvement, the following procedure will be followed:

2.2.1. The QAM will assign an identification number to facilitate tracking.

2.2.2. The QAM will work with the appropriate section chief to document the problem, potential problem, improvement opportunity, or risk.

2.2.3. The appropriate branch chief and/or section chief will designate and assign personnel to address the action, risk, or improvement and assign a reasonable target date for completion. The designated personnel make-up the Corrective Action Team (CAT), which will address the actions, risks, and/or improvements. If determined necessary, the QAM can be part of the CAT.

2.2.3.1. The CAT will evaluate the issue and prepare an action plan. The action plan will be as detailed as deemed necessary to address the problem, provide estimated target dates for implementation and designate individual(s) responsible for completing the task.

2.2.3.2. For a corrective action, the CAT will determine the root cause of the problem. This can be done utilizing the "5-Why Process" or "Fishbone Diagrams." Preventive actions, risk assessments, and quality improvements do not require a root cause analysis.

2.2.3.3. A proposed action will be developed by the CAT that will determine how to correct the problem and prevent it from recurring; prevent a nonconformance from happening in the future; or recommend improvements to the LSASD process, as appropriate.

2.2.3.4. The CAT shall consider the risks and opportunities associated with divisional activities in order to; give assurance the management system achieves its intended results, enhances opportunities to achieve the purpose and objectives of the division, prevent or reduce undesired impacts and potential failures , and achieve improvement.

2.2.3.5. The CAT will present the proposed solution, including target dates and the personnel responsible for completing the action to the affected management and the QAM for approval. Once approved, the solution will be implemented by the appropriate personnel.

2.2.4. As a result of the proposed action, if any policies or technical/administrative procedures require updates, the QAM will ensure they are conducted in accordance with the LSASD Operating Procedure for Document Control (LSASDPROC-1000).

2.2.5. The QAM will notify all affected personnel either verbally through training or in writing (email or memo) of any changes that result from the action and improvement process.

2.2.6. Management is responsible for ensuring the required changes are implemented through direct communication with their staff and reviews of project records.

2.2.7. The QAM, or designee, will formally monitor the effectiveness of corrective actions by conducting a review of the corrective action. The time frame for reviews will be determined by the QAM and will be based on the magnitude of the problem. Multiple follow-ups may be conducted to ensure the effectiveness of the action or improvement.

2.2.8. If the QAM, or designee, determines that the action or improvement is not effective, based on the magnitude of the problem, the CAT or management will re-evaluate the problem and either modify the newly enacted solution or propose an alternate solution. In those instances, the previous steps may be repeated by preparing a new action for tracking. As a result of the re-evaluation, management may need to reassign new or additional members to the CAT due to expertise with a specific issue or to bring a new perspective to a problem.

2.2.9. Once the problem has been adequately addressed, the QAM will close- out the action.

2.2.10. The QAM will summarize actions and improvements generated during the year and report them to management during the annual management review. All records associated with actions and improvements will be maintained by the QAM on the LAN.

2.3. A correction of work will be utilized when a nonconformance is identified as a singular occurrence, nonsystematic in nature. In these instances, the nonconformance is corrected on the spot, or soon thereafter. The correction will be made by the staff responsible for the original nonconformance, as appropriate. If a correction is performed during an internal audit it will be documented in the auditor's auditing records. If a correction is implemented at any other time throughout the year, the staff that identifies the nonconformance and makes the correction must report the correction to the QAM who will then document it using the LSASD Tracking Log for Corrections (LSASDFORM-1002). Periodically, the QAM will review the tracking log to determine if trends are present that need to be addressed through a corrective action or preventive action. The correction of work process does not apply to error corrections or other processes that utilize an established LSASD process, such as the "line through, initial and date" process for incorrect data correction.

3. Tracking

3.1. The QAM will use the following tools for tracking the status of each Corrective actions, preventive actions, quality improvements, or risk assessment.

- LSASDFORM-1001 – LSASD Action, Improvement, Risk Form
- LSASDFORM-1000 - Corrective Action Tracking Log
- LSASDFORM-1002 Summary of Risk Inventory

4. Definitions

4.1. **Corrective Action** - An action initiated in response to an identified nonconformance, to define a problem, attempt to identify the root cause and determine how to prevent the problem from recurring.

4.2. **Corrective Action Team (CAT)** - A corrective action team is designated by management to address corrective actions, preventive actions or quality improvements. The corrective action team may consist of one or more people. A Branch Chief, Section Chief, and/or QAC may be part of the team if appropriate.

4.3. **Nonconformance** - Departure from the policies and procedures in the LSASD Quality Management System or technical operations, or the absence of a specified requirement.

4.4. **Audit** - A planned and documented investigative evaluation of an activity or process to determine its adequacy and effectiveness as well as compliance with established standards, policies, procedures, or other applicable documents.

4.5. **Complaint** - A written or verbal notification received from within LSASD or from an individual or organization within or outside of LSASD that a specified aspect of LSASD's operation regarding the Quality Management System, environmental data collection or analysis is alleged to be unsatisfactory.

4.6. **Quality Assessment** - An evaluation of the performance or effectiveness of the Quality Management System conducted by LSASD personnel. It may include internal review of quality system procedures, quality control checks, competency/proficiency tests, observations of field work or management reviews.

4.7. **Preventive Action** - A process to identify and correct potential sources of nonconformities concerning the Quality Management System or its technical operations.

4.8. **Quality Improvement** - A process to identify and document opportunities for improving the effectiveness of Quality Management System or its technical operations.

4.9. **Correction of work** – A process to correct on the spot, or soon thereafter, nonconforming work identified as a onetime occurrence that are not systematic in nature.

4.10. **Risk** - The organization shall consider the risks and opportunities associated with activities impacting the LSASD quality system 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 operations; and, achieve improvements.

References

LSASD Corrective Action Tracking Log (LSASDFORM-1000), most recent version.
LSASD Action and Improvement Form (LSASDFORM-1001), most recent version.
LSASD Operating Procedure for Document Control (LSASDPROC-1000), most recent version.
LSASD Tracking Log for Corrections (LSASDFORM-1002), most recent version.
LSB Laboratory Operations and Quality Assurance Manual.

Revision History

History	Effective Date:
LSASDPROC-1005-R0, Actions and Improvements, Original Issue	October 1, 2017
Revised the SOP to include risk assessments which is required by ANAB under the new forensic portion of accreditation. Other clarifications and edits.	July 2021