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# CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

## CORRECTIVE ACTION REQUEST

CAR No. 91-01 Associated AR,SR,NCR NO. AR 91-1

### PART 1: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Contrary to the CQAM, Rev. 2, Change 2, Sections 5 and 6:

- 1 Draft TOP-001-07, "High Level Waste Management Systems Functional Analysis" was referenced in RDCO Intermediate Milestone No. 20-3702-026-123-000 as being used for quality affecting activities, and had not been formally approved and distributed.
2. Revised Project Plans for Seismic Rock Mechanics and Performance Assessment Research were not reviewed by the Director, Systems Engineering and Integration as required.

Initiated by: R. W. Folck Date: 7/26/91

### PART 2: PROPOSED ACTION

Responsible Element Manager: Item 1 - T. Romine  
Item 2 - H. Garcia

a) Root Cause:

See Attached.

Action Party: Item 1 - T. Romine  
Item 2 - B. Mabrito

b) Corrective Action to Preclude Recurrence:

See Attached.

Target Date for Completion: 9/15/91

Response provided by: W.C. Patrick Date: 8/01/91

### PART 3: APPROVAL

Comments/Instructions: NONE

Director of QA: R. Engelhardt for BEM Date: 8/1/91

### PART 4: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

1. TOP00107 was issued 11/13/91
2. An Effectivity Page with blocks for required approvals for Project Plans and Ops Plans was created 8/91 and has been used for all Plans subsequent to that date.

Verified by: ReBuen Date: 11/18/91

Attachment to Corrective Action Request (CAR) No. 91-01  
Associated with AR 91-1

**PART 2: PROPOSED ACTION**

**a) Root Cause:**

CAR No. 91-01 cites two items that do not comply with the provisions of the CQAM, as discussed, in turn, below.

Item 1. Quality affecting work was being conducted without the benefit of an approved technical operating procedure. This finding identified a recurring problem in the development, approval, and use of procedures within the Waste Systems Engineering and Integration Element (See CAR No. 90-05 and 90-06). The underlying conditions prevailing at the time the earlier problems arose were present with regard to the currently cited problem as well. TOP-001-07 was developed during a time frame when client approval was required prior to issuance of a Center procedure. The Center experienced the paradox of (a) having direction to conduct and complete the Repository Functional Analysis but (b) not having approval of the procedure necessary to conduct such work. Under verbal approval of the NRC, the work was executed with the unapproved procedure with the understanding that the work would be reevaluated and revised, if necessary, following approval of the procedure.

Item 2. A change in operating practice occurred which led to several Project Plans being issued without the signature of the Director of Systems Engineering and Integration (DSE&I) being affixed to the Project Plan to certify its approval in accordance with Section 6.4.3 item (6) of the CQAM. This operating practice was allowed to be implemented without appropriate changes to the CQAM. Reviews of the quality assurance records related to the cited Project Plans show that the DSE&I did review, comment, and approve each, following the provisions of QAP-002 for conducting such reviews. Nonetheless, the implicit CQAM requirement for the appearance of an approval signature on the document was not met.

**b) Corrective Action to Preclude Recurrence:**

Item 1. The Center has obtained NRC concurrence that Center procedures may be developed and implemented without the express approval of the NRC. This will preclude recurrence. To address the specific finding, the Center will review, approve, and issue TOP-001-07. Following issuance, the results of the RFA will be evaluated to determine whether any changes to the RFA report or other documentation are needed. Changes will be made, as appropriate.

Item 2. Upon further review, it has been determined that the signature policy related to Operations Plans and Project Plans should be changed. As noted in Section 5 of the CQAM, these plans provide technical, management (including fiscal), and quality assurance direction. Consequently, the appropriate approvals are as follows: Technical Director, Director of Administration, Director of Systems Engineering and Integration, and Director of Quality Assurance, or their designees. Approval at the highest management level of the Center is reflected in the President's transmittal of such Plans to the client organization. Pertinent sections of the CQAM will be modified to include the Director of Administration and the appropriate approval signatures will be affixed to the modified Operations and Project Plans, as they are issued.