

GEOSCIENCES AND ENGINEERING DIVISION

QUALITY ASSURANCE PROCEDURE

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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>
All	0	08/08/05

Supersedes Procedure No. QAP-009 Rev. 2, Change 2, dated 7/21/2004

Approvals

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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 Director of Quality Assurance (QA) is responsible for implementing this procedure.

2.2 The individual identifying the nonconforming condition is responsible for initiating the Nonconformance Report.

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
- Nonconformance Report 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 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

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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 Initiation of Nonconformance Reports

3.3.1 The individual identifying the nonconforming condition shall initiate the Nonconformance Report, Form QAP-9 by providing the following information:

- Project Number
- Description of the nonconforming condition, including, as applicable, (i) identification of the good, service, activity, software, or affected inspection, experiment, or test and (ii) reference to the requirement not complied with
- Date initiated
- Name of the individual initiating the Nonconformance Report

3.3.2 QA staff shall assign a unique Nonconformance Report number and enter the Nonconformance Report information into the tracking log.

3.3.3 QA staff shall identify the individual responsible for determining disposition, usually the cognizant manager or PI in the "Action Required by" block. The Nonconformance Report shall be forwarded to this individual for action, and a copy shall be retained in the QA files.

3.4 Disposition

3.4.1 Within 10 days of initiation of the Nonconformance Report, the individual responsible for action shall complete Part 2 of the Nonconformance Report describing the disposition, action to correct the nonconformance, and a target date for implementation of the corrective action.

The disposition shall be accept (item, results, data, software, etc) as-is, rework, repair, scrap, return to supplier, or other). The basis for the disposition shall justify the selection of the disposition, which is generally a determination that the nonconformance does or does not adversely impact data, results, or products. Use-as-is and repair dispositions may require a technical evaluation by qualified specialists.

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.).

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3.4.2 The individual proposing the disposition and corrective action shall sign and date Part 2 of the Nonconformance Report and forward the Nonconformance Report to the manager (line or project manager, as appropriate) responsible for the affected activity for approval.

3.5 Disposition Approval

3.5.1 The proposed disposition and corrective action shall be evaluated by the manager responsible for the affected activity. The evaluation shall consider the impact of the disposition in light of contractual and technical requirements. The manager shall indicate concurrence with the proposed action by signature and date in Part 3 of the Nonconformance Report, along with any comments or instructions regarding the disposition.

3.5.2 The Nonconformance Report shall be forwarded to the Director of QA for evaluation of the proposed disposition and corrective action. The Director of QA shall indicate concurrence with the proposed actions by his signature and date in Part 3 of the Nonconformance Report or return it for modification. The Director of QA shall include any appropriate comments or instructions in Part 3, such as special corrective action requirements or reinspection requirements for reworked or repaired items.

3.5.3 The Director of QA 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.

3.6 Close-Out

Corrective actions shall be evaluated by QA staff within 10 working days of the target date for completion of corrective actions. The evaluation shall consist of review of objective evidence, reinspection, or surveillance to verify the approved disposition and corrective action are complete. Close out shall be indicated by signature and date in Part 4 of the Nonconformance Report.

3.7 Release of Nonconforming Items

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

3.8 Distribution of the Nonconformance Report

QA staff shall distribute copies of the completed Nonconformance Report to the manager, PI, and others determined by the Director of QA as indicated on the Nonconformance Report.

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4. NONCONFORMANCE REPORT TRACKING LOG

4.1 QA staff shall maintain a system for issuing Nonconformance Report numbers, tracking responses, and closing out nonconformances. The tracking log shall include:

- Nonconformance report number, date initiated, and project number
- Brief description of the nonconforming condition
- Response due date and response date
- Approved date
- Corrective action target date
- Date closed out

4.2 Reminders for response due dates and corrective action target dates should be provided to the responsible individual and cognizant QA staff three days prior. When required actions are overdue, written notice should be sent to the responsible individual with copies to the Director of QA, manager, and PI.

5. 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.

6. RECORDS

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