

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

44/1124
25/40
1/13/03
no

CAR No: 2001-04

Associated AR, SR, NCR No: From Trend Analysis

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

In accordance with QAP-010 Corrective Action, paragraph 4.1, this corrective action request is being initiated to document an identified adverse trend. The adverse trend was identified in the area of development and control of CNWRA software. (Reference Adverse Trend Analysis Report dated June 15, 2001 - attached). Among the nonconforming findings identified were software design verifications not being documented, software requirements descriptions not written or approved, and software being used which was not under proper control.

Initiated by: *Dharm Mahabadi*

Date: 7/13/2001

PART B: PROPOSED ACTION

Responsible EM: B. Sagar
Response Due: August 10, 2001

1) Extent of Condition:

SI CS - 8/2/2001
(SEE email message)

See attached pages.

2) Root Cause:

3) Remedial Action:

Proposed Completion Date:

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: 10/31/2001

B. Sagar
Element Manager:

Date: 8/31/2001

PART C: APPROVAL Comments/Instructions

Director of QA: *Dharm Mahabadi*

Date: 9/4/2001

PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

See attached text for verification of corrective action implementation.

Distribution: QA Records - original - QA Director
All Element Managers
All CNWRA Directors
B. Sagar, Technical Director
W. Patrak, CNWRA Assistant
M. Christman, SWRE QA
A. Bekki, Software QA consultant

Verified by: *M. Christman* Date: 11/6/02

NOTE: Verify implementation of the corrective actions proposed in the previously closed CAR 2001-03. Eten 10/18/2001

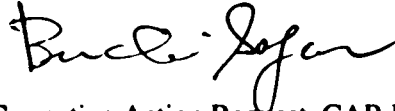
26/40

MEMORANDUM

TO: Bruce Mabrito

August 30, 2001

FROM: Budhi Sagar



SUBJECT: Response to Corrective Action Request, CAR No.: 2001-04

Response to Corrective Action Request No. 2001-04, initiated on July 13, 2001 is enclosed. Please note that the recommended actions include addition of information during planning to the QRAM such as identification of a schedule for surveillance of those activities that require application of TOP-018. As a result of this recommendation, more surveillances may have to be conducted in FY2002.

CC: CNWRA Directors
CNWRA Element Managers

4/6 1/13/05
27/40

**RESPONSE TO CORRECTIVE ACTION REQUEST 2001-04: ADVERSE TREND
IN SOFTWARE DEVELOPMENT AND CONTROL**

EXTENT OF CONDITION

To determine the extent of condition, raw data on unsatisfactory findings with respect to development and control of software as recorded on quality assurance surveillance reports, nonconformance reports, and corrective action requests generated in CY 1998, 1999, and 2000 were analyzed in detail. Following is a description of this data.

CY 1998.

Nonconformance report # 2 was based on surveillance report # 2, which found that for the CNWRA developed TPA V 3.2 code: (i) software headings did not identify the SPCR numbers, (ii) design verification report was missing, and (iii) code development was not being documented in scientific notebook or by alternate means.

Nonconformance report # 11 was based on surveillance report # 25 on a Gas Research Institute project, which found a software obtained from a commercial Company (OLI) was not put under TOP-018 control before its use in the project.

Surveillance report # 28 was related to derivatives of the TPA V 3.2 code, i.e., a post processor, a version for the PC, and a version for parallel processing. The SRDs and the SDPs for these derivatives were approved after these versions were developed.

Nonconformance # 3 noted that the development of the TPA code was not being recorded in a scientific note book.

CY 1999.

Surveillance report # 12 found that design verification of the acquired code UDEC was not documented.

Surveillance report # 24 found procedural defects in an electronic scientific note book on the TPA code.

Nonconformance report # 2 found that seven codes for interpretation of geophysical data were partially developed without approved SRDs and SDPs.

Nonconformance report # 5 found that development of a code named UNSAPRP was started without an approved SRD.

Corrective Action Request # 5 was initiated when it was found that a subcontractor was allowed to start code development without an approved SRD.

CY 2000.

1/13/03
28/40

Nonconformance report # 3 was based on Surveillance reports # 3A issued and is related to absence of documentation of design verification after minor bugs were fixed in the TPA and the 3DStress codes.

Nonconformance report # 7 found a defect in QRAM for SDS which did not identify the use of TOP-018 controls even when software was to be used in the project.

Nonconformance report # 10 found that design verification testing of CNWRA developed code MULTIFLO was not documented.

Base on the data reported above, three primary issues related to software development and use can be identified: (i) development of software is started before the SRD and the SDP are approved, (ii) software is used before all the controls required by TOP-018 are implemented, and (iii) design verification is not documented appropriately. Several of the CNWRA codes were the subject of the unsatisfactory findings, therefore, the condition is determined to be broad.

ROOT CAUSE

The root cause appears to be a lack of management controls in the implementation of TOP-018 requirements to software development and use. It is not uncommon that staff begins to test ideas about code structure by actually writing a small piece of the code. Such experimental development is allowed by TOP-018 as an aid towards developing a good quality SRD. Some times, this experimental coding gets out of hand and it turns into a full fledged code before the preliminary steps of writing the SRD and the SDP are completed. Similarly, acquired codes from commercial sources sometimes get used before applying all the TOP-018 controls because of time pressure to complete certain projects. Time pressure is also the reason for lack of documentation even when the code testing is actually performed.

REMEDIAL ACTION

All of the nonconformances noted above were remedied soon after they were initiated. No other short-term remedial action is required. Rather, the emphasis is on long-term action to preclude recurrence.

CORRECTIVE ACTION TO PRECLUDE RECURRENCE

The following actions will be taken to preclude recurrence and halt the adverse trend noted in the previous three years.

1) Greater management oversight will be exerted at the time of quality planning. At the time the QRAM is developed or updated: (i) the application of various requirements of TOP-018 will be explicitly identified and (ii) schedule for surveillance to check compliance with TOP-018 requirements also will be identified. If because of non-specific scope, these cannot be identified at the time of preparation of the initial Operations Plans (or equivalent for other non-NRC projects), then this lack of specificity would be noted with an estimated date when the QRAM will be revised to include this information. The Element Manager will be responsible for updating the QRAM as and when the information becomes available. Any plans for experimental code development prior to development of an SRD will be noted on the QRAM.

2) Implementation of the QRAM will be checked at least once a quarter in FY 2002 to determine its completeness and effectiveness. Checks will specifically include: (i) new code development activity, (ii)

11/13/83
48/12
29/40

acquisition of new scientific and engineering codes, and (iii) documentation of code development and testing. Element Managers will seek delay of deliverables when needed rather than ignore application of software controls.

3) Experimental development of code will be allowed without an SRD in special circumstances only and with approval of the Element Manager. An example of special circumstance is the case when a code is to be used temporarily for non-regulatory purposes. For most code development, it would be preferred that an SRD be developed first based on whatever information is available. This SRD may have to be modified as knowledge is gained during code development. ~~A scientific notebook will be used to record Element manager's approval for any experimental development.~~ BS

4) Any subcontract or consultant contract requiring code development will either include an SRD as part of the scope or require the same to be produced by the subcontractor/consultant as the first deliverable. If the subcontractor/consultant is required to develop the SRD (and other documents such as the SDP), then the contract will state that software development will begin only after approval of the SRD (and the SDP if required) by the CNWRA project manager.



Element manager's approval for any experimental development will be documented (e.g. e-mail, memorandum) ^{and} provided to the software custodian, and included in the software documentation package.

BS
11/21/2001

101 1/13/03
30/40 49/121

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CAR
2001-04

MEMORANDUM

TO: Rodney M. Weber
Manager, Institute Quality Assurance

June 15, 2001

FROM: Bruce Mabrito, Director of Quality Assurance



SUBJECT: Adverse Trend Analyses for Years 1998-2000

Introduction

On June 8, 2001, an analyses was performed on quality records that documented unsatisfactory findings. The documents reviewed included Corrective Action Requests (CARs), Nonconformance Reports (NRs), and Surveillance Reports (SRs). Each finding was reviewed to determine against which criterion of 10 CFR Part 50 Appendix B (Appendix B) it was written. The year the finding was identified is also recorded. This information is presented on the attached page.

Findings

The information, based on calender years 1998, 1999 and 2000, can be broken down into basically three categories. The first category is when there were either no findings or just a few findings generated. The second category is when there were a greater number of findings generated and the last category when there were a significant number of findings generated. Appendix B criterion 1-2, 4-11, and 13-18 are contained in the first and least significant category (no findings or very few). The second category, where a greater number of findings were identified, was written against Appendix B criterion 12, Control of Measuring and Test Equipment. In the last and most significant category, the category with the most findings, CNWRA QA Manual section 3, Scientific/Engineering Investigation and Analyses Control. CNWRA section 3 differs from Appendix B Criterion 3 because of the different work activities and mission of the CNWRA.

Analyses

Analyses of this data explains why these findings are basically concentrated into two of the eighteen areas of Appendix B. Criterion 12, Control of Measuring and Test Equipment, had a total of 12 unsatisfactory findings over the past three years. These 12 findings are the result of the quality program requiring a nonconformance report to be generated each time a piece of measuring and test equipment is found to be out of tolerance. These nonconformance reports are used to track and document the closeout activities associated with each, particular piece of equipment.

1/13/03
50/121

31/40

The analyses for section 3, Scientific/Engineering Investigation and Analyses, is somewhat more involved. Section 3 of the CNWRA Quality Assurance Manual, written for general compliance to Criterion 3 of Appendix B, contains 2 major requirements in which the CNWRA has had a history of findings generated. Section 3 requires technical activities be primarily controlled by the scientific notebook method. Findings have included scientific notebooks not being turned in on time for review, corrections not initialed or dated, and electronic notebooks turned in that were incomplete. Section 3 also contains quality planning activities and planning documents required for controlling software. These two areas accounted for the majority of the 22 findings in section 3.

Conclusion

Based on the results of this analysis, the data shows that although the calibration of test instrumentation will continue to be tracked with nonconformance reports, there have been no true adverse trends associated in this area.

After an extensive review of scientific notebooks performed in September through October 2000, procedural compliance has now been established. Examinations performed after this review have determined no adverse trend exist.

With regard to section 3, Scientific/Engineering Investigation and Analysis, there may be an adverse trend. The past two CNWRA annual audits have identified problems in the CNWRA corrective action program. As a result of these findings, a greater emphasis has been placed on identifying and, when required, initiating corrective action requests.

Additional problems related to control of software have been identified during both the annual audit process, as evidenced by the initiation of corrective action requests, and during normal surveillance activities. Based on the findings written over the past three year period and the diversification of the software findings it has been determined that a separate CAR will be initiated to document the adverse trend on the development and control of software.

- cc: Element Managers
- Directors
- W. Patrick
- M. Ehnstrom

**CNWKA ADVERSE TREND ANALYSES
(A HISTORICAL PERSPECTIVE)
1998-2000**

1/13/03
~~5/1/03~~
33/40

Appendix B Criterion	1998	1999	2000	Total	Risk
I	0	0	0	0	1
II	N5	C4	C1.C7.N7.N9	6	1
III	N3.N1.N2.N3 C1.S2.S25.S28	N2.N3.N5.N6. C1.C5.S21.S24	N2.N3.C2 S2.S12.S14	22	5
IV	0	0	N1	1	1
V	0	0	N8.C3	2	1
VI	S5	0	C5	2	1
VII	C2	C2.N1.S6	0	3	1
VIII	N4.S7	0	0	2	1
IX	0	0	0	0	1
X	0	0	N10	1	1
XI	S3	0	0	1	1
XII	N6.N7.N8.N9.N10 N12. S4. S26	N4	N4.N5.N6	12	3
XIII	0	0	0	0	1
XIV	0	0	0	0	1
XV	0	0	0	0	1
XVI	0	C3	C6	2	5
XVII	0	0	0	0	1
XVIII	0	0	0	0	1

S= Surveillance
C= Corrective Action
N= Nonconformance Report

1= Low Risk = 0 to 7 Findings
3= Moderate Risk = 8 to 15 Findings
5= High Risk = 16 to 22 Findings or
Repetitive Findings/Problems

1/13/03
504
1121
33/40

Subject: Corrective Action Request 2001-04

Date: Wed, 08 Aug 2001 20:07:12 -0500

From: Bruce Mabrito <bmabrito@gargol.cnwra.swri.edu>

Organization: CNWRA

To: "Budhi Sagar (bsagar)" <bsagar@gargol.cnwra.swri.edu>

CC: mehnstrom@swri.org, Maria Padilla <mjpadilla@gargol.cnwra.swri.edu>

"rfolck@satx.rr.com" <rfolck@satx.rr.com>

"Lucy Gutierrez (lgutierrez)" <lgutierrez@gargol.cnwra.swri.edu>

"Bruce Mabrito (bmabrito)" <bmabrito@gargol.cnwra.swri.edu>

"Wesley Patrick (wpatrick)" <wpatrick@gargol.cnwra.swri.edu>

"Patrick Mackin (pmackin)" <pmackin@gargol.cnwra.swri.edu>

John Russell <jlrussell@gargol.cnwra.swri.edu>

August 8, 2001

All:

Corrective Action Request (CAR) 2001-04 was written following an extensive three year CNWRA trend analysis that identified an adverse trend in the area of development and control of CNWRA scientific and engineering software.

CAR 2001-04 was written 7/13/2001 by B. Mabrito (CNWRA QA Director), the response due date was 8/10/2001, and the responsible party identified was B. Sagar (CNWRA Technical Director).

Since the writing of the CAR, B. Sagar has been on either travel or vacation or in meetings for the majority of the time. Based on the need for the CNWRA Technical Director to perform an extensive root cause analysis and determination of the extent of condition, I am extending the due date for this CAR from 8/10/2001 to 8/31/2001. Even with this extension, and considering the Integrated IRSR work, the internal QA Audit, and the many other CNWRA end-of-the-year deliverables, this CAR will need to be given adequate priority to provide effective root cause analysis, and remedial and corrective actions.

A copy of this email message will be printed out, signed, and put with CAR 2001-04, extending the response date to August 31, 2001.

 8/8/2001

Bruce Mabrito
CNWRA QA Director

Date

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

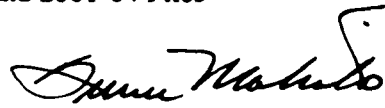
11/13/03
52/102
34/40

MEMORANDUM

October 31, 2001

TO: Corrective Action Requests No. 2001-03 and 2001-04 Files

FROM: Bruce Mabrito, Director of CNWRA QA



SUBJECT: Status/Extension on CAR 2001-03 and CAR 2001-04

This memorandum to the CAR No. 2001-03 and CAR No. 2001-04 files is an explanation of the progress to date on closing out these CARs and provides for an extension in the target dates for completion.

Corrective Action Request 2001-03 describes shortcomings in the CNWRA quality program regarding the process of validation of certain CNWRA scientific and engineering software.

Corrective Action Request 2001-04 describes the CNWRA Trend Analysis performed in June 2001 and it identifies deficiencies in areas of development and control of CNWRA scientific and engineering software.

Close out of these two CARs is based on the "connection" of requirements contained in Technical Operating Procedure-018, Development and Control of Scientific Software. As of this date, to address CAR 2001-03, the following activities have taken place: (i) an overall CNWRA validation plan with commitment dates for each software has been submitted; (ii) TOP-018 has been revised to include improvements, some of which were recommended during two audits; (iii) there has been retirement of some CNWRA scientific and engineering software that were determined not to be needed for regulatory reviews; and (iv) there is a commitment in the FY2002 CNWRA Operations Plans to validate "Category I" (highly likely that these codes will be used in regulatory reviews-validate) software during FY2002.

As of this date, to address CAR 2001-04, the following has been accomplished: (i) Quality Requirements Application Matrix (QRAM) forms have been modified to identify special requirements for CNWRA S&E software, including new code development activity, acquisition of new scientific and engineering codes, and documentation of code development and testing; (ii) there is a requirement for quarterly surveillance of CNWRA S&E software in TOP-018 and in the CNWRA published Surveillance Schedule; (iii) TOP-018 has been revised to allow certain specific initial code development activities only if approved by the Element Manager; and (iv) the CNWRA Technical Director has mandated that scientific and engineering code validation be identified on the Commitment Control Log so that progress can be tracked weekly during the Management meetings. Quality Assurance personnel are sensitive to the situations that have developed regarding scientific and engineering software at the CNWRA, and will continue to monitor all software issues closely.

1/13/03
54/121

Due to other pressing operational QA matters, including answering other Nonconformance Reports and Corrective Action Requests, progress has been made in these two CARs but action has not been completed in the specified time limit to close them out. 35/40

Based on the above information and the currently anticipated QA activity in the CNWRA, I am extending the formal target date for completion of CAR 2001-03 and CAR No. 2001-04 to November 19, 2001.

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

D:\wpfil\memo\generic.carfolder.wpd


CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

36/40

MEMORANDUM

October 24, 2002

TO: QA Records Corrective Action Request 2001-04 Folder

FROM: Bruce Mabrito, Director of Quality Assurance 

SUBJECT: Closure of Corrective Action Request (CAR) 2001-04

REFERENCE: CAR 2001-04, A Scientific and Engineering Software CAR

This memorandum to the CAR 2001-04 folder is to document progress and closure of CAR 2001-04.

CAR 2001-04 was originated July 13, 2001 by the QA Director based on an adverse trend analysis. A response on August 31, 2001 identified the root cause as appearing "to be a lack of management controls in the implementation of TOP-018 requirements to software development and use." The emphasis was on long-term action to preclude recurrence.

Implementation of the TOP-018 requirements has been a priority since the response date, and quarterly software surveillance checks have been made by CNWRA QA. The areas of concentration were new code development activity; acquisition of new scientific and engineering software codes, and documentation of code development and testing. QA surveillances 2002-1, 2002-07, 2002-17, and 2002-25 have all been in-depth surveillances of CNWRA developed or acquired software. In addition to the surveillances, there has been substantial emphasis by the CNWRA Element Managers on making sure software utilized by the CNWRA staff is controlled, and that plans are being made and implemented to validate CNWRA software.

It was determined by CNWRA QA that due to the wording of the CAR 2001-04 response, actual closure of the CAR could not take place until the once-a-quarter surveillances in FY2002 had been completed. All those surveillances are now complete and the surveillances have confirmed implementation of TOP-018, and if not, compliance was obtained at the time of the surveillance.

Based on a complete review of the CAR 2001-04 and a review of the individual software-emphasized surveillances, I have determined that this CAR can now be closed. CDs are being used to capture the codes in the QA Records Room, the mandated surveillances have been completed in a timely manner, there is a new awareness of the importance of implementing TOP-018, and the CNWRA Element Managers have emphasized compliance with TOP-018. In addition, it has become evident that quarterly surveillances on CNWRA software and TOP-018 compliance is a benefit and this practice is likely to continue.

Bruce Mabrito

From: Bruce Mabrito [bmabrito@swri.edu]
Sent: Friday, October 25, 2002 1:57 PM
To: Dirs_Managers
Cc: Mark Ehnstrom; Randolph W. Folck; Maria Padilla; Thomas A. Mayces; Tech_Group
Subject: Software Requirements Description // Consultants and Subcontractors

CNWRA Management and Technical Staff are reminded that any consultant or subcontractor developing scientific and/or engineering software are required to have an approved Software Requirements Description.

B. Sagar has specified (in a response to a 2001 Corrective Action Request) that "any subcontract or consultant contract requiring code development will either include an SRD as part of the scope, or require the same to be produced by the subcontractor/consultant as the first deliverable."

Please be sure to comply with this requirement when dealing with consultants and subcontractors. If you have questions, call me at ext. 5149 Bruce


38/40

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

MEMORANDUM

July 16, 2002

TO: Corrective Action Request Folder 160 – CAR No. 2001-04
Principal Investigators

FROM: Bruce Mabrito
Director, Quality Assurance 

SUBJECT: Rationale to Maintain CAR No. 2001-04 in an Open Status Until 11/29/2002

One of the corrective actions to preclude recurrence on CAR No. 2001-04 was to check on the implementation of the Quality Requirements Application Matrix (QRAM) forms once a quarter during FY2002 to determine its completeness and effectiveness as related to CNWRA scientific and engineering software.

In the course of the CNWRA QA surveillance program, we have made scientific and engineering software a special subject of surveillance. Each quarter, a surveillance is performed that concentrates on scientific and engineering software and it concentrates on new code development activity, acquisition of new scientific and engineering codes, and documentation of code development and testing.

This surveillance activity is directly attributed to CAR 2001-04 which was written because of an adverse trend analysis report in this specific area.

Due to the nature of this CAR and the specific wording of CAR 2001-04, the CNWRA intends to wait until the last review of FY2002 is performed before determining whether or not the corrective action was effectively implemented.

If there are any questions regarding this approach, contact Bruce Mabrito or Randy Folck.

cc: B. Sagar M. Ehnstrom R. Folck
M. Padilla QA Memos Folder 207

Closeout for Corrective Action 2001-04

39/40

The quarterly surveillances scheduled in FY-02 are complete. These surveillances assured that compliance with TOP-018 requirements is being essentially achieved. Although CAR 2001-04 references surveillances of QRAMs to determine completeness and effectiveness, surveillance requirements contained in TOP-018 are a greater measure to assure software is being controlled from the conceptual stage through validation testing. The Director of QA reviewed the FY-02 quarterly surveillances on October 24, 2002 and found them to be satisfactory. (See attached memorandum). QRAMs for FY-03 show an increased awareness in the quality planning phase concerning software controls. Some QRAMs specifically request surveillance to be performed at a certain time dependent upon certain software activities. Addressing activities with regard to controls of consultants/subcontractors, the CNWRA does have evidence showing actions to preclude recurrence have taken place. A Software Requirements Description (SRD) was delivered to the CNWRA as first deliverable item by Bayesian Systems. The Director of QA on October 25, 2002 sent an E-mail to the CNWRA Management and Technical Staff again reminding them of this requirement. The software activities performed in the past 10 months by CNWRA staff show a greater sensitivity concerning software, and controls imposed on the development and use of scientific and engineering software. Based on these results, corrective actions have been implemented and are judged successful.

Mark R. Ehnstrom 11/6/02