

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

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NONCONFORMANCE REPORT

Project No. 20.01402.158

NCR No. 2001-13

PART 1: DESCRIPTION OF NONCONFORMANCE

- 1. Receipt inspection instructions were not included on purchase documents as required by CQAM 10.6.
- 2. Implementing procedure for purchase document control (QAP-016) does not make mandatory the inclusion of receiving inspection criteria (i.e., does not flow down the requirement of CQAM Section 10.6).

Initiated by: Robert Brient

Date: 8/24/2001

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION : H. Garcia/B. Mabrito
Response 9/10/2001

Disposition:

Reword QAP-016, Procurement, to comply with CQAM requirements.

Basis of Disposition:

Review of Receipt Travelers document acceptance of procured items by Principal Investigators and/or Element Managers or designated alternate.

Action to correct nonconformance:

Revise and clarify QAP-016, Procurement, and CQAM section 10.6 and section 4.4.2, to possibly include receiving inspection instructions located or referenced on the procurement document. Receiving inspections at the CNWRA are primarily "visual inspection" to ensure that the item ordered is delivered in acceptable condition..

[Signature]

9/10/2001

Target date for completion: 10/24/2001

Proposed by: *[Signature]*

Date: 9/10/01

PART 3: APPROVAL

9/10/01

Element Manager: *[Signature]*

Date: 9/10/2001

Director of QA: *[Signature]*

Date: 9/12/2001

Comments/Instructions:

PART 4: CLOSE OUT

Section IV was revised to require procurement documents contain receiving inspection activities and acceptance requirements. Section I was also revised and requires receiving inspection planning activities to be described in the procurement procedure. QAP-016, Procurement,

Distribution:

- Original-CNWRA/QA DIRECTOR QA Records
- Element Managers
- B. Soyars, H. Garcia*
- M. Ehrstrom*

Verified by: *[Signature]* Date: 1/15/02

was revised and now describes receiving inspection planning activities.

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MEMORANDUM

October 24, 2001

TO: Nonconformance Reports No. 2001-13 and 2001-14 Files

FROM: Bruce Mabrito, Director of CNWRA QA



SUBJECT: Status/Extension on NCR 2001-13 and NCR 2001-14

This memorandum to the NCR No. 2001-13 and NCR No. 2001-14 files is an explanation of the progress to date on closing out these NCRs and provides for an extension in the target dates for completion.

These nonconformance reports describe shortcomings in the CNWRA quality program on receipt inspection instructions, receiving inspection criteria, inspection status and inspection status identification.

Draft changes have been made to Quality Assurance Procedure-016, Procurement, and changes are being made to the CNWRA Quality Assurance Manual (CQAM). Both the QAP and the CQAM areas were identified in the two NCRs as areas in which to provide corrections.

Changes to QAP-016 are being checked by the CNWRA Director of Administration. Changes to the CQAM are being checked by CNWRA QA staff, and will be formally reviewed by an Element Manager and the CNWRA President.

Due to other pressing QA matters, and answering NCRs and Corrective Action Requests from the QA audit, progress has been made but will not be complete in the specified time limit to completely close out these two subject NCRs.

Based on this information and the currently anticipated QA activity in the CNWRA, I am extending the formal target date for completion of NCR No. 2001-13 and NCR No. 2001-14 to November 16, 2001.

- cc: B. Mabrito
- H. Garcia
- M. Ehnstrom/30
- T. Mayces/30
- M. Padilla/CNWRA QA
- R. Folck/QA Consultant

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10.5 INSPECTION HOLD POINTS AND FINAL INSPECTION

Inspection hold points, shall be established. These include technical and programmatic reviews of the documents in the review process and confirmatory analyses on material received by the CNWRA, when required. QA verification on the document review sheet is equivalent to a final inspection on products.

10.6 INSPECTION, PLANNING, AND SAMPLING

- Receiving inspection planning activities for quality affecting products shall be described in the procurement procedure. To determine satisfactory performance of vendors not currently listed on the SwRI ASL, confirmatory analyses shall be accomplished. A modified sampling plan for non-ASL organizations shall be used to establish a history of providing products which perform satisfactorily in actual use through confirmatory analysis. The Quality Requirements Application Matrix shall be completed by EMs and jointly approved by the Technical Director and the QA Director. Nonconformances identified in inspection, planning and sampling shall be documented in accordance with section 15. Special circumstances may require confirmatory analysis of multiple items from the same purchase order (as discussed in section 7, paragraph 7.1.1).

10.7 IN-PROCESS INSPECTION

QA surveillances are performed at the CNWRA as in-process inspections.

10.8 RECORDS

QA records shall be maintained in accordance with section 17 of this CQAM.

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by client requests.

3087 B. Mabrito

Approvals

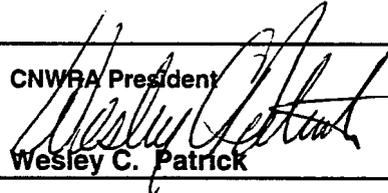
Director of Quality Assurance


Bruce Mabrito

Date

1/10/2002

CNWRA President


Wesley C. Patrick

Date

1/10/2002

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4.4.2 Technical Reuirements

Technical requirements shall be specified in CNWRA procurement documents. When necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items, material, equipment, or services to be furnished.

The CNWRA procurement documents shall identify required receiving inspection activities, and acceptance requirements.

4.4.3 Quality Assurance Program Requirements

Procurement documents for quality-affecting items shall require that the supplier have a documented QA program that implements applicable portions or all of the requirements of 10CFR Part 50, Appendix B, or the quality requirements of 10CFR Part 63, or ANSI/ASME NQA-1-1986. The extent of the program required shall depend upon the type and use of the material, equipment, item or service being procured. If necessary, procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.

Adaptations and clarifications have been made to certain nuclear QA requirements and criteria that are not applicable to scientific investigations and analyses performed by the CNWRA. These adaptations and clarifications are summarized in CQAM section 2.

4.4.4 Right of Access

Procurement documents shall provide for access to the supplier's facilities and records for inspection or audit by CNWRA staff, designated representative, and/or other parties authorized by the CNWRA.

4.4.5 Documentation Reuirements

Procurement documents shall identify the documentation required to be submitted to the CNWRA for information, review, or approval. When the CNWRA requires the supplier to maintain specific QA records, the retention times and disposition requirements shall be prescribed.