

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

18/121

CAR No: 2001-06

Associated AR, SR, NCR No: AR2001-02

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

CARs 2001-02 and 2001-03 had been verified and closed-out, however the specified actions had not been completed. This finding is similar to one identified during the January 2001 follow-up audit (see CAR 2001-01).

Initiated by: Robert Brient

Date 8/24/2001

PART B: PROPOSED ACTION

Responsible EM: B. Mabrito

Response Due: 9/24/2001

1) Extent of Condition:

A review was performed on CARs initiated from 1998-2001 to identify if any did not have an independent review for verification of corrective action implementation (close out). The review found only CAR 2001-02 to fit this category. The CNWRA Director of QA had approved and verified close out on CAR 2001-02 and this was the only time in these years the same person had performed both activities.

CARs issued since the June 2000 audit were evaluated during the January 2001-1 audit and during the recently completed audit. The extent of the condition is limited to those identified by the audit team and documented on this CAR.

2) Root Cause:

CAR 2001-02: Required the Director of QA to draft an electronic memorandum discussing the importance of controlling scientific and engineering software and to send the memo to Principal Investigators and Element Managers. Although sent at the time of the closeout of the CAR, confirmation of this activity could not be produced.

CAR 2001-03: It was assumed all required activities needed to close CAR 2001-03 were included in a TOP-018 Draft that was going through technical review at the time. The draft of TOP-018 did not contain all commitments in CAR 2000-03. In addition, verification of corrective action would be accomplished through closure of another CAR, CAR 2001-04. This was inappropriate to transfer close out activities from one CAR to another.

3) Remedial Action:

Proposed Completion Date: 9/28/2001

CAR 2001-02: During the 2001-02 audit, the Director of Quality Assurance sent the required electronic memorandum to the PIs and EMs. A copy of this E-mail is contained in the CAR 2001-02 documentation.

CAR 2001-03: Annotate CAR 2001-04 with instructions to verify implementation of corrective actions proposed in the previously closed CAR 2001-03.

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 10/18/2001

QA staff responsible for verification of corrective action implementation will receive additional training in the evaluation of objective evidence in proper CAR closure. This training will include all individuals who perform CNWRA Quality Assurance actions and may provide input to close out verifications.

Element Manager:



Date:

9/19/2001

PART C: APPROVAL

Comments/Instructions

Director of QA:



Date:

9/24/2001

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

Actions specified in the Remedial actions is completed. Objective evidence of Training provided is attached.

Distribution:

Original-CNWRA/QA DIRECTOR QA Records
Element Managers
CNWRA Directors
W. Patrick, CNWRA President
M. Ehnstrom
R. Flock

Verified by:



Date:

10/18/2001

QUALITY ASSURANCE TRAINING

Closing of Corrective Action Requests at the CNWRA

Presented by Bruce Mabrito

CNWRA Director of Quality Assurance

October 18, 2001

19/12

CNWRA QUALITY ASSURANCE

- **Corrective Action definition: Action taken to eliminate the cause(s) of an existing nonconformance or other undesirable condition in order to prevent recurrence.**
- **Remedial Action definition: The action necessary to correct the nonconforming condition (but not the cause). This action is similar to disposition of nonconformances (i.e., repeat the activity, accept-as-is, etc.).**
- **QAP-010, Corrective Action, states that a Corrective Action Request shall be initiated by a CNWRA QA staff member.**
- **Corrective Action process shall be completed within 60 calendar days from initiation.**
- **Actions Needed: Extent of Condition, Root Cause, Remedial Action, and Corrective Action to Preclude Recurrence.**

20/12

CNWRA QUALITY ASSURANCE

- **Completed CAR Response shall be reviewed by Director of QA, considering many factors.**
- **Director of QA shall indicate concurrence with the responses in Part C by signature and date. If not adequate, the individual responsible for corrective action shall be contacted so an adequate response can be obtained.**
- **The CNWRA President shall be the final arbitrator in cases where agreement cannot be reached.**
- **Verification of Corrective Action Implementation: Within two weeks after the corrective action completion date, QA staff shall review and verify the implementation of the specified corrective action. The review shall determine whether the corrective action is sufficient to preclude recurrence.**
- **Satisfactory implementation is indicated by signature and date.**

21/12/15

CNWRA QUALITY ASSURANCE

- **The CAR shall be tracked by use of a tracking log.**
- **CNWRA QA shall retain a record copy of the CAR while it is routed for responses and approval.**
- **If the CAR is not received by the due date, written notice of the overdue condition shall be provided to appropriate CNWRA management. This can be made in electronic or other forms.**
- **NOTE: The CAR is considered closed only when all the required actions have been completed and verified. ADDITIONAL NOTE: We have been closing CARs prematurely and that is a problem. See the attached CAR 2001-06 for details.**

20/1/21

CNWRA QUALITY ASSURANCE

- **Recommendation: Each and every CNWRA CAR and NCR will receive a second or third review before it is closed.**
- **This second or third review is intended to ensure that the verification and closure of the CAR or NCR is indeed justified.** *NOT proceduralized. [Signature]*
- **We've been burned on this and I do not intend on getting burned again. I will wear Nomex gloves (to prevent me from getting burned), or, I will ask some of you to review the CAR/NCR to get your view on the closure. With this multiple input, I sense that we will not prematurely close CARs/NCRs.**
- **If you have suggestions regarding this, please let me know. We are always open to considering other options that ensure higher quality, productivity and improving the decision making process.**

24/121

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES MEETING ATTENDANCE

SUBJECT OF MEETING *QA Training - "Closing of Corrective Actions Reports"*

DATE: *10/18/01* LOCATION: *SWRI Bldg 189 Conf Rm A132*

PERSON	ORGANIZATION	TITLE/FUNCTION	TELEPHONE NUMBER
<i>Thomas A. Meyers</i>	<i>CC-30 IQS</i>	<i>Sr. QA Technologist</i>	<i>522-2365</i>
<i>Mark R. Ekstrom</i>	<i>SWRI QA</i>	<i>" " "</i>	<i>" -3530</i>
<i>Randy Folck</i>	<i>Process Transition</i>	<i>consultant</i>	<i>550-4236</i>
<i>MARIA Padilla</i>	<i>CNWRA</i>	<i>clerk</i>	<i>522-6833</i>
<i>Bruce MARRITO</i>	<i>CNWRA</i>	<i>Dir QA</i>	<i>522-5149</i>
<i>Training was conducted by B. MARRITO 10/18/2001 with these QA staff present. The attached videotapes were used in the training. <i>Bruce MARRITO 10/18/2001</i></i>			

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

25/121

CAR No: 2001-06

Associated AR, SR, NCR No: AR2001-02

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

CARs 2001-02 and 2001-03 had been verified and closed-out, however the specified actions had not been completed. This finding is similar to one identified during the January 2001 follow-up audit (see CAR 2001-01).

Initiated by: Robert Brient

Date 8/24/2001

PART B: PROPOSED ACTION

Responsible EM: B. Mabrito

Response Due: 9/24/2001

1) Extent of Condition:

A review was performed on CARs initiated from 1998-2001 to identify if any did not have an independent review for verification of corrective action implementation (close out). The review found only CAR 2001-02 to fit this category. The CNWRA Director of QA had approved and verified close out on CAR 2001-02 and this was the only time in these years the same person had performed both activities.

CARs issued since the June 2000 audit were evaluated during the January 2001-1 audit and during the recently completed audit. The extent of the condition is limited to those identified by the audit team and documented on this CAR.

2) Root Cause:

CAR 2001-02: Required the Director of QA to draft an electronic memorandum discussing the importance of controlling scientific and engineering software and to send the memo to Principal Investigators and Element Managers. Although sent at the time of the closeout of the CAR, confirmation of this activity could not be produced.

CAR 2001-03: It was assumed all required activities needed to close CAR 2001-03 were included in a TOP-018 Draft that was going through technical review at the time. The draft of TOP-018 did not contain all commitments in CAR 2000-03. In addition, verification of corrective action would be accomplished through closure of another CAR, CAR 2001-04. This was inappropriate to transfer close out activities from one CAR to another.

3) Remedial Action:

Proposed Completion Date: 9/28/2001

CAR 2001-02: During the 2001-02 audit, the Director of Quality Assurance sent the required electronic memorandum to the PIs and EMs. A copy of this E-mail is contained in the CAR 2001-02 documentation.

CAR 2001-03: Annotate CAR 2001-04 with instructions to verify implementation of corrective actions proposed in the previously closed CAR 2001-03.

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 10/18/2001

QA staff responsible for verification of corrective action implementation will receive additional training in the evaluation of objective evidence in proper CAR closure. This training will include all individuals who perform CNWRA Quality Assurance actions and may provide input to close out verifications.

Element Manager:



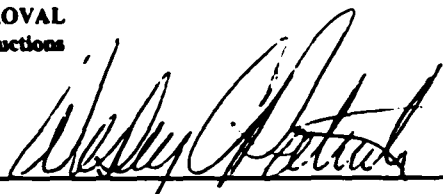
Date:

9/19/2001

PART C: APPROVAL

Comments/Instructions

Director of QA:



Date:

9/24/2001

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

Distribution:

Original-CNWRA/QA DIRECTOR QA Records

Element Managers

CNWRA Directors

W. Patrick, CNWRA President

M. Ehnstrom

R. Flock

Verified by:

Date: