

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

QUALITY ASSURANCE PROCEDURE

Proc. QAP-009

Revision 0

Page 1 of 9

Title

QAP-009 NONCONFORMANCE CONTROL

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 10/5/90. This procedure consists of the pages and changes listed below.

Page No.
ALL

Change
0

Date Effective
10/5/90

SUPERSEDED

Superseded by Rev 0, Chg 1 - 10/5/90

Supersedes Procedure No. NONE

Approvals

Written By <i>Robert B. Brient</i> ROBERT B. BRIENT	Date 9/25/90	Technical Review <i>Robert E. Engelhardt</i> ROBERT E. ENGELHARDT	Date 10/1/90
Quality Assurance <i>Bruce E. Mabrito</i> BRUCE E. MABRITO	Date 10/4/90	Cognizant Director <i>Henry P. Garcia</i> HENRY P. GARCIA	Date 10/5/90

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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 nonconformances of items, materials, software, and activities to specified requirements.

2. RESPONSIBILITIES

- (1) The Director of Quality Assurance is responsible for implementation of this procedure.
- (2) The individual identifying the nonconforming condition is responsible for initiating the NCR.
- (3) The individual identified as responsible for corrective action is responsible for proposing a disposition and for correction of the cause of the nonconformance.

3. PROCEDURE

3.1 Identification

- (1) Nonconforming items shall be identified by tagging with a "Hold Tag" (Figure 1) or equivalent. The hold tag shall be directly attached to the item or lot of items if practical. The means of attachment shall be such that the item's end use shall not be adversely affected.
- (2) When direct attachment of the hold tag is impractical, the tag shall be attached to the package, container, or shelf in a segregated hold area holding the item(s).
- (3) Hold tags shall be completed by the individual identifying an item or items as nonconforming, and shall include:
 - o Identification of the item(s)
 - o Quantity

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- o Brief description of the nonconformance
- o Date initiated
- o Individual initiating
- o Nonconformance Report number

3.2 Segregation

- (1) Designated hold areas shall be utilized for the storage of nonconforming items when practical. The hold areas shall be clearly identified and access restricted to quality assurance personnel.
- (2) When physical conditions, such as size, weight, or access limitations preclude segregation, the nonconforming items shall be separated from conforming items of the same type as much as possible. Depending upon the size of the item, additional hold tags or similar signs may be used to clearly identify the item as nonconforming and provide instructions to prevent inadvertent use of the item.
- (3) Nonconforming items shall not be released from segregated storage nor shall hold tags be removed until properly dispositioned. Quality assurance personnel are solely authorized to release items and remove hold tags.

3.3 Initiation of the Nonconformance Reports

- (1) Nonconforming conditions, including items (materials, parts, software, or components) and specific noncompliance to procedural requirements, shall be reported through the use of the Nonconformance Report (NCR), CNWRA Form QAP-9 (Figure 2).
- (2) The individual identifying the nonconforming condition shall initiate the NCR by providing the following information:

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- (a) Project number
- (b) Description of the nonconforming condition, as applicable:
 - o The item name, part number, serial number
 - o Affected inspection, experiment, or test
 - o Description of the nonconformance, with reference to the requirement not complied with
 - o Date initiated
 - o Name of the individual initiating the NCR
- (3) Quality Assurance shall assign a unique NCR number and enter the NCR into the tracking log.
- (4) Center QA shall determine the individual responsible for disposition and corrective action. The original NCR shall be forwarded to this individual and a copy retained in the quality assurance files.

3.4 Disposition

- (1) The individual responsible for corrective action shall, within 10 working days of initiation of the NCR, complete Part 2 of the NCR, proposing:
 - (a) Disposition (accept as-is, rework, repair, scrap, or return to supplier) of the nonconforming item(s) or of the experiment, test, or other activity affected by noncompliance to a procedural requirement. The disposition shall include a basis for the disposition and, as appropriate, a technical evaluation by qualified specialists.
 - (b) Action to correct the cause of the nonconformance and a target date for implementation of the corrective action. If the action has already been taken, appropriate

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objective evidence of the corrective action shall be included with the NCR when practical.

- (2) The individual proposing the disposition and corrective action shall sign and date Part 2 of the NCR and forward the NCR to the Element Manager responsible for the affected activity.

3.5 Disposition Approval

- (1) The proposed disposition and corrective action shall be evaluated by the Element Manager responsible for the affected activity. The evaluation shall consider the impact of the disposition in light of contractual, and specification requirements. The Element Manager shall indicate concurrence with the proposed actions by signature and date in Part 3 of the NCR, along with any comments or instructions regarding the disposition.
- (2) The NCR shall then be forwarded to the Director of Quality Assurance for evaluation of the proposed disposition and corrective action in light of contractual and QA program requirements. The Director of Quality Assurance shall indicate concurrence with the proposed actions by his signature and date in Part 3 of the NCR form.
- (3) The Director of Quality Assurance shall include any comments or instructions in Part 3, such as special corrective action requirements and reinspection requirements for reworked or repaired items.

3.6 Distribution of the NCR

QA shall distribute copies of the approved NCR to the Element Manager and initiator.

3.7 Release of Nonconforming Items

Quality Assurance personnel shall release items on hold and remove hold tags based on the approved disposition of the NCR.

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3.8 Nonconformance Report Tracking Log

- (1) QA shall maintain a system of issuing NCR numbers and tracking responses and closeout. Manual or computer systems are acceptable, provided the following information is recorded:
 - (a) NCR number, date initiated, project number
 - (b) Brief description of the nonconforming condition
 - (c) Response due date and response date
 - (d) Date approved
 - (e) Corrective action target date
 - (f) Date closed out
- (2) Reminders for response due dates and corrective action target dates shall be provided three days prior to the action date to the responsible individual and cognizant QA personnel. Written notices shall be sent to the responsible individual, with copies to the Director of Quality Assurance and Element Manager when required actions are three days overdue.

3.9 Close-out

- (1) If corrective action is taken prior to approval of the NCR, the Director of Quality Assurance shall evaluate the objective evidence provided or otherwise verify implementation of corrective action. Satisfactory implementation shall be indicated by signature and date in Part 4 of the NCR.
- (2) Corrective actions targeted for implementation after approval shall be evaluated by Quality Assurance after the corrective action target date. The evaluation shall consist of review of objective evidence, reinspection, or surveillance to verify

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that the approved disposition and corrective action is complete. Close-out shall be indicated by signature and date in Part 4 of the NCR.

- (3) If Quality Assurance determines that the nonconformance has a major impact or is generic to the system, then Quality Assurance shall initiate a Corrective Action Request in accordance with CQAM Section 16.

4. RECORDS

- (1) Nonconformance report originals, with attachments, shall be maintained as QA records in accordance with CQAM Section 17 and retained in Quality Assurance files for a minimum of six years.
- (2) NCR tracking logs and notices shall be retained in Quality Assurance files for two years.

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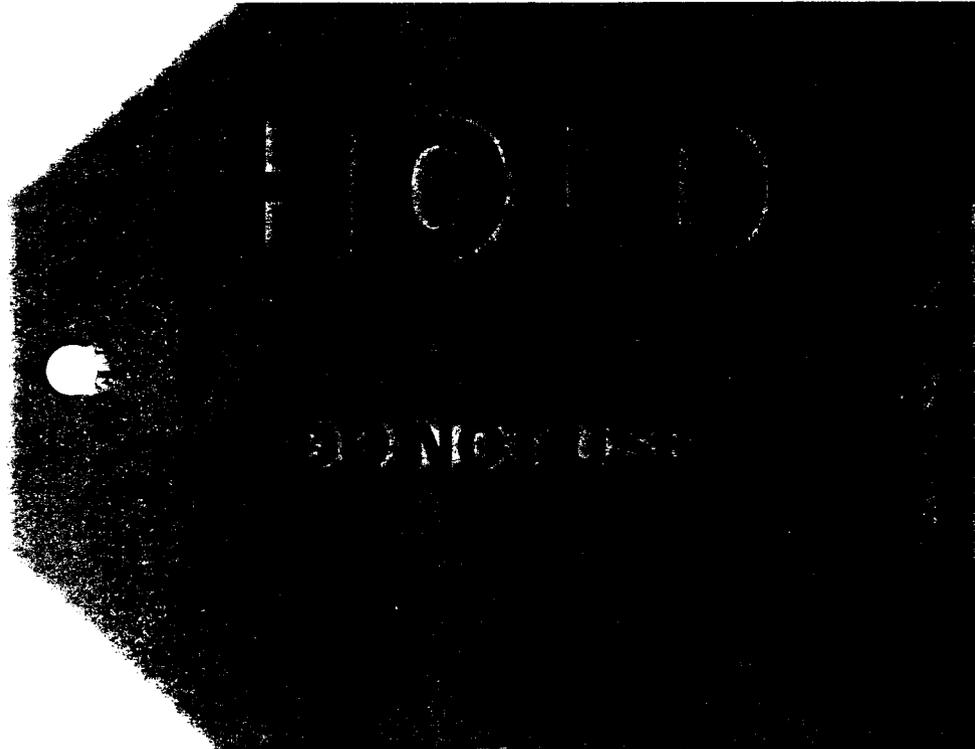


Figure 1

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

NONCONFORMANCE REPORT

Project No. _____ NCR No. _____

PART 1: DESCRIPTION OF NONCONFORMANCE

Initiated by: _____ Date: _____

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

Disposition:

Basis of Disposition:

Action to correct nonconformance:

Target date for completion: _____

Proposed by: _____ Date: _____

PART 3: APPROVAL

Element Manager: _____ Date: _____

Director of QA: _____ Date: _____

Comments/Instructions:

PART 4: CLOSE OUT

Comments:

Verified by: _____ Date: _____

CNWRA FORM QAP 9-1

Figure 2

**CENTER FOR NUCLEAR WASTE
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Title

QAP-009 NONCONFORMANCE CONTROL

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 10/5/90. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	8/16/91
2 - 3	0	10/5/90
4	1	8/16/91
5 - 9	0	10/5/90

SUPERSEDED

Supersedes Procedure No. QAP-009 Rev. 0, Change 0

Approvals

Written By <i>Robert Bues</i>	Date <i>8/14/91</i>	Technical Review <i>R. Engelhardt</i>	Date <i>8/15/91</i>
Quality Assurance <i>Diana Malato</i>	Date <i>8/15/91</i>	Cognizant Director <i>[Signature]</i>	Date <i>8/16/91</i>

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- (2) When direct attachment of the hold tag is impractical, the tag shall be attached to the package, container, or shelf in a segregated hold area holding the item(s).
- (3) Hold tags shall be completed by the individual identifying an item or items as nonconforming, and shall include:
 - Identification of the item(s)
 - Quantity

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- Brief description of the nonconformance
- Date initiated
- Individual initiating
- Nonconformance Report number

3.2 Segregation

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- (3) Nonconforming items shall not be released from segregated storage nor shall hold tags be removed until properly dispositioned. Quality assurance personnel are solely authorized to release items and remove hold tags.

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- (2) The individual identifying the nonconforming condition shall initiate the NCR by providing the following information:
 - (a) Project number

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- (b) Description of the nonconforming condition, as applicable:
- The item name, part number, serial number
 - Affected inspection, experiment, or test
 - Description of the nonconformance, with reference to the requirement not complied with
 - Date initiated
 - Name of the individual initiating the NCR
- (3) Quality Assurance shall assign a unique NCR number and enter the NCR into the tracking log.
- (4) The Center QA staff shall identify the individual authorized and responsible for determining disposition, usually the Element Manager or Principal Investigator. This individual shall have demonstrated competence in the area of evaluation, adequate understanding of requirements, and access to pertinent background information. The original NCR shall be forwarded to this individual and a copy retained in the quality assurance files.

3.4 Disposition

- (1) The individual responsible for corrective action shall, within 10 working days of initiation of the NCR, complete Part 2 of the NCR, proposing:
- (a) Disposition (accept as-is, rework, repair, scrap, or return to supplier) of the nonconforming item(s) or of the experiment, test, or other activity affected by noncompliance to a procedural requirement. The disposition shall include a basis for the disposition and, as appropriate, a technical evaluation by qualified specialists.

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(b) Action to correct the cause of the nonconformance and a target date for implementation of the corrective action. If the action has already been taken, appropriate objective evidence of the corrective action shall be included with the NCR when practical.

- (2) The individual proposing the disposition and corrective action shall sign and date Part 2 of the NCR and forward the NCR to the Element Manager responsible for the affected activity.

3.5 Disposition Approval

- (1) The proposed disposition and corrective action shall be evaluated by the Element Manager responsible for the affected activity. The evaluation shall consider the impact of the disposition in light of contractual, and specification requirements. The Element Manager shall indicate concurrence with the proposed actions by signature and date in Part 3 of the NCR, along with any comments or instructions regarding the disposition.
- (2) The NCR shall then be forwarded to the Director of Quality Assurance for evaluation of the proposed disposition and corrective action in light of contractual and QA program requirements. The Director of Quality Assurance shall indicate concurrence with the proposed actions by his signature and date in Part 3 of the NCR form.
- (3) The Director of Quality Assurance shall include any comments or instructions in Part 3, such as special corrective action requirements and reinspection requirements for reworked or repaired items.

3.6 Distribution of the NCR

QA shall distribute copies of the approved NCR to the Element Manager and initiator.

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3.7 Release of Nonconforming Items

Quality Assurance personnel shall release items on hold and remove hold tags based on the approved disposition of the NCR.

3.8 Nonconformance Report Tracking Log

(1) QA shall maintain a system of issuing NCR numbers and tracking responses and closeout. Manual or computer systems are acceptable, provided the following information is recorded:

- (a) NCR number, date initiated, project number
- (b) Brief description of the nonconforming condition
- (c) Response due date and response date
- (d) Date approved
- (e) Corrective action target date
- (f) Date closed out

(2) Reminders for response due dates and corrective action target dates shall be provided three days prior to the action date to the responsible individual and cognizant QA personnel. Written notices shall be sent to the responsible individual, with copies to the Director of Quality Assurance and Element Manager when required actions are three days overdue.

3.9 Close-out

(1) If corrective action is taken prior to approval of the NCR, the Director of Quality Assurance shall evaluate the objective evidence provided or otherwise verify implementation of corrective action. Satisfactory implementation shall be indicated by signature and date in Part 4 of the NCR.

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- (2) Corrective actions targeted for implementation after approval shall be evaluated by Quality Assurance after the corrective action target date. The evaluation shall consist of review of objective evidence, reinspection, or surveillance to verify that the approved disposition and corrective action is complete. Close-out shall be indicated by signature and date in Part 4 of the NCR.
- (3) If Quality Assurance determines that the nonconformance has a major impact or is generic to the system, then Quality Assurance shall initiate a Corrective Action Request in accordance with CQAM Section 16.

4. RECORDS

- (1) Nonconformance report originals, with attachments, shall be maintained as QA records in accordance with CQAM Section 17 and retained in Quality Assurance files for a minimum of six years.
- (2) NCR tracking logs and notices shall be retained in Quality Assurance files for two years.

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Title **QAP-009 NONCONFORMANCE CONTROL**

EFFECTIVITY AND APPROVAL

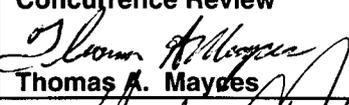
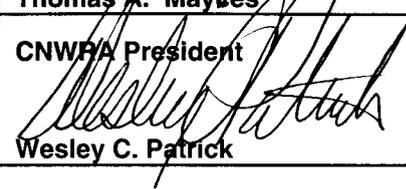
Revision 1 of this procedure became effective on 8/20/2002. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
ALL	0	8/20/2002

SUPERSEDED

Supersedes Procedure No. QAP-009 Rev. 0, Change 1

Approvals

Written By  Mark R. Ehnstom	Date 8/15/02	Concurrence Review  Thomas A. Maynes	Date 8/15/02
Quality Assurance  Bruce Mabrito	Date 8/15/2002	CNWRA President  Wesley C. Patrick	Date 8/15/2002

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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 nonconformance of goods, services, and activities, including software, with respect to specified requirements.

2. RESPONSIBILITIES

- (1) The CNWRA Director of Quality Assurance is responsible for implementing of this procedure.
- (2) The individual identifying the nonconforming condition is responsible for initiating the Nonconformance Report.
- (3) The individual identified as responsible for corrective action is responsible for proposing a disposition and correcting the cause of the nonconformance.

3. PROCEDURE

3.1 Identification

- (1) Nonconforming items should be identified by tagging with a "Hold Tag" (Figure 1) or equivalent. The hold tag shall be directly attached to the item or lot of items if practical. The tag shall be placed such that the end use of the item is not adversely affected.
- (2) When direct attachment of the hold tag is impractical, the tag shall be attached to the package, container, or shelf in a segregated hold area holding the item(s).
- (3) Hold tags shall be completed by the individual identifying an item or items as nonconforming, and shall include:
 - Identification of the item(s)
 - Quantity
 - Brief description of the nonconformance

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- Date initiated
- Individual initiating
- Nonconformance Report number

3.2 Segregation

- (1) Items shall be removed from the work area and segregated to prevent inadvertent use.
- (2) When physical conditions, such as size, weight, or access limitations preclude segregation, the nonconforming items shall be separated from conforming items of the same type as much as possible. Depending on the size of the item, 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) Nonconforming items shall not be released from the segregated area nor shall hold tags be removed until the item is properly dispositioned.

3.3 Initiation of Nonconformance Reports

- (1) Nonconforming goods, services, activities (including software), and specific noncompliance to procedural requirements shall be reported through the use of the Nonconformance Report, CNWRA Form QAP-009 (Figure 2).
- (2) The individual identifying the nonconforming condition shall initiate the Nonconformance Report by providing the following information:
 - (a) Project number
 - (b) Description of the nonconforming condition, as applicable:
 - Identify the good, service, activity, or software
 - Affected inspection, experiment, or test
 - Description of the nonconformance, with reference to the requirement not complied with
 - Date initiated
 - Name of the individual initiating the Nonconformance Report

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- (3) Quality Assurance staff shall assign a unique Nonconformance Report number and enter the Nonconformance Report information into the tracking log.
- (4) The CNWRA Quality Assurance staff shall identify the individual authorized and responsible for determining disposition, usually the Element Manager or Principal Investigator. The Nonconformance Report shall be forwarded to this individual and a copy retained in the quality assurance files.

3.4 Disposition

- (1) The individual responsible for corrective action shall, within 10 days of initiation of the Nonconformance Report, complete Part 2 of the Nonconformance Report, proposing:
 - (a) Disposition (accept as-is, rework, repair, scrap, return to supplier, or other) of the nonconforming item(s) or of the experiment, test, or other activity affected by noncompliance to a procedural requirement. The disposition shall include a basis for the disposition and, as appropriate, a technical evaluation by qualified specialists.
 - (b) Action to correct the cause of the nonconformance and a target date for implementation of the corrective action. If the action has already been taken, appropriate objective evidence of the corrective action shall be included with the Nonconformance Report when practical.
- (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 Element Manager responsible for the affected activity.

3.5 Disposition Approval

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

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- (2) The Nonconformance Report shall then be forwarded to the Director of Quality Assurance for evaluation of the proposed disposition and corrective action. The Director of Quality Assurance shall indicate concurrence with the proposed actions by his signature and date in Part 3 of the Nonconformance Report form.
- (3) If Quality Assurance determines that the nonconformance has a major impact or is generic to the system, then Quality Assurance shall initiate a Corrective Action Request in accordance with Center Quality Assurance Manual Section 16.
- (4) The Director of Quality Assurance shall include any comments or instructions in Part 3, such as special corrective actions requirements and reinspection requirements for reworked or repaired items.

3.6 Close-out

- (1) If corrective action is taken prior to approval of the Nonconformance Report, the Director of Quality Assurance shall evaluate the objective evidence provided or otherwise verify implementation of corrective action. Satisfactory implementation shall be indicated by signature and date in Part 4 of the Nonconformance Report.
- (2) Corrective actions targeted for implementation after approval of the Nonconformance Report shall be evaluated by Quality Assurance after the corrective action target date. The evaluation shall consist of review of objective evidence, reinspection, or surveillance to verify that the approved disposition and corrective action are complete. Close-out shall be indicated by signature and date in Part 4 of the Nonconformance Report form.

3.7 Release of Nonconforming Items

Quality Assurance personnel 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

Quality Assurance shall distribute copies of the completed Nonconformance Report to the Element Manager, Principal Investigator, and others indicted on the Nonconformance Report form.

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4.0 NONCONFORMANCE REPORT TRACKING LOG

(1) Quality Assurance shall maintain a system of issuing Nonconformance Report numbers and tracking responses and closeout. Manual or computer systems are acceptable, provided the following information is recorded.

- (a) Nonconformance Report number, date initiated, project number
- (b) Brief description of the nonconforming condition
- (c) Response due date and response date
- (d) Date approved
- (e) Corrective action target date
- (f) Date closed out

(2) Reminders for response due dates and corrective action target dates should be provided three days prior to the action date to the responsible individual and cognizant Quality Assurance personnel. Written notice should be sent to the responsible individual, with copies to the Director of Quality Assurance and Element Manger or Principal Investigator when required actions are overdue.

5. NONCONFORMANCE TRENDING ANALYSIS

On an annual basis, CNWRA Nonconformances and other relevant information shall be evaluated for trends requiring corrective action. This annual evaluation shall typically be performed approximately six months after the annual CNWRA audit to provide sufficient time to identify adverse trends and allow the results to be published and acted upon. 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 CNWRA management and the Advisory Committee for Quality Improvement through the Institute Quality Assurance manager.

6. RECORDS

Nonconformance Reports, originals with attachments, and tracking logs shall be maintained as Quality Assurance records in accordance with the Center Quality Assurance Manual Section 17 and retained in Quality Assurance files.

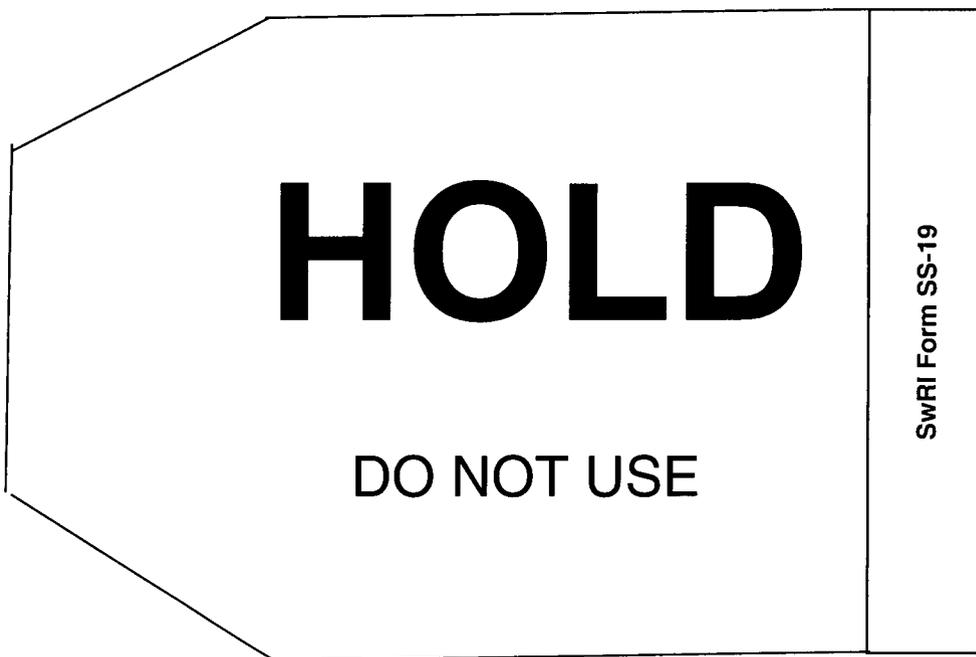
**CENTER FOR NUCLEAR WASTE
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QUALITY ASSURANCE PROCEDURE

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(Example)
Figure 1

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
NONCONFORMANCE REPORT

Project No. _____

NCR No. _____

PART 1: DESCRIPTION OF NONCONFORMANCE

Initiated by: _____

Date: _____

Action Required by: _____

Response Date: _____

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

Disposition:

Basis of Disposition:

Action to Correct Nonconformance:

Target date for completion: _____

Proposed by: _____

Date: _____

PART 3: APPROVAL

Element Manager: _____ Date: _____

Director of QA: _____ Date: _____

Comments/Instructions:

PART 4: CLOSE OUT

Comments:

Verified by: _____ Date: _____

Distribution:
Original-CENTER QA Records
ORIGINATOR
PRINCIPAL INVESTIGATOR
ELEMENT MANAGERS
TECHNICAL DIRECTOR
ADMINISTRATIVE DIRECTOR

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EFFECTIVITY AND APPROVAL

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<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1	1	7/29/2003
2-5	0	8/20/2002
6	1	7/29/2003
7-8	0	8/20/2002

Supersedes Procedure No. QAP-009 Rev. 1, Change 0

Approvals

Written By <i>Mark R. Ehnstrom</i> Mark R. Ehnstrom	Date 7/24/03	Coincurrence Review <i>Rodney Weber</i> Rodney Weber	Date 7/24/03
Quality Assurance <i>Robert Brient</i> Robert Brient	Date 7/24/03	Cognizant Director <i>Robert Brient</i> Robert Brient	Date 7/24/03

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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 nonconformance of goods, services, and activities, including software, with respect to specified requirements.

2. RESPONSIBILITIES

- (1) The CNWRA Director of Quality Assurance is responsible for implementing of this procedure.
- (2) The individual identifying the nonconforming condition is responsible for initiating the Nonconformance Report.
- (3) The individual identified as responsible for corrective action is responsible for proposing a disposition and correcting the cause of the nonconformance.

3. PROCEDURE

3.1 Identification

- (1) Nonconforming items should be identified by tagging with a "Hold Tag" (Figure 1) or equivalent. The hold tag shall be directly attached to the item or lot of items if practical. The tag shall be placed such that the end use of the item is not adversely affected.
- (2) When direct attachment of the hold tag is impractical, the tag shall be attached to the package, container, or shelf in a segregated hold area holding the item(s).
- (3) Hold tags shall be completed by the individual identifying an item or items as nonconforming, and shall include:
 - Identification of the item(s)
 - Quantity
 - Brief description of the nonconformance

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- Date initiated
- Individual initiating
- Nonconformance Report number

3.2 Segregation

- (1) Items shall be removed from the work area and segregated to prevent inadvertent use.
- (2) When physical conditions, such as size, weight, or access limitations preclude segregation, the nonconforming items shall be separated from conforming items of the same type as much as possible. Depending on the size of the item, 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) Nonconforming items shall not be released from the segregated area nor shall hold tags be removed until the item is properly dispositioned.

3.3 Initiation of Nonconformance Reports

- (1) Nonconforming goods, services, activities (including software), and specific noncompliance to procedural requirements shall be reported through the use of the Nonconformance Report, CNWRA Form QAP-009 (Figure 2).
- (2) The individual identifying the nonconforming condition shall initiate the Nonconformance Report by providing the following information:
 - (a) Project number
 - (b) Description of the nonconforming condition, as applicable:
 - Identify the good, service, activity, or software
 - Affected inspection, experiment, or test
 - Description of the nonconformance, with reference to the requirement not complied with
 - Date initiated
 - Name of the individual initiating the Nonconformance Report

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- (3) Quality Assurance staff shall assign a unique Nonconformance Report number and enter the Nonconformance Report information into the tracking log.
- (4) The CNWRA Quality Assurance staff shall identify the individual authorized and responsible for determining disposition, usually the Element Manager or Principal Investigator. The Nonconformance Report shall be forwarded to this individual and a copy retained in the quality assurance files.

3.4 Disposition

- (1) The individual responsible for corrective action shall, within 10 days of initiation of the Nonconformance Report, complete Part 2 of the Nonconformance Report, proposing:
 - (a) Disposition (accept as-is, rework, repair, scrap, return to supplier, or other) of the nonconforming item(s) or of the experiment, test, or other activity affected by noncompliance to a procedural requirement. The disposition shall include a basis for the disposition and, as appropriate, a technical evaluation by qualified specialists.
 - (b) Action to correct the cause of the nonconformance and a target date for implementation of the corrective action. If the action has already been taken, appropriate objective evidence of the corrective action shall be included with the Nonconformance Report when practical.
- (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 Element Manger responsible for the affected activity.

3.5 Disposition Approval

- (1) The proposed disposition and corrective action shall be evaluated by the Element Manager responsible for the affected activity. The evaluation shall consider the impact of the disposition in light of contractual and technical requirements. The Element Manager shall indicate concurrence with the proposed actions by signature and date in Part 3 of the Nonconformance Report, along with any comments or instructions regarding the disposition.
- (2) The Nonconformance Report shall then be forwarded to the Director of Quality Assurance for evaluation of the proposed disposition and corrective action. The Director of Quality Assurance shall indicate concurrence with the proposed actions by his signature and date in Part 3 of the Nonconformance Report form.
- (3) If Quality Assurance determines that the nonconformance has a major impact or is generic to the system, then Quality Assurance shall initiate a Corrective Action Request in accordance with Center Quality Assurance Manual Section 16.

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- (4) The Director of Quality Assurance shall include any comments or instructions in Part 3, such as special corrective actions requirements and reinspection requirements for reworked or repaired items.

3.6 Close-out

- (1) If corrective action is taken prior to approval of the Nonconformance Report, the Director of Quality Assurance shall evaluate the objective evidence provided or otherwise verify implementation of corrective action. Satisfactory implementation shall be indicated by signature and date in Part 4 of the Nonconformance Report.
- (2) Corrective actions targeted for implementation after approval of the Nonconformance Report shall be evaluated by Quality Assurance after the corrective action target date. The evaluation shall consist of review of objective evidence, reinspection, or surveillance to verify that the approved disposition and corrective action are complete. Close-out shall be indicated by signature and date in Part 4 of the Nonconformance Report form.

3.7 Release of Nonconforming Items

Quality Assurance personnel 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

Quality Assurance shall distribute copies of the completed Nonconformance Report to the Element Manager, Principal Investigator, and others indicated on the Nonconformance Report form.

4.0 NONCONFORMANCE REPORT TRACKING LOG

- (1) Quality Assurance shall maintain a system of issuing Nonconformance Report numbers and tracking responses and closeout. Manual or computer systems are acceptable, provided the following information is recorded.
- (a) Nonconformance Report number, date initiated, project number
 - (b) Brief description of the nonconforming condition
 - (c) Response due date and response date
 - (d) Date approved
 - (e) Corrective action target date
 - (f) Date closed out

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- (2) Reminders for response due dates and corrective action target dates should be provided three days prior to the action date to the responsible individual and cognizant Quality Assurance personnel. Written notice should be sent to the responsible individual, with copies to the Director of Quality Assurance and Element Manger or Principal Investigator when required actions are overdue.

5. NONCONFORMANCE TRENDING ANALYSIS

On an annual basis, CNWRA Nonconformances and other relevant information shall be evaluated for trends requiring corrective action. This annual evaluation shall typically be performed approximately six months after the annual CNWRA audit to provide sufficient time to identify adverse trends and allow the results to be published and acted upon. 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 CNWRA management.

6. RECORDS

Nonconformance Reports, originals with attachments, and tracking logs shall be maintained as Quality Assurance records in accordance with the Center Quality Assurance Manual Section 17 and retained in Quality Assurance files.

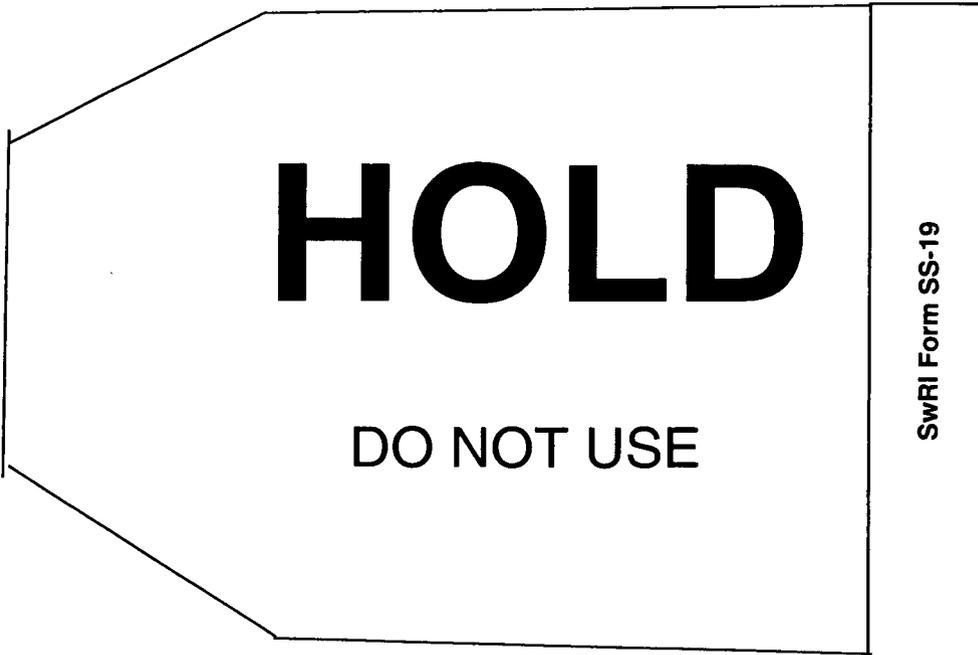
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(Example)
Figure 1

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**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
NONCONFORMANCE REPORT**

Project No. _____

NCR No. _____

PART 1: DESCRIPTION OF NONCONFORMANCE

Initiated by: _____

Date: _____

Action Required by: _____

Response Date: _____

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

Disposition:

Basis of Disposition:

Action to Correct Nonconformance:

Target date for completion: _____

Proposed by: _____

Date: _____

PART 3: APPROVAL

Element Manager: _____

Date: _____

Director of QA: _____

Date: _____

Comments/Instructions:

PART 4: CLOSE OUT

Comments:

Verified by: _____

Date: _____

Distribution:

Original-CENTER QA Records
ORIGINATOR
PRINCIPAL INVESTIGATOR
ELEMENT MANAGERS
TECHNICAL DIRECTOR
ADMINISTRATIVE DIRECTOR