

Region 4
U.S. Environmental Protection Agency
Science and Ecosystem Support Division
Athens, Georgia

OPERATING PROCEDURE

Title: Preventive Action and Quality Improvement

Effective Date: April 12, 2017

Number: SESDPROC-017-R4

Authors

Name: Hunter Johnson

Title: Field Quality Manager, Science and Ecosystem Support Division


Signature: 

Date: 4/5/17

Approvals

Name: John Deatrick

Title: Chief, Field Services Branch

Signature: 

Date: 4/11/17

Name: Hunter Johnson

Title: Field Quality Manager, Science and Ecosystem Support Division

Signature: 

Date: 4/5/17

Revision History

The top row of this table shows the most recent changes to this controlled document. For previous revision history information, archived versions of this document are maintained by the SESD Document Control Coordinator on the SESD local area network (LAN).

History	Effective Date
SESDPROC-017-R4, <i>Preventive Action and Quality Improvement</i> , replaces SESDPROC-017-R3 General: Corrected any typographical, grammatical, and/or editorial errors. Also, any references to retired forms have been replaced with the appropriate reference. In addition, any references to former Division organizational structure was updated to reflect current structure. Title Page: Changed the Author and Field Quality Manager from Bobby Lewis to Hunter Johnson. Updated cover page to represent SESD reorganization. John Deatrick was not listed as the Chief of the Field Services Branch	April 12, 2017
SESDPROC-017-R3, <i>Preventive Action and Quality Improvement</i> , replaces SESDPROC-017-R2	June 20, 2013
SESDPROC-017-R2, <i>Preventive Action and Quality Improvement</i> , replaces SESDPROC-017-R1	October 30, 2009
SESDPROC-017-R1, <i>Preventive Action and Quality Improvement</i> , replaces SESDPROC-017-R0	November 1, 2007
SESDPROC-017-R0, <i>Preventive Action and Quality Improvement</i> , Original Issue	October 8, 2007

TABLE OF CONTENTS

1	General Information	4
1.1	Purpose	4
1.2	Scope/Application	4
1.3	Documentation/Verification	4
1.4	Definitions	4
1.4.1	Audit	4
1.4.2	Corrective Action	4
1.4.3	Complaint	4
1.4.4	Quality Assessment	5
1.4.5	Nonconformance	5
1.4.6	Preventive Action	5
1.4.7	Quality Improvement	5
2	Methodology	6
2.1	Summary of Procedure	6
2.2	Identification of Preventive Action or Quality Improvement	6
2.3	Preventive Action or Quality Improvement Process	6
2.4	Records	7

1 General Information

1.1 Purpose

This document defines the procedure to identify, implement and monitor preventive actions and opportunities for improvements within the SESD Field Branch Quality System (FBQS) and technical operations.

1.2 Scope/Application

This procedure applies to SESD managers, the branch Quality Assurance Officers (QAOs), the Field Quality Manager (FQM) and those who participate in the preventive action process at SESD. This procedure contains direction developed solely to provide internal guidance to SESD employees. Mention of trade names or commercial products in this operating procedure does not constitute endorsement or recommendation for use.

1.3 Documentation/Verification

This procedure was prepared by persons deemed technically competent by SESD management, based on their knowledge, skills and abilities. The official copy of this procedure resides on the SESD local area network (LAN). The Document Control Coordinator is responsible for ensuring the most recent version of the procedure is placed on the LAN and for maintaining records of review conducted prior to its issuance.

1.4 Definitions

1.4.1 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. *Internal audits* are conducted by the FQM or other SESD trained auditors. *External audits* are conducted by outside entities.

1.4.2 Corrective Action

An action initiated in response to an identified nonconformance, in order to define a problem, address a problem and attempt to identify the root cause of a problem.

1.4.3 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 FBQS or environmental data collection or analysis is alleged to be unsatisfactory.

1.4.4 Quality Assessment

An evaluation of the performance or effectiveness of the FBQS 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.

1.4.5 Nonconformance

Departure from the policies and procedures in the FBQS or technical (field) operations or absence of a specified requirement.

1.4.6 Preventive Action

A process to identify and correct potential sources of nonconformities concerning the FBQS or its technical operations.

1.4.7 Quality Improvement

A process to identify and document opportunities for improving the effectiveness of FBQS or its technical operations.

2 Methodology

2.1 Summary of Procedure

This procedure discusses how to identify and handle potential sources of nonconformities and opportunities for improvement within the FBQS and technical operations. 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 conducted to improve the effectiveness of the FBQS and technical operations.

2.2 Identification of Preventive Action or Quality Improvement

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

2.3 Preventive Action or Quality Improvement Process

Upon identification or notification of the need for a preventive action or quality improvement, the following procedure will be followed:

1. The FQM will assign an identification number to facilitate tracking. Preventive action tracking numbers will begin with PA and quality improvements will begin with QI, followed with a seven digit number. The first four digits will represent the fiscal year. The last three digits will begin at 001 and increase sequentially with each additional action. The last three digits will start over at 001 at the beginning of each fiscal year (Ex. PA2007-001).
2. The FQM will track preventive actions and quality improvements using the Action and Improvement Tracking Log (SESDFORM-062) and will initiate the action on the Action and Improvement Form (SESDFORM-061).
3. The appropriate management in consultation with the FQM will designate personnel to address the preventive action or quality improvement needed.
4. Designated personnel will evaluate the issue and prepare an action plan that will include a description of the original issue, preventive action or quality improvement to be taken and a timeframe to implement the action. The action plan will be attached to the Action and Improvement Form.

5. Management and the FQM will approve the action plan in writing (via signature page) for implementation. The FQM will ensure the action plan is implemented via direct communication with designee(s) and/or e-mail notification from designee(s) that the action plan has been fully implemented.
6. The FQM will monitor the effectiveness of the preventive action or quality improvement through internal audits or review of the actions taken to determine any reduction in deficiencies or improvements to operations. The time frame for internal audits and reviews will be determined by the FQM.
7. Once effectiveness has been established, the FQM will document the close-out of the preventive action or quality improvement on the Action and Improvement Form (SESDFORM-061). If actions taken are not deemed effective, then the FQM will contact the affected management to develop a mutually acceptable course of action.

The FQM will summarize preventive actions and quality improvements generated during the year and report them to management for inclusion in the annual management review.

2.4 Records

Records associated with preventive actions and quality improvements will be maintained by the FQM. The records may include but are not limited to:

1. Action and Improvement Form (SESDFORM-061)
2. Action and Improvement Tracking Log (SESDFORM-062)
3. Action Plan
4. Documentation associated with implementation of the action plan
5. Internal Audit Reports
6. Records associated with determination of effectiveness.