

Region 4 U.S. Environmental Protection Agency Laboratory Services and Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Complaint Resolution and Control of Nonconforming Work	ID: LSASDPROC-1006-R1
Issuing Authority: Deputy Director, LSASD	
Effective Date: November 26, 2019	Review Due Date: November 26, 2023

Purpose

This procedure is specific to the Region 4 Laboratory Services and Applied Science Division (LSASD) to maintain conformance to technical and quality system requirements. This document defines the procedure utilized by R4 LSASD to evaluate and resolve any complaints or nonconforming work regarding LSASD's Quality Management System (QMS), products or services.

Scope/Application

This procedure applies to all work conducted by personnel operating within LSASD's QMS. This procedure details the required LSASD's process for adhering to the ISO/IEC 17025 standard for complaint resolution and control of nonconforming work. 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 Methodology

1.1 Complaint Resolution

Complaints may originate from internal or external sources. If complaints associated with LSASD's quality management system or technical operations are received from external sources by staff members, the complaints shall be forwarded to the appropriate management (typically the Section Chief) and the Quality Assurance Coordinator (QAC). All internal complaints shall be routed to the appropriate Section Chief and Quality Assurance Coordinator for processing.

Upon receipt, all complaints will be handled in the following manner:

1. The Section Chief will contact the source of the complaint to discuss the relevant details and to gather all information needed to determine if the complaint is valid. The Section Chief will assume responsibility for gathering any information needed to validate the complaint and documenting the complaint using the Complaint Evaluation Form (LSASDFORM-1004). A Complaint Evaluation Form will be completed for all complaints received.
2. If the information gathered concerning the complaint determines the complaint does not relate to LSASD activities, it will not be considered a valid complaint, this will be noted on the LSASD Complaint Evaluation Form (LSASDFORM-1004). The complainant will be notified of the outcome of the complaint investigation via email and the Complaint Evaluation Form will be routed to the QAC for retention.
3. If the complaint is determined to be valid, the QAC will be consulted to determine if the complaint is a nonconformance within the LSASD QMS or technical operations. If a valid complaint is deemed a nonconformance, the QAC will follow the process described below in Section 1.2.
4. If a valid complaint is not deemed a nonconformance, the Section Chief and QAC will determine if the issue is a candidate for a preventive action or quality improvement. If the complaint is a candidate for a preventive action or quality improvement, the issue will be addressed in accordance with the LSASD Operating Procedure Actions and Improvements (LSASDPROC-1005). If the complaint is not a candidate for a preventive action or quality improvement, the Section Chief will work with the source of the complaint to resolve the issue. The resolution will be noted on the LSASD Complaint Evaluation Form (LSASDFORM-1004). The Section Chief will notify the complainant of the resolution via email and route the Complaint Evaluation Form to the QAC once the resolution is complete.

1.1.1 Communications

If the complaint is valid and a corrective action, preventative action, or quality improvement is initiated, the Section Chief will inform the complainant of LSASD's complaint resolution process and will communicate (through email) the progress and completion of the action, at the complainant's request.

The receipt, evaluation and resolution of any complaints received by LSASD will be communicated to management, at a minimum during the annual Management Review.

1.1.2 Complaint Resolution Records

All aspects of complaint receipt, evaluation and resolution will be noted by the appropriate Section Chief on the LSASD Complaint Evaluation Form (LSASDFORM-1004). Once a complaint has been received, the Section Chief will notify the QAC of the complaint and will route the LSASD Complaint Evaluation Form (LSASDDFORM-1004) to the QAC for retention upon resolution of the complaint.

1.2 Control of Nonconforming Work

Identification of nonconforming work associated with the quality management system or sampling, measurement or analytical activities can occur at various points within the management system and technical operations. Nonconforming work may be identified several ways including customer complaints, quality control, instrument calibration, checking of consumable supplies, staff observations, report reviews, management reviews and internal and external audits.

A nonconformance occurs anytime there is a departure from the policies and procedures in the LSASD quality system or technical operations or when there is an absence of a specified requirement. Nonconformances will require a formal corrective action if 1) there is potential for the nonconformance to recur somewhere else in the quality system or, 2) if there is an adverse impact on the quality of the work generated. The corrective action will explore the root cause of the nonconformance and provide a plan for eliminating the root cause.

Personnel within LSASD will address nonconformances according to the following procedure.

1. When nonconforming work occurs, project leaders, laboratory analysts, management and the QAC have the authority and responsibility to stop work if appropriate. Depending on the conditions, notification of stop work will be verbally communicated to staff conducting the work, then noted in a logbook or through an email chain to all affected personnel.

NOTE 1: Field investigators and laboratory analysts that identify nonconforming work during field operations or laboratory work will notify the Project Leader or Laboratory Section Chief as soon as possible. Project Leaders or Section Chiefs will determine if it is necessary to stop work during field or laboratory operations.

NOTE 2: All staff are authorized to stop work due to safety concerns.

2. Whenever a nonconformance occurs, field and laboratory personnel will take immediate action to correct the issue if appropriate.
3. The individual who identified the nonconformance will complete the Nonconforming Work Form (LSASDFORM-1005) and notify the QAC as soon as possible.
4. The QAC in consultation with the Section Chief will evaluate the significance of the nonconformance.
5. The QAC will determine the risk of recurrence of the nonconformance to recur somewhere else in the quality system or if there is an adverse impact on the quality of the work generated. If so, it will be addressed through formal corrective action (LSASDPROC-1005).
6. If the nonconformance is not addressed through the corrective action process, it will be evaluated by the QAC to determine if it is an opportunity for a Preventive Action or Quality Improvement.
7. Affected management and the QAC in consultation with the project leader or laboratory analyst will determine if the results generated from the nonconforming work are acceptable or if the work should be repeated.
8. Affected management and the QAC will also determine if the customer should be notified of the nonconformance and if any previously released data should be recalled.
9. If work was stopped due to the nonconformance, the QAC or management will determine when it is appropriate for work to resume. The QAC or Section Chief will notify staff to resume work through an email to all affected personnel.

1.2.1 Recalled Data

If it is necessary to recall data due to a nonconformance, it will be the responsibility of the affected management to contact the customer and notify them of the recalled data. This may be done via email or a memorandum. If it is necessary to issue another report, this will be handled in accordance with the LSASD Applied Science Branch Operating Procedure for Report Preparation and Distribution (LSASDPROC-003) or the Laboratory Services Branch Operating Procedure for Data Reporting and Preparing Project Files (ASB SOP 118G) and/or Laboratory Operations and Quality Assurance Manual (LOQAM). Copies of any correspondence with the customer regarding recalled data shall be forwarded to the QAC.

1.2.2 Control of Nonconforming Work Records

Information related to occurrences of nonconforming work will be recorded on the LSASD Nonconforming Work Form (LSASDFORM-1005). The QAC will maintain all records associated with occurrences of nonconforming work. These records may include:

1. LSASD Nonconforming Work Form (LSASDFORM-1005)
2. Notification for stopping work (emails, memos, verbal communication)
3. Records of customer notification (emails, memos, verbal communication)
4. Records of recalled data (emails, memos, verbal communication)
5. Notification for resuming work (emails, verbal communication)
6. Corrective Action Tracking Log Form (LSASDFORM-1000)

2 **References**

Complaint Evaluation Form, LSASDFORM-1004, current version

Nonconforming Work Form (LSASDFORM-1005, current version)

Corrective Action Tracking Log Form (LSASDFORM-1000, current version)

LSASD Operating Procedure for Corrective Action, preventive Actions and Quality Improvements (LSASDPROC-1005, current version)

LSASD Applied Science Branch Operating Procedure for Report Preparation and Distribution (ASBPROC-003, current version)

Laboratory Services Branch Operating Procedure for Data Reporting and Preparing Project Files (ASB SOP 118G), current version

Laboratory Services Branch Laboratory Operations and Quality Assurance Manual, current version

3 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 LSASD Document Control Coordinator on the LSASD local area network (LAN).

History	Effective Date
SESDPROC-1006-R0, Complaint Resolution and Control of Nonconforming Work, Original Issue	October 1, 2017
Updated all references to SESD to LSASD, references to Analytical Services Branch to Laboratory Services Branch, and Field Services Branch to Applied Science Branch. Replaced all references to the Quality System Manager (QAM) with Quality Assurance Coordinator (QAC). Added language to Section 1.1 ad 1.2 to include when notifications of the complaint process and resolution are required and how they are communicated. Updated Revision to R1 and renamed to LSASDPROC-1006 instead of SESDPROC-1006.	November 26, 2019

Document Review Form
 (for SESD's Internally Controlled Documents)

Format Review			
<i>(To be completed by SESD Document Control Coordinator)</i>			
Format Checked by DCC?	<input checked="" type="radio"/> Yes <input type="radio"/> No	Document Effective Date:	11/26/19
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Document Author			
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LSASD Deputy Director	Danny France		11-26-19

**Document Review Form
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Evaluation of Document's Base Method (Not Applicable for all SEDS Documents)			
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Current Method Reference/Revision Number/Date:	N/A		
<i>If different, describe the changes made to the method which were included in the document:</i>			
<i>If the method has been revised and it is chosen not to update the document to reflect those revisions, explain why:</i>			
Secondary Review			
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