

Region 4 U.S. Environmental Protection Agency Science and Ecosystem Support Division Athens, Georgia	
Operating Procedure	
Title: Actions and Improvements	ID: SESDPROC-1005-R0
Issuing Authority: Deputy Director, SESD	
Effective Date: October 1, 2017	

Purpose

This Operating Procedure is specific to the Region 4 Science and Ecosystem Support Division (SESD) to maintain conformance to technical and quality system requirements. This procedure defines the process for handling Corrective Actions, Preventive Actions, Quality Improvements and Correction of Work associated with the SESD Quality Management System (QMS).

Scope/Application

The requirements of this procedure apply to all personnel who perform work under the SESD 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 General

This procedure discusses how corrective action, preventive actions, quality improvements and correction of work will be handled. Corrective actions will be taken to address nonconforming work within the SESD 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.

Any person within or outside SESD can identify the need for actions or improvements. They may be identified through audits (internal and external), complaints (internal and external), customer feedback or quality assessments. Quality assessments include observations of work, internal reviews of quality system procedures, quality control checks, competency/proficiency test evaluations and management reviews.

1.2 Tracking

Corrective actions, preventive actions and quality improvements will be uniquely identified to facilitate tracking. An eight-digit identification number will be assigned to each action or improvement by the appropriate System Manager for actions and improvements in their system. Tracking numbers will begin with A for the Analytical Service Branch, F for the Field Services Branch, and Q for the Quality Assurance Section. The next two letters will identify its category, CA for corrective actions, PA for preventive actions, QI for quality improvements. The first four digits will represent the fiscal year. The last three digits will begin at 001 and increase sequentially with each additional corrective action. The last three digits will start over at 001 at the beginning of each fiscal year (Ex. ACA2017-001 for an Analytical Service Branch corrective action). The System Manager will track actions and improvements using the Corrective Action Tracking Log (SESDFORM-1000).

1.3 Process

Corrective actions, preventive actions and quality improvements will be documented using the SESD Action and Improvement Form (SESDFORM-1001). Upon identification or notification of the need for an action or improvement, the following procedure will be followed:

1. The System Manager will assign an identification number to facilitate tracking.
2. The System Manager will document the problem, potential problem or improvement opportunity.

3. The appropriate management and System Manager will designate personnel to address the action or improvement and assign a reasonable target date for completion. The designated personnel make-up the Corrective Action Team (CAT), which will address both actions and improvements
4. 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.
5. 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 and quality improvements do not require a root cause analysis.
6. 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; or recommend improvements to the SESD process, as appropriate.
7. The CAT will present the proposed solution, including target dates and the personnel responsible for completing the action to the affected management and the System Manager for approval. Once approved, the solution will be implemented by the appropriate personnel.
8. As a result of the proposed action, if any policies or procedures require updates, the System Manager will ensure they are conducted in accordance with the SESD Operating Procedure for Document Control (SESDPROC-1000).
9. The System Manager will notify all affected personnel either verbally or in writing (email or memo) of any changes that result from the action and improvement process.
10. Management is responsible for ensuring the required changes are implemented through direct communication with their staff and reviews of project records.
11. The System Manager, 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 System Manager 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.
12. If the System Manager, 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 propose another solution. In those instances, the previous steps may be repeated. As a result of the re-evaluation, management may need to reassign members of the CAT due to expertise with a specific issue or to bring new perspective to a problem.

13. Once the problem has been adequately addressed, the System Manager will close-out the corrective action.

The System Managers 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 appropriate System Manager.

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 appropriate System Manager who will then document it using the SESD Tracking Log for Corrections (SESDFORM-1002). Periodically, the System Manager 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 SESD process, such as the "line through, initial and date" process for incorrect data correction.

2 Definitions

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

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

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

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.

Complaint - A written or verbal notification received from within SESD or from an individual or organization outside of SESD that a specified aspect of SESD's operation regarding the QMS or environmental data collection or analysis is alleged to be unsatisfactory.

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

Preventive Action - A process to identify and correct potential sources of nonconformities concerning the QMS or its technical operations.

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

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.

3 References

SESD Corrective Action Tracking Log (SESDFORM-1000), most recent version.

SESD Action and Improvement Form (SESDFORM-1001), most recent version.

SESD Operating Procedure for Document Control (SESDPROC-1000), most recent version.

SESD Tracking Log for Corrections (SESDFORM-1002), 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 SESD Document Control Coordinator.

History	Effective Date
SESDPROC-1005-R0, Actions and Improvements, Original Issue	October 1, 2017