

GEOSCIENCES AND ENGINEERING DIVISION
QUALITY ASSURANCE PROCEDURE

Proc. QAP-010

Revision 4 Chg 2

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Title: **QAP-010 CORRECTIVE ACTION**

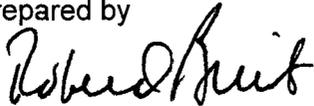
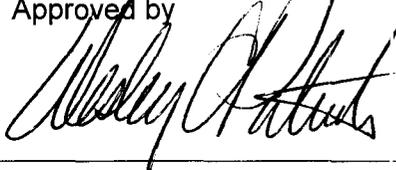
EFFECTIVITY AND APPROVAL

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

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	2	06/29/2009
2	0	03/18/2005
3-5	1	05/28/2008
6	2	06/29/2009
7	1	05/28/2008

Change 1: Change from paper-based to electronic-based report processing.
 Change 2: Change close-out due date

Supersedes Procedure No. QAP-010, Revision 4, Chg 1 dated 05/28/2008.

Prepared by 	Date 6/16/2009	Approved by 	Date 6/16/2009
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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 (CARs).

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 CAR.

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Adverse conditions may be indicated by the following

- Repeated occurrences of nonconformances of similar type and cause, as identified in accordance with 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 CAR. 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 Processing a Corrective Action Request

A condition adverse to quality shall be identified, root cause determined, and remedial and corrective actions proposed and approved using the SwRI Quality Reporting System (QRS) tool.

4.3.1 Accessing the Quality Reporting System

QRS is accessed at <https://iqsweb.itc.swri.edu/qrs/qrs-login.pl>.

Account Name: First initial and last name, all lower case, no spaces.

Password: Use your BAMS password, which can be obtained from Information Management System.

Upon entry to QRS, click on *Report Menu*.

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4.3.2 Initiating a Corrective Action Request

The CAR shall be initiated in QRS by clicking on the *Initiate Report* tab, then *Submit CAR*. The initiator shall provide the following information.

Report Type: Select CAR using the pull down menu.

Division: Click the box on the right and select *20-Geosciences and Engineering*. Below the Division, click the box on the right and select the Department/Section associated with the nonconforming condition. When multiple organizations are involved, select the next higher organizational level that encompasses all affected organizations.

Project No.: Using the system icon on the right, enter the project number (partial or full) or select *Division 20* to obtain a list of all projects, then select the project number most closely associated with the condition.

Quality Program: Select *GED (20) QAM*, then click *Add Program*.

Associated Report (Optional): Identify associated Nonconformance or Surveillance Report(s) (must be listed in QRS) if applicable.

Description of the Discrepancy Requiring Corrective Action: Include, as applicable, (i) identification of the item, service, activity, software, or affected inspection, experiment, or test and (ii) reference to the requirement not complied with. Electronic files providing more details may be attached to the CAR.

Issued To: Identify the individual responsible for corrective action using the pull down menu, usually the cognizant manager or principal investigator (PI).

Response Due Date: Using the pull-down menu, set the due date for 20 working days after the initiation date (rather than using the default date generated by QRS).

SwRI cc: Standard QRS distribution of CARs includes the responsible manager and director of QA. Using the pull down menu, add the GED vice president, CNWRA president, affected directors, assistant directors, and managers and any additional distribution as needed.

External cc: If an information copy to an external party is needed the email address may be entered.

4.3.3 Response

QRS will notify the person responsible for the response by email and require action. Access to QRS shall be obtained as described in Section 4.3.2. The original assignee may reassign responsibility to a more appropriate person if necessary.

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Prior to the *Response Due Date*, the individual responsible for action shall enter the response. QRS notifies the individual responsible for action if the response is overdue, and subsequently, an escalation notification of delinquent responses is sent to the responsible manager and director of QA.

Remedial Action to Correct Discrepancy: 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 an extent of condition investigation to determine if other items or activities are similarly affected and require remedial action.

Root Cause Category: Using the pull down menu, identify the most appropriate root cause category based on the outcome of the root cause determination.

Description of Root Cause: The condition shall be investigated to determine its root cause. Root causes are often the lack of 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.

Proposed Corrective Action: The action to be taken to address the root cause of the condition shall be identified. 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.

Target Date for Action: The date should consider the time necessary to complete all of the actions necessary to address the condition. Corrective actions should be completed within 60 calendar days from initiation of the correction action request unless complexity or other circumstances of the CAR justify a longer period. The target date should consider the possible adverse impacts that may occur until the condition is corrected. A stop work order should be applied if continuing activities without correction may result in additional nonconformances. Written justification to extend the completion date is required.

SwRI cc: Standard distribution of responses includes the CAR initiator, the responsible manager, and director of QA. Add any additional distribution as needed using the pull down menu.

External cc: If an information copy to an external party is needed, the email address may be entered.

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4.3.4 Approvals

After the response is submitted, QRS notifies the responsible manager that approval action is required. The manager’s evaluation shall consider the impact of the condition in light of contractual and technical requirements.

Approval: The manager shall indicate concurrence with the proposed action if appropriate. If the proposed action is inadequate, the response shall be rejected and QRS will return the CAR to the individual responsible for action for revision.

Comments: The manager may provide any comments or instructions regarding the remedial or corrective action when needed.

QRS notifies the director of QA for evaluation of the proposed action.

Approval: The director of QA shall indicate concurrence with the proposed action if appropriate. If the proposed action is inadequate, the response shall be rejected and QRS will return the CAR to the individual responsible for action for revision.

Comments: Director of QA may enter comments or instructions regarding the remedial or corrective action when needed. These may include special corrective action requirements or re-inspection requirements for reworked or repaired items.

4.3.5 Close-Out

QRS notifies QA staff at the *Target Date for Action* to verify that the proposed action has been completed and is sufficient. Corrective actions shall be evaluated by QA staff within one month of the target date. The evaluation shall consist of review of objective evidence, re-inspection, or surveillance to verify the approved corrective action is complete.

Verification of Action Taken: Describe the verification measures taken to confirm that proposed actions have been completed.

SwRI cc: Standard distribution of responses includes the CAR initiator, the responsible manager, and director of QA. Add any additional distribution as needed using the pull down menu.

External cc: If an information copy to an external party is needed, the email address may be entered.

Electronic files providing objective evidence of actions taken may be attached to the CAR.

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4.4 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

CARs, trend analyses, and supporting documentation shall be maintained as QA records in accordance with QAP-012, "Quality Assurance Records Control."