GEOSCIENCES AND ENGINEERING DIVISION QUALITY ASSURANCE PROCEDURE	Proc. QAP–010 Revision 4 Chg 0 Page 1 of 6

Title: **QAP–010 CORRECTIVE ACTION**

EFFECTIVITY AND APPROVAL

Revision 4 of this procedure became effective on August 18, 2005. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
All	0	08/18/05

Supersedes Procedure No. QAP–010, Revision 3, Chg 2 dated 7/15/2004

Prepared by	Date	Approved by	Date
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QAP–010 CORRECTIVE ACTION

1. PURPOSE

The purpose of this procedure is to provide the Geosciences and Engineering Division (Division) methods to identify and correct conditions adverse to quality.

2. RESPONSIBILITIES

2.1 The Director of Quality Assurance (QA) is responsible for the overall administration of this procedure.

2.2 The cognizant manager is responsible for proposing and implementing corrective action in accordance with this procedure.

2.3 Division staff are responsible for identifying conditions adverse to quality.

2.4 QA staff are responsible for initiating, tracking, and closing-out corrective action requests.

3. DEFINITIONS

Conditions Adverse to Quality—Conditions that have a potential to unfavorably affect quality if not addressed.

Corrective Action—Measures taken to rectify conditions adverse to quality, and to preclude recurrence.

Remedial Action—Action taken to correct an adverse condition, but not its cause(s). This action is similar to disposition actions for nonconformances as described in QAP–009, Nonconformance Control.

4. PROCEDURE

4.1 Introduction

Conditions adverse to quality shall be identified, reported, and corrected in accordance with this procedure. Any person performing Division activities affecting quality may identify conditions adverse to quality. Persons other than QA staff identifying such conditions shall report them to an appropriate QA staff member, usually the Director of QA. The Director of QA shall determine whether the condition is significant enough to initiate a corrective action request.

Adverse conditions may be indicated by the following

- Repeated occurrences of nonconformances of similar type and cause, as identified in accordance QAP–009, Nonconformance Control.
- Trends of nonconformances suggesting ineffective implementation of quality system elements.
- Individual occurrences of significant quality problems, including those identified during audits and surveillances.
- Conditions that, if not corrected, could result in nonconformances.
- Client complaints.

4.2 Stop Work Authority

Any person performing activities affecting quality has the authority to stop work if continuing will result in a nonconforming condition. Persons stopping their work are obligated to report to their supervisor or to QA staff so that the conditions that could lead to nonconformance are appropriately corrected.

The Director of QA has stop work authority on all activities of the Division affecting quality when there is evidence of a breakdown of the QA system. Stop work shall be exercised by verbal means and documented in a corrective action request. Work in the affected area shall immediately cease unless such action would create an adverse health and safety condition. Work shall not be resumed until the Director of QA has evidence of corrective action completion. A stop work order shall be canceled by a written memorandum signed by the Director of QA and Division Vice President. Only the Division Vice President or the President of Southwest Research Institute® can override a stop work order.

4.3 Corrective Action Request

4.3.1 QA staff shall complete the top portion and Part A of the Corrective Action Request, form QAP–14, through the following steps.

- Obtain a corrective action request control number from the tracking log.
- Identify the associated nonconformance report, audit report, or surveillance report number, if applicable.
- Describe the condition adverse to quality, including the requirement violated.

- Identify the person responsible for corrective action, usually the principal investigator or manager responsible for the affected activity.

- Assign a response due date of 20 working days after the date of initiation, unless special circumstances warrant shorter or longer time. Response due dates longer than 20 working days shall be approved by the Director of QA.

- Sign and date Part A of the Corrective Action Request form.

QA staff shall retain a copy of the initiated Corrective Action Request while it is routed for responses and approval.

4.3.2 The individual responsible for corrective action shall investigate the condition adverse to quality and describe the following in Part B of the Corrective Action Request form.

- Extent of Condition—The condition adverse to quality shall be investigated to determine if other items or activities are similarly affected. This investigation will identify the extent to which corrective actions must be applied.

- Root Cause—The condition shall be investigated to determine its root cause. Root causes are often the lack of proper training, qualification, or procedural guidance necessary to properly perform an activity. The analysis of the root cause shall be sufficient to provide effective corrective action to preclude recurrence of the condition adverse to quality. QA staff should be consulted for guidance in root cause analysis methods.

- Remedial Action and Proposed Completion Date—The action to be taken to correct (i.e., to bring into compliance) those items and activities found to be nonconforming shall be identified. A schedule for timely completion shall be established and documented as the proposed completion date. The extent of the remedial action, in terms of the population of items or activities subject to the corrective action, shall be based on the results of the extent of condition investigation.

- Corrective Action to Preclude Recurrence and Proposed Completion Date—The action to be taken to address the root cause of the condition shall be identified, together with a schedule for timely completion. The corrective action shall be of sufficient scope and degree to reasonably expect that the condition will not recur and shall be appropriate for the root cause identified through investigation. Corrective actions may involve changing procedures and retraining staff, which establish a new baseline for the affected activity.

Corrective actions should be completed within 60 calendar days from initiation of the correction action request unless complexity or other attributes of the corrective action request justify a longer period. Written justification to extend the completion date shall be maintained in the appropriate corrective action request folder.

- Sign and date Part B of the Correction Action Request Form.

4.3.3 The completed corrective action response shall be reviewed by the Director of QA considering (i) scope and the extent of conditions investigated, (ii) sufficiency of the remedial action, (iii) thoroughness and technique used in the root cause determination, (iv) appropriateness of the action to preclude recurrence, and (v) timeliness of the completion dates.

If the corrective action response does not provide adequate investigation, corrective actions, or appropriate completion dates, the individual responsible for corrective action shall be contacted so an adequate response can be obtained. The Division Vice President shall be the final arbitrator in cases where agreement on the adequacy of corrective actions cannot be reached.

Any comments or instructions regarding the proposed actions shall be provided in Part C of the form. The Director of QA shall indicate concurrence with the responses in Part C by signature and date.

4.4 Verification of Corrective Action Implementation

Within two weeks after the corrective action completion date(s), QA staff shall review and verify the implementation of the specified actions. The review shall determine whether the corrective actions are sufficient to preclude recurrence. Satisfactory implementation shall be indicated by signature and date in Part D of the form, along with any pertinent comments.

4.5 Corrective Action Request Distribution

Corrective action requests shall be distributed to the originator, responsible manager, assistant director, department director, Division Vice President, and others as determined by the Director of QA.

4.6 Corrective Action Request Tracking

4.6.1 A corrective action request report tracking log shall be maintained by QA staff containing the following information

- Corrective Action Request number
- Date initiated

- Brief description of the condition adverse to quality
- Scheduled corrective action completion date
- Verification completion date

4.6.2 If the corrective action response is not received by the due date, written notice of the overdue condition shall be provided to the responsible manager. This notice can be made in electronic or other form.

4.6.3 The corrective action request shall be considered closed when all required actions have been completed and verified.

4.7 Trend Analysis

Conditions adverse to quality shall be evaluated annually or as determined by the Director of QA to identify possible trends needing additional corrective action or other appropriate attention. The results of the trend analysis shall be reported to Division management.

5. RECORDS

Corrective action requests, trend analyses, and supporting documentation shall be maintained as QA records in accordance with QAP–012, "Quality Assurance Records Control."