

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 99-2

Associated AR, SR, NCR No: CNWRA Audit 99-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY Quality requirements are not consistently identified in standard consulting agreements, subcontracts, internal SwRI work orders, or purchase orders as required by the CNWRA QA Manual, Section 7. In addition, QAP-016 is deficient in providing a more detailed instruction of all requirements identified in this section.

Initiated by: T.C. Trbovich *TeY* Date: 6/11/99

PART B: PROPOSED ACTION

1) Extent of Condition:
See attached page.

2) Root Cause:
See attached page.

3) Remedial Action:
See attached page.

4) Corrective Action to Preclude Recurrence:
See attached page.

Responsible EM: ~~B. E. Mabrito~~ *BSM*
Response Due: 7/12/99
H. F. Garcia
per W. Patrick
6/18/99

Proposed Completion Date:
See attached page.

Proposed Completion Date:
See attached page.

Element Manager: *[Signature]* Date: 7/8/99

PART C: APPROVAL

Comments/Instructions: Reviewed by *LWD* 13/07/99

Director of QA: *[Signature]* Date: 7/12/99

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

All items of CAR 99-2 proposed actions have been addressed. CAR # QAP-016 in place. Implementation in progress.

Verified by: *[Signature]* Date: 11/19/99

Distribution: *Element Managers*
B. Singer / H. Garcia / P. Amelin
W. Patrick
M. Ehrstrom

CORRECTIVE ACTION REQUEST NO. 2

Quality requirements are not consistently identified in standard consulting agreements, subcontracts, internal SwRI work orders, or purchase orders as required by the CNWRA QA Manual, Section 7. In addition, QAP-016 is deficient in providing a more detailed instruction of all requirements identified in this section.

Extent of Condition: The audit identified instances where quality requirements were not specified on documents for the procurement of services. A revision to QAP-016 was made earlier in the year, but was not sufficiently detailed to specify documents such as SwRI work orders, subcontract agreements, and consultant services contracts.

Root Cause: As the CNWRA increased its demand for additional consultants, subcontractors, and SwRI personnel to support CNWRA core staff in their project activities, the procedural controls for assuring that quality requirements are included in procurement documents have not been applied consistently.

Remedial Action: In the interim, before corrective action is concluded, the Director of Administration will ensure that all documents for securing quality-affecting services are reviewed by a QA staff person. For requesting the initiation of a subcontract agreement, the QA staff person will affix the proper quality requirements when needed and sign the appropriate block of the Purchase Requisition. QA requirements for CNWRA work to be performed by other SwRI divisions will be documented on an appropriate Statement of Work (SOW). This SOW can be included with the purchase requisition for a subcontract agreement, attached to the consultant services contract, or made part of the memorandum from the CNWRA staff member to the SwRI person responsible for performing the service. The cognizant CNWRA EM and QA staff person will review the SOW to assure proper quality requirements are being specified, at least until a revised QAP-016 has been issued to provide better guidance.

Proposed Completion Date: One week from response to this CAR.

Corrective Action to Preclude Recurrence: Procedure QAP-016 will be revised to more fully encompass the procurement activities of the CNWRA. Personnel performing procurement activities will be instructed in the new procedure to assure full compliance with the newly revised procedure.

Proposed Completion Date: September 13, 1999

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

17/66

MEMORANDUM

November 19, 1999

TO: QA Records Corrective Action Request 99-2 File

FROM: Bruce Mabrito, Director of Quality Assurance 

SUBJECT: Closure of CAR 99-2

REFERENCE: CAR 99-2 from Annual CNWRA QA Audit

This memorandum to Corrective Action Request 99-2 file is to document closure of this CAR.

The final required actions to close out CAR 99-2 have now taken place.

Since July 12, 1999, when the proposed action was accepted by CNWRA Quality Assurance, purchase requisitions for securing quality-affecting services have been reviewed by a QA staff person. Since that date, considerable work was invested in revising the CNWRA Quality Assurance Manual (CQAM), concentrating on Section 4, Procurement Document Control, and Section 7, Procurement Control. In September 1999, Revision 3 to the CQAM was submitted to the NRC for approval. The CNWRA received correspondence dated October 26, 1999 from the NRC accepting the CQAM and the concepts outlined in the CQAM.

Following acceptance of the CQAM by the NRC, a concerted effort was made to revise QA Procedure-016, Procurement. The reason for waiting on QAP-016 was because the umbrella document, the CQAM, contained the important overview and conceptual approach to addressing the procurement situation at the CNWRA. Once the CQAM approach was endorsed by the NRC, we next proceeded with revising the implementing procedure. QAP-016 was completed November 12, 1999. It was distributed to key CNWRA staff and is being implemented by the CNWRA staff and the CNWRA Financial Clerk. Training by e-mail was distributed to CNWRA staff who are involved in purchasing quality-affecting goods and services. CNWRA QA staff are working more closely with the procurement staff to review procurement documents.

The above text also describes the reason why closure of this CAR went beyond the proposed completion date of September 13, 1999.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. <u>QAP-016</u> Revision <u>2</u> Page <u>1</u> of <u>12</u>
---	---

Title **QAP-016 PROCUREMENT**

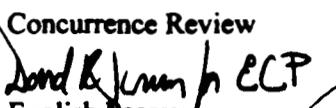
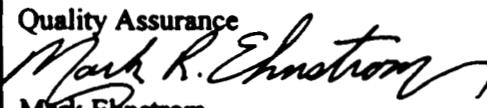
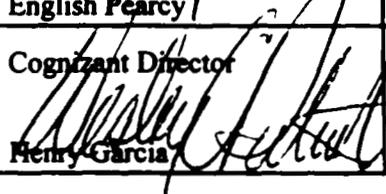
EFFECTIVITY

Revision 2 of this procedure became effective on 11/12/99. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change No.</u>	<u>Date Effective</u>
All	0	11/12/99

UNCONTROLLED

Supersedes Procedure No. QAP-006 Rev 1 and QAP-016 Rev 1

Approvals			
Written by  Bruce Mabrito	Date 11/12/99	Concurrence Review  English Percy	Date 11/12/99
Quality Assurance  Mark Ehstrom	Date 11/12/99	Cognizant Director  Henry Garcia	Date 11/14/99

5 of 8
19/66

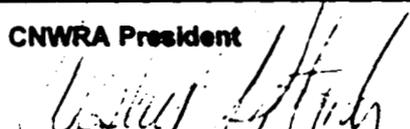
CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE MANUAL	Revision 3, Change 0 September 1999 Page 1 of 1
--	--

EFFECTIVITY AND APPROVAL

Revision 3 of this manual became effective on September 27, 1999. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	09/27/99

**CNWRA
CONTROLLED
COPY M. Padilla**

Approvals			
Director of Quality Assurance 	Date 9/23/99	CNWRA President 	Date 9/23/99



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

6 of 8
20/66

1402-159-910
6/22/1999
SUBJECT: 710 ✓
PROJECT: 710-1402-159

October 26, 1999

Henry F. Garcia
Director of Administration
Center for Nuclear Waste
Regulatory Analyses
Southwest Research Institute
6220 Culebra Road, Bldg. 189
San Antonio, Texas 78228-0510

Subject: Revisions to the CNWRA Quality Assurance Manual - Intermediate Milestone No. 1402-159-910

Dear Mr. Garcia:

We have reviewed Revision 3, Change 0 of the CNWRA Quality Assurance Manual and find it acceptable. This action satisfies the requirements of Intermediate Milestone No. 1402-159-910.

If you have any questions regarding this matter, I can be reached on (301) 415-7796.

Sincerely,

Deborah A. DeMarco
NRC CNWRA Deputy Program Manager
Program Management, Policy Development
and Analysis Staff, NMSS

cc: J. Linehan
B. Meehan

cc: J. Linehan
B. Meehan
WCF

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES CONTROLLED DOCUMENT TRANSMITTAL AND ACKNOWLEDGEMENT RECORD

TO: Roseanne Ard
CNWRA
6220 Culebra Road

FROM:
Document Control
CNWRA/Division 20
Southwest Research Institute
6220 Culebra Rd.
San Antonio, Texas 78238

Date Sent: 11/12/99

Attached are the following CNWRA controlled documents:

Document Number	Revision/Change Number	Title
QAP-016	2/0	PROCUREMENT
		NOTE: CHANGES TO QAP-016 INCLUDE A MORE STRUCTURED QUALIFICATION OF CNWRA SUBCONTRACTORS AND REQUIREMENTS TO DOCUMENT ACCEPTABILITY OF RECEIVED PRODUCTS BY CNWRA STAFF. PROCEDURE CHANGES ALSO INCLUDE NEW REQUIREMENTS ON PURCHASE ORDERS TO CNWRA SUBCONTRACTORS AS REQUIRED BY THE CNWRA QA MANUAL. PURCHASE REQUISITIONS FOR QUALITY-AFFECTING PRODUCTS (BOTH "GOODS" AND "SERVICES") WILL NOW CONTAIN COMPLETE TECHNICAL AND QUALITY DESCRIPTIONS. FORMAL RECEIPT INSPECTION WILL BE DOCUMENTED ON THE RECEIPT TRAVELER OR IN A SCIENTIFIC NOTEBOOK OR OTHER PROJECT RECORD.

Instructions to Recipients:

1. Review and become familiar with the subject documents. Please contact the author for further clarification, if necessary.
2. For revisions and changes, destroy or mark as obsolete the superseded documents or document pages and insert the current document or pages.
3. Sign and date the acknowledgement below attesting that the attached controlled documents, revisions, and changes have been reviewed and understood, and that obsolete documents and pages have been removed.
4. Upon completion, return this form to Document Control at the address indicated above within 30 days.

Roseanne Ard

11/17/99

Acknowledged by

Date

22/66

QAP-016 Procurement Training

Date: 11/18/99
Sender: Bruce Mabrito
To: #SA-WO TECH
cc: Rosie Ard, Maria Padilla, Paul Maldonado, mehnstrom@swri.org, #SA-WO_SUPPORT, blong@swri.edu
bcc: Bruce Mabrito, Bonnie Caudle, Henry Garcia, English Percy, Narasi Sridhar, Gordon Wittmeyer
Priority: Normal
Subject: Training on QAP-016, Procurement

Recently our procurement procedure, QAP-016, was revised and distributed. This revision incorporated a number of changes to better control the procurement process. Among the more significant changes were the following.

- Tighter QA controls are put on the procurement of goods and services
- The addition of utilizing the Southwest Research Institute Approved Suppliers List (ASL) for quality-affecting purchases
- Completion of an SwRI Quality Questionnaire for subcontractors to evaluate either an in-place quality system or to require the implementation of the CNWRA quality system (these letters went out to some 10 CNWRA subcontracts this week)
- Quality-affecting purchases (such as mineral samples, plates/material for testing, etc.) must have clear written instructions on the Purchase Requisition that include technical and quality requirements
- Scientific investigations, experiments, tests, chemical analyses by those outside the CNWRA (which means "outside companies") must be approved as a subcontractor and have their own quality system or work under the CNWRA quality system with verification of traceability to national or international standards (SwRI ASL vendors are exempted from this since they have been previously checked and approved)
- Code development consultants must be cleared through the CNWRA Source Evaluation Committee which includes completion of their professional qualifications and conflict of interest clearance.

The latest QAP-016 was sent out last week and staff members who typically order goods and services throughout the CNWRA have been provided a copy. Please consult the procedure if you are making any purchases that will affect the quality of your data which could be used in licensing or for clients. As always, the easiest way to take care of calibration of instruments is to call the SwRI Calibration Lab (x 5460) and have them put your critical instruments under their calibration recall system. The SwRI Cal Lab has an accepted QA system which meets any national or international requirements.

If you have specific questions, do not hesitate in calling me at x 5149 or Mark Ehnstrom at x 3530. Thanks.
 Bruce Mabrito