

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No. 90-07

Associated AR,SR,NCR NO. Audit 90-03

PART 1: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Contrary to 10 CFR Part 50, Appendix B, Criterion V "Instructions, Procedures, and Drawings" and CQAM Section 5, activities affecting quality are being performed without documented instructions or procedures. These activities include software documentation control, sample control, and control of existing data requiring qualification. In addition to correction of the deficiency and action to preclude recurrence, work performed prior to corrective action shall be evaluated to determine the impact of the deficiency and disposition of affected products.

Initiated by: R. W. Folck

Date: 12/19/90

PART 2: PROPOSED ACTION

Responsible Element Manager: A. Whiting/W. Patrick

a) Root Cause:

See Attached

b) Corrective Action to Preclude Recurrence:

See Attached

Target Date for Completion: May 17, 1991

Response provided by: Wesley C. Patrick

Date: 1/15/91

PART 3: APPROVAL

Comments/Instructions: NONE

Director of QA: [Signature]

Date: 1/15/91

PART 4: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

TOP-012 for Sample Control issued 12/19/90
TOP-018 for Software Configuration Control issued 8/21/91
QAP-015 for Existing Data Control issued 5/16/91

Verified by: [Signature]

Date: 9/3/91

MEMORANDUM

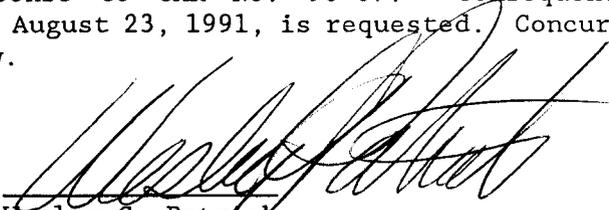
July 1, 1991

To: Quality Assurance File
From: W.C. Patrick
Subject: CAR No. 90-07, Audit No. 90-03

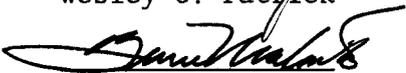
The purpose of this memorandum is to request an extension of the Target Completion Date for the subject Corrective Action Request (CAR) No. 90-07. With one exception, all actions identified have been completed or, in the case of ongoing processes, have been implemented. The exception is software documentation control (item (c)(1) in the initial CAR documentation).

The Center developed and issued a Configuration Management and Control Manual August 6, 1990. It followed this by issuing a draft Code Configuration Procedure April 1, 1991. Comments on the latter document were received from the NRC staff June 24, 1991 (see S. Coplan to B. Sagar). Given the extent of these comments and need to resolve certain policy issues such as the organizational extent of application of the procedure, it appears that additional time is needed to complete the response to CAR No. 90-07. Consequently, a revised Target Completion Date of August 23, 1991, is requested. Concurrences in this date are as indicated below.

Requested by:


Wesley C. Patrick

Approved by:


Bruce Mabrito

cc: J. Latz
CNWRA Directors
CNWRA Element Managers

Attachment to Corrective Action Request CAR No. 90-07
Associated with AR, SR, NCR No. Audit 90-03

PART 2: PROPOSED ACTION

a) Root Cause:

CAR No. 90-07 cites three specific classes of activities that are potentially adverse to quality. These are: (1) software documentation control, (2) sample control, and (3) control of existing data requiring qualification. For each of the three classes of activities, documented instructions or procedures were not in place prior to commencement of activities. The root causes are that (1) no mechanism was in place to identify activities which require specific procedures and (2) the available tracking system (Commitment Control Log) was not being used effectively to monitor progress toward completion of those procedures which were being developed.

b) Corrective Action to Preclude Recurrence:

The following actions will be taken to preclude recurrence of this condition:

- The CNWRA Monthly Quality Assurance Status Report will be used, beginning not later than the February issue, to identify required procedures for activities affecting quality.
- Each procedure that is identified will be assigned a tentative (topical) title and number, and will be tracked in the CNWRA Commitment Control Log.
- Project Plans and Operations Plans will be updated to include identification of procedures which are anticipated to be needed in the conduct of the scope of work. This will be accomplished as the Plans are revised at the request of the NRC.

To correct the specific nonconforming conditions cited in CAR 90-07, appropriate procedures controlling software documentation and existing data will be developed and issued by April 19 and May 17, 1991, respectively. Corrective action for the lack of a sample control procedure was completed with the issuance of TOP-012 on December 18, 1990.

c) Evaluation of Impact of Deficiency and Disposition of Affected Products:

CAR No. 90-07 directs that "work performed prior to corrective action shall be evaluated to determine the impact of the deficiency and disposition of affected products." This matter is addressed here for each of the three classes of activities.

- (1) Software documentation control. The results of QA Audit 90-03 and this analysis suggest that although appropriate software controls were not in place, the staff has been appropriately controlling software consistent with good scientific practice. A Configuration Management and Control Manual had been developed and a procedure for software control was under development at the time of the audit.

Regarding the disposition of affected products, a review of the technical papers and Quarterly Research Reports that have been developed and published to date indicate that (a) all these products clearly identify the status of the software in use via appropriate version-naming conventions and references and (b) all products constitute evaluations of the codes, or preliminary or exploratory uses of the codes, none of which are represented to be "final," "representative," or for use in the hearing process. Consequently, all of these products should stand. No further actions are required.

- (2) Sample control. QA Audit 90-03 and follow-up analysis indicate that the deficiencies are limited to the area of documentation requirements. However, even in these cases, the samples examined were traceable to appropriate documentation. A sample control procedure was developed and implemented December 18, 1990. Taking these factors into account, there is no impact of this deficiency on any product developed to date and such products should stand.
- (3) Qualification of existing data. Existing data have been used in Center work (a) to compare Center research results with literature values, (b) as the basis for evaluation of DOE plans and programs, including their qualification of existing data, (c) to serve as examples in demonstrating modeling needs and capabilities (e.g. structural geologic modeling), and (d) in preliminary assessments of the importance of parameters to repository performance (e.g. geochemical and rock mechanical modeling). In addition, existing data have been used to perform preliminary calculations of the characteristics and behavior. In all these cases, the associated CNWRA reports and open-literature publications have clearly stated both the source and the purpose of the use of such data. Consequently, there is no impact of this deficiency on any product developed to date and such products should stand.

Note that the Seismic Rock Mechanics Project will later use existing data as the basis for model qualification and validation. It is anticipated that such use will require that the data be qualified.

As an added measure, each CNWRA product (deliverable) will be evaluated as part of the document review process to ensure that no impacts arise during the time when procedures are being developed and implemented.

Attachment to Corrective Action Request CAR No. 90-07
Associated with AR, SR, NCR No. Audit 90-03
(Revised May 3, 1991)

PART 2: PROPOSED ACTION

a) Root Cause:

CAR No. 90-07 cites three specific classes of activities that are potentially adverse to quality. These are: (1) software documentation control, (2) sample control, and (3) control of existing data requiring qualification. For each of the three classes of activities, documented instructions or procedures were not in place prior to commencement of activities. The root causes are that (1) no mechanism was in place to identify activities which require specific procedures and (2) the available tracking system (Commitment Control Log) was not being used effectively to monitor progress toward completion of those procedures which were being developed.

This proposed corrective action has been modified May 3, 1991, to note a change in approach to resolution of one issue, and to provide an update of progress on responding to CAR No. 90-07. All modifications are shown in italic type for easy identification.

b) Corrective Action to Preclude Recurrence:

The following actions will be taken to preclude recurrence of this condition:

- The CNWRA Monthly Quality Assurance Status Report will be used, beginning not later than the February issue, to identify required procedures for activities affecting quality. *(Implemented and being conducted on an ongoing basis.)*
- Each procedure that is identified will be assigned a tentative (topical) title and number, and will be tracked in the CNWRA Commitment Control Log. *(Implemented for all items in this CAR.)*
- Project Plans and Operations Plans will be updated to include identification of procedures which are anticipated to be needed in the conduct of the scope of work. This will be accomplished as the Plans are revised at the request of the NRC.

To correct the specific nonconforming conditions cited in CAR 90-07, appropriate procedures controlling software documentation and existing data will be developed and issued by June 15, 1991 and May 17, 1991, respectively. Corrective action for the lack of a sample control procedure was completed with the issuance of TOP-012 on December 18, 1990.

In pursuing corrective actions regarding software documentation, it became apparent that the Center's position regarding documentation of scientific and engineering software, as specified by NUREG-0856, should be changed. Since the primary objective of NUREG-0856 is to establish the validity of repository design activities involving the use of computer codes, it does not directly apply to the

NRC or the Center (because they are the reviewers and evaluators of such design activities). Consequently, the Center has focused its efforts on assuring that individual software evaluation, development, and utilization activities undertaken by the Center are properly conducted, and accurately reported or otherwise documented. Such tasks are most appropriately controlled by software configuration controls and technical and/or peer reviews. A software configuration control procedure will be issued by June 15, 1991, to implement the required provisions. Furthermore, the CQAM will be revised consistent with this approach.

c) Evaluation of Impact of Deficiency and Disposition of Affected Products:

CAR No. 90-07 directs that "work performed prior to corrective action shall be evaluated to determine the impact of the deficiency and disposition of affected products." This matter is addressed here for each of the three classes of activities.

- (1) Software documentation control. The results of QA Audit 90-03 and this analysis suggest that although appropriate software controls were not in place, the staff has been appropriately controlling software consistent with good scientific practice. A Configuration Management and Control Manual had been developed and a procedure for software control was under development at the time of the audit.

Regarding the disposition of affected products, a review of the technical papers and Quarterly Research Reports that have been developed and published to date indicate that (a) all these products clearly identify the status of the software in use via appropriate version-naming conventions and references and (b) all products constitute evaluations of the codes, or preliminary or exploratory uses of the codes, none of which are represented to be "final," "representative," or for use in the hearing process. Consequently, all of these products should stand. No further actions are required.

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As an added measure, each CNWRA product (deliverable) will be evaluated as part of the document review process to ensure that no impacts arise during the time when procedures are being developed and implemented.

Amended corrective action response provided by:

Wesley C. Patrick 5/6/91
Wesley C. Patrick Date

Amended CAR approved by:

Bruce Mabrito 5/6/91
Bruce Mabrito Date
Director of QA