

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

15/40

CORRECTIVE ACTION REQUEST

CAR No: 2002-02

Associated AR, SR, NCR No: SR 2002-18

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

In accordance with CQAM Section 4 titled "Procurement Document Control," paragraph 4.4.2, procurement documents are not identifying receiving inspection activities and acceptance requirements. In addition procurement documents and the procurement procedure do not address the "right of access" to the suppliers' facilities or records for inspection or audits by CNWRA staff or designated representatives as specified in paragraph 4.4.4.

In accordance with Quality Assurance Procedure QAP-016 titled "Procurement" paragraph 5.1.1 quality affecting procurement documents are not all clearly identified with the statement "Quality Affecting Purchase."

These nonconforming conditions are similar to findings identified on Nonconformance Report No. 2001-13

Initiated by: Thomas A. Mayces *TAM*

Date July 18, 2002

PART B: PROPOSED ACTION

Responsible Individual: B. Mabrito
Response Due: 8/15/2002

1) Extent of Condition: *A review of purchase documents found that inspection criteria was not being placed on project purchase requisitions. None of the quality affecting purchase documents referenced "right of access." The statement "Quality Affecting Purchase" was not placed on some requisitions.*

2) Root Cause: *The procedure did not address "right of access" requirement. The procedure was also over restrictive in identifying the statement signifying an acceptable receipt inspection. Incomplete inspection criteria was being placed on procurement documents.*

3) Remedial Action: *The procedure will be evaluated for revision to include statements containing the requirements for the inspection criteria to be specified and for the "right of access" to be placed on each quality affecting procurement document. The revision will also allow more freedom in statements showing acceptable receipt of quality affecting items.*

Proposed Completion Date: 8/16/02

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 8/16/02

Training was provided to CNWRA staff on the new requirements contained in the revised procedure, QAP-016 Revision 6 Change 0.

Element Manager:

Summa Malufo

Date:

8/15/2002

PART C: APPROVAL
Comments/Instructions

Clear establishment of the "right to access" in QAP-016 and training with respect to this new requirement as well as the need to document receiving inspections should prove effective. Ongoing surveillance will be used to evaluate effectiveness.

Director of QA:

W. J. Johnson, President

Date:

8/13/2002

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

A review of 5 quality affecting purchase requisitions found that they referenced the appropriate Q - clause for right of access. The purchase requisitions also made reference to QAP-016 for inspection criteria. Training had been provided by the Director of QA on August 14, 2002. (Reference PR# 624875, 637636, 637637, 655634, + 624998)

Distribution:

- Original-CNWRA/QA DIRECTOR QA Records
- ORIGINATOR
- PRINCIPAL INVESTIGATORS
- ELEMENT MANAGERS
- TECHNICAL DIRECTOR
- CNWRA PRESIDENT

Verified by:

Thomas A. Mayces

Date:

12/23/02

16/40

**Center for Nuclear Waste Regulatory Analyses
(210) 522-5149**

From: **Bruce Mabrito**

Date: 8/16/2002

To: *Wes -*

*I wrote this CAR before the
audit because our surveillances did
not indicate full compliance. The
audit did not find similar situations,
but this did need to be documented.
Please review and sign for me in
the approval block. Thanks. *Bruce**

*Bruce: looks good.
Note that my response to
calls for surveillance to
verify. *Wes 8/19**

Bruce Mabrito

17/40

From: Bruce Mabrito [bmabrito@cnwra.swri.edu]
Sent: Wednesday, August 14, 2002 9:12 PM
To: Staff_Group
Subject: Procurement Procedure Training

Training Objective: To reinforce the requirements of the CNWRA procurement process and inform CNWRA staff to procedure changes.

Training Content: Portions of QAP-016, Procurement, Rev. 6, Chg. 0.

QAP-016, Procurement, Revision 6, Change 0, was distributed recently to key CNWRA staff and others who frequently utilize the CNWRA/SwRI purchasing system. This revision incorporates changes recommended by CNWRA staff and provides more clear guidance to staff members.

Discussion: The CNWRA uses individuals and organizations, including core staff, students, SwRI staff, consultants and subcontractors, to perform quality-affecting activities that are incorporated into CNWRA reports and products. Activities potentially affecting quality include: scientific investigations, experiments, tests, analytical services, reviews, code development, receiving inspections and numerical analyses. The results from these activities are accepted or rejected by appropriate, qualified CNWRA technical staff based on their case-by-case assessment of the resultant quality of the work relative to project requirements and evaluation criteria.

Note that quality-affecting "goods" (such as test materials, physical or chemical calibration standards, etc.) may be procured from approved sources on the SwRI Approved Suppliers List (ASL) or shall be qualified through the method described in QAP-018, Procedure for Confirmatory Analyses. Note also that quality-affecting goods shall not be purchased via the "procurement card" or "petty cash" account, or without an SwRI purchase requisition.

Procurement of scientific and engineering software shall be controlled from initiation of procurement documents through validation testing to assure the software performs as described in development and controlling documents. See Technical Operating Procedure-018 for more information.

Calibration services are best provided by the SwRI Calibration Laboratory. If they are not able to provide the calibration services, they should be able to provide you with an approved calibration source on the SwRI ASL. Calibration from the manufacturer of an instrument is NOT ALWAYS TRACEABLE to a national or international standard and the SwRI Calibration Lab should be contacted first.

When filling out a purchase requisition, be sure to state if the purchase is quality-affecting. Call QA at ext. 5149, 3530, or 6833 and we can assist you decide on whether the purchase is quality-affecting. Also identify whether the supplier is on the SwRI ASL. List the scope of work or a detailed description of the goods or services required. List any applicable codes, regulations, specifications, standards, drawings, or CNWRA procedures or technical requirements on the purchase requisition. List any special certification requirements or special documentation.

When you receive the goods or services you ordered, use the "Instructions for Performing Receiving Inspections on Quality-Affecting Items" in the back of QAP-016 as a reference. Our technical staff are experts in many of these goods ordered and we rely SOLELY ON YOU to inspect and accept such goods and services. If a good or item is acceptable, write on the SwRI Receipt Traveler "Accepted" or "Items Accepted," or "OK." You must clearly indicate

on the Receipt Traveler that you have accepted the item. If it is not acceptable, immediately notify the supplier and the SwRI Shipping and Receiving Department. We will be automatically billed if we do not take action within five work days of the delivery. That is how the SwRI procurement system is set up.

18/40

Any technical services accepted can be shown on the voucher/invoice from a consultant or a subcontractor. If technical services are not acceptable, work with your Element Manager to ensure that we do not pay for them. Our contracts are written so that if they do not meet our requirements, we do not pay them.

If you have any questions regarding this QAP-016 Procurement procedure, contact me at ext. 5149 and we'll discuss it. Bruce Mabrito, CNWRA QA

Bruce Mabrito

ATTACH TO
CAR
19/40

From: Bruce Mabrito [bmabrito@cnwra.swri.edu]
Sent: Thursday, July 18, 2002 8:51 PM
To: Tech_Group
Cc: Mark Ehnstrom; Thomas A. Mayces; Randolph W. Folck; Maria Padilla; Henry Garcia
Subject: TRAINING: RECEIVING INSPECTIONS

TRAINING OBJECTIVE: To remind CNWRA staff of the requirements of the Receiving Inspection process.

TRAINING CONTENT: Portions of Quality Assurance Procedure-016, Procurement

The following instructions are to be followed to perform satisfactory receiving inspections on quality affecting goods and services at the CNWRA. Satisfactory acceptance of any good or service must be documented in accordance with QAP-016 requirements. Any unacceptable or unsatisfactory receiving should be processed in accordance with QAP-016 paragraph 7.6, "Control of Nonconformances."

Acceptance of goods and services, which includes but is not limited to chemicals, equipment calibration, test samples, computer software, science and engineering reports, and other quality affecting purchases shall be performed by assuring the following criteria are satisfied:

- + Assure that goods or services are properly labeled
- + Requested documentation listed on the purchase requisition has been received and includes physical, dimensional, or other specified characteristics, as applicable
- + The correct amount or number of the goods or services was sent
- + The goods or services are in the proper configuration
- + The inspection you perform must identify any requirements that have not been met and shall identify any associated nonconformance reports documenting final resolution
- + The item is clean and free from shipping damage

The CNWRA staff can call on CNWRA QA for any assistance in showing how these items can be inspected. Remember, we worked hard to make it permissible for CNWRA Technical staff to conduct their own inspections of goods and services, rather than have QA staff perform those inspections, with the potential delays, etc. involved with that approach.

If you have any questions regarding this receiving inspection process, contact me at ext. 5149. Bruce Mabrito, CNWRA QA

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

20/40

MEMORANDUM

September 18, 2002

TO: QA Records Corrective Action Request 2002-02 Folder

FROM: Bruce Mabrito, Director of Quality Assurance

SUBJECT: Extension of Time on CAR 2002-02

REFERENCE: CAR 2002-02



This memorandum to the Corrective Action Request (CAR) 2002-02 folder is to document progress and extend the time for final close out.

CAR 2002-02 was originated July 18, 2002; it was responded to by CNWRA QA staff on August 15, 2002. The proposed action was accepted and approved by CNWRA President W. Patrick on August 18, 2002, with the proviso that an evaluation should be made into the effectiveness of the changes. Training had been provided earlier (on July 18, 2002 and on August 14, 2002) via email messages.

Several checks were made in August and September to see if there were enough procurement documents to determine if improvements had been made. It was determined that there was not a sufficient number of procurement documents generated (that were for quality-affecting purchases) to show whether an acceptable or unacceptable trend had been established.

It is anticipated that when a sufficient number of quality-affecting procurement documents are available for review, then an effective evaluation can be made. The exact date of such a review is not possible to pin down at this time.

I am extending the target closure date for this CAR until the end of calendar year 2002, or December 31, 2002.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

21/40

MEMORANDUM

October 14, 2002

TO: QA Records Corrective Action Request 2002-02 Folder
FROM: Mark Ehnstrom *(ME)*
SUBJECT: CAR 2002-02 Review – Insufficient Documents Available
REFERENCE: CAR 2002-02

Based on a review of Purchase Requisitions/Material Receiving Reports on 10/14/2002, there is not a sufficient number of documents to show an acceptable trend to close CAR 2002-02.

Follow-up for close out activities for this CAR should again be performed in 6-8 weeks to identify if significant documentation exists at that time for possible CAR close out.