

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

OPERATING PROCEDURE

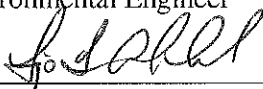
Title: Preventive Action and Quality Improvement

Effective Date: November 1, 2007

Number: SESDPROC-017-R1

Authors

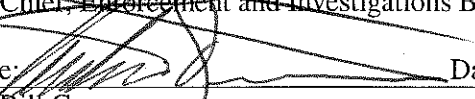
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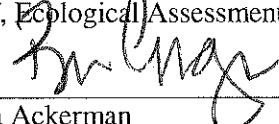
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Approvals

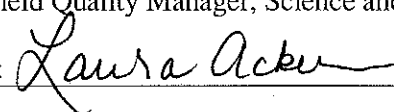
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Revision History

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 Field Quality Manager.

History	Effective Date
<p>SESDPROC-017-R1, <i>Preventive Action and Quality Improvement</i>, replaces SESDPROC-017-R0</p> <p>Title Page Changed title for Antonio Quinones from Environmental Investigation Branch to Enforcement and Investigations Branch.</p> <p>Section 2.3, #3 Corrected typo “wit” to “with”.</p>	November 1, 2007
<p>SESDPROC-017-R0, <i>Preventive Action and Quality Improvement</i>, Original Issue</p>	October 8, 2007

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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 Quality System 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.

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 H: drive of the SESD local area network. The Field Quality Manager is responsible for ensuring the most recent version of the procedure is placed on the H: drive 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 field branches quality system 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 SESD Field Branches Quality System 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 SESD Quality System or technical (field) operations, or absence of a specified requirement.

1.4.6 Preventive Action

A process to identify opportunities for improvement and potential sources of nonconformities concerning the SESD Quality System 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 SESD Quality System 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 SESD quality system 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), 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 Preventive Action/Quality Improvement Tracking Log (SESDFORM-030) and will initiate the action required (preventive action or quality improvement) on SESD Preventive Action/Quality Improvement Form (SESDFORM-031).
3. The Section Chief 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. Preparation of the action plan will be documented on SESDFORM-031 and attached thereto.
5. The Section Chief and FQM will approve the action plan for implementation or request that the designee(s) reevaluate the plan. The Section Chief will ensure the action plan is

implemented via direct communication with designee(s) and 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 in consultation with management.
7. Once effectiveness has been established, the FQM will document the close-out of the preventive action or quality improvement on SESDFORM-031. If actions taken are not deemed effective, then the FQM contacts 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. SESD Preventive Action/Quality Improvement Form (SESDFORM-031)
2. SESD Preventive Action/Quality Improvement Tracking Log (SESDFORM-030)
3. Action Plan
4. Documentation associated with implementation of the action plan
5. Internal Audit Reports
6. Records associated with determination of effectiveness.