

GEOSCIENCES AND ENGINEERING DIVISION
QUALITY ASSURANCE PROCEDURE

Proc. QAP-009

Revision 3 Chg 3

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Title: **QAP-009 NONCONFORMANCE CONTROL**

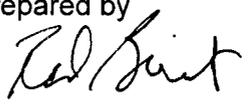
EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on August 8, 2005. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-2	3	05/12/2010
3	1	05/28/2008
4-6	3	05/12/2010

- Change 1: Change from paper-based to electronic-based report processing.
- Change 2: Change close-out due date
- Change 3: Reflects QA title change

Supersedes Procedure No. QAP-009, Revision 3, Chg 2 dated 06/29/2009.

Prepared by 	Date 4/28/2010	Approved by 	Date 4/20/2010
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QAP-009 NONCONFORMANCE CONTROL

1. PURPOSE

The purpose of this procedure is to provide the methods for identifying, segregating, reporting, dispositioning, and controlling nonconforming goods, services, and activities, including software.

2. RESPONSIBILITIES

- 2.1 The Quality Assurance (QA) staff are responsible for implementing this procedure.
- 2.2 The individual identifying the nonconforming condition is responsible for initiating the Nonconformance Report (NCR).
- 2.3 The manager or principal investigator (PI) is responsible for proposing a disposition and correcting the cause of the nonconformance.

3. PROCEDURE

3.1 Identification

- 3.1.1 Nonconforming items should be identified by tagging with a hold tag (Form SS-19 or equivalent). The hold tag should be directly attached to the item or lot of items, if practical.
- 3.1.2 When direct attachment of the hold tag is impractical, the tag shall be attached to the package or container, or the item shall be placed in a segregated hold area.
- 3.1.3 Hold tags shall include:
 - Identification of the item(s)
 - Quantity
 - Brief description of the nonconformance
 - Date initiated
 - Individual initiating
 - NCR number (see Section 3.3)

3.2 Segregation

- 3.2.1 Nonconforming items shall be removed from the work area and segregated to prevent inadvertent use. When physical conditions such as size, weight, or access limitations

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preclude complete segregation, the nonconforming item shall be separated from conforming items of the same type as much as possible and additional hold tags or similar marking may be used to clearly identify the item as nonconforming and provide instructions to prevent inadvertent use of the item.

3.2.2 A nonconforming item shall not be released from a segregated hold area nor shall hold tags be removed until the item is properly dispositioned (see Section 3.4).

3.3 Processing a Nonconformance Report

A nonconforming condition shall be identified, its disposition determined, and approved using the SwRI Quality Reporting System (QRS) tool.

3.3.1 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*.

3.3.2 Initiating a Nonconformance Report

The individual identifying the nonconforming condition shall initiate a NCR in QRS by clicking on the *Initiate Report* tab, then *Submit NCR*. The initiator shall provide the following information.

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 nonconforming condition.

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

Associated Report (Optional): Identify an associated Audit or Surveillance Report listed in QRS if the nonconforming condition was identified during the audit or surveillance.

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Supplied Part Nonconformance Section (Optional): If the nonconforming condition relates to a purchased item or service, identify the supplier and other pertinent information.

Description of the Nonconformance: 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 (e.g., supplier documentation, affected reports, etc.) may be attached to the NCR.

Issued to: Identify the individual responsible for determining disposition using the pull down menu, usually the responsible manager or PI.

Response Due Date: Using the pull-down menu, set the due date for 10 working days after the initiation date (rather than using the default date generated by QRS).

SwRI cc: Standard distribution of initiated NCRs includes the responsible manager and QA staff. Add any additional distribution as needed using the pull down menu.

External cc: If an information copy to an external party is needed (e.g., the supplier with a nonconforming delivery), the email address may be entered.

3.4 Disposition

QRS will notify the person responsible for the response by email and require action. Access to QRS is described in Section 3.3.1. The original assignee may reassign responsibility to a more appropriate person if necessary.

Prior to the *Response Due Date*, the individual responsible for action shall enter the disposition, action to correct the nonconformance, and a target date for implementation of the corrective action. 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 QA staff.

Disposition: The disposition most appropriate to the nonconforming condition shall be selected from the pull down menu.

Customer Approval of Disposition: Indicate Yes if contract requirements require customer approval of the nonconformance disposition. Note: GED contracts to date have not had customer approval requirements.

Proposed Action to Address Nonconformance: The action to correct the cause of the nonconformance shall describe how the disposition will be implemented (i.e., actions to be performed, repairs or rework needed, etc.). A stop work order should be applied if continued operation may result in additional nonconformances.

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Target Date for Action: The date should provide sufficient time to complete all of the actions necessary to address the nonconformance. The date should consider the possible adverse impacts that may occur until the condition is corrected.

SwRI cc: Standard distribution of responses includes the NCR initiator, the responsible manager, and QA staff. Add any additional distribution using the pull down menu.

External cc: If an information copy to an external party is needed (e.g., the supplier with a nonconforming delivery), the email address may be entered.

3.5 Approvals

3.5.1 Manager Approval

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 disposition 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 NCR to the individual responsible for action for revision.

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

3.5.2 QA Approval

QRS notifies QA staff for evaluation of the proposed disposition and corrective action.

Approval: QA staff 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 NCR to the individual responsible for action for revision.

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

QA staff shall determine if the nonconformance indicates a significant condition adverse to quality. If so, the QA staff shall initiate a Corrective Action Request in accordance with QAP-010, Corrective Action.

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3.6 Close-Out

QRS notifies QA staff on the *Target Date for Action* to determine if 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 disposition and corrective action are complete.

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

SwRI cc: Standard QRS distribution of responses includes the NCR initiator, the responsible manager, and QA staff. Using the pull down menu add the cognizant PI, assistant director/director and any additional distribution as appropriate.

External cc: If an information copy to an external party is needed (e.g., the supplier with a nonconforming delivery), the email address may be entered.

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

3.7 Release of Nonconforming Items

QA staff shall release items on hold and remove hold tags based on the approved disposition of the NCR.

4. NONCONFORMANCE TRENDING ANALYSIS

Nonconformances and other relevant information shall be evaluated for trends on an annual basis. The results of the analysis shall be used to initiate additional corrective action measures, as necessary. The results of the trend analysis shall be reported to Division management.

5. RECORDS

NCRs with attachments and trend analysis reports shall be maintained as QA records in accordance with QAP-012, "Quality Assurance Records Control."