



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

QA: L

SEP 2 1994

L. Dale Foust
Technical Project Officer
for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
Bank of America Center, Suite P-110
101 Convention Center Drive
Las Vegas, NV 89109

EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR)
YM-94-065 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT YMP-94-01 OF CIVILIAN RADIOACTIVE WASTE
MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR
(SCPb: N/A)

The YMQAD staff has evaluated the response (inclusive of the supplemental information received on August 31, 1994) to CAR YM-94-065. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Kenneth O. Gilkerson at 794-7738.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4934

Enclosure:
CAR YM-94-065

cc w/encl:
T. A. Wood, HQ (RW-14) FORS
R. L. Johnson, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. L. Robertson, M&O/TRW, Vienna, VA
R. P. Ruth, M&O/TRW, Las Vegas, NV
Richard Jiu, M&O/Duke, Las Vegas, NV
D. G. Horton, OQA (RW-3), NV
R. M. Nelson, Jr., YMSCO, NV

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

YMP-5

9409150349 940902
PDR WASTE
WM-11 PDR

102.7
WM-11
NH03

ORIGINAL
THIS IS A RED STAMP

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8 CAR NO.: YM-94-065
PAGE: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document QAP-3-8, R4, QAP-3-9, R4, QAP-3-10, R4		2 Related Report No. YMP-94-01	
3 Responsible Organization M&O		4 Discussed With J. Naff/B. Saunders/A. Segrest/F. A'rth	
5 Requirement: 1) QAP-3-8, Paragraph 5.2 requires that specifications shall be checked for completeness and technical adequacy using the topics in Attachment I. QAP-3-9, Paragraph 5.24 requires that design analyses be checked to ensure the necessary detail in accordance with the Design Analysis Outline (Continued on next page)			
6 Adverse Condition: 1) No objective evidence exists for the discipline (structural) checks for Package 2C in the areas of design analysis, specifications and drawings for the identified items. Additionally, it was found that the M&O intends to utilize the relevant Review Summaries as the sole source of documentation to substantiate and validate the corresponding checks/reviews. 2) The checker for the Steel Set and Lagging Design Analysis did not receive a complete design analysis for review. The analysis was delivered to the checker over the period of one week in "pieces" and in various stages of completion. Additionally, the checker informed the audit team that they did not ensure that the design output was reasonable as compared to the inputs and the referenced Design Analysis Outline was not utilized. This checking process was completed 4/1/94. 3) For both the specifications and drawings concerning the structural discipline, it was found that the design analyses had not been completed and/or even checked. The checking process for all documents appears to have taken place at about the same time, with little or no controls applied to the procedure mandated requirements. (Continued on next page)			
9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No <u> </u> If Yes, Check One: <input checked="" type="checkbox"/> A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
3 Response Due Date: 20 Working days From Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
12 Recommended Actions: 1) Review other areas of the 2C Package and assure that checks/reviews were consistent. 2) Assure that the checking process for any ongoing design activities is conducted correctly.			
7 Initiator Richard G. Feck <i>[Signature]</i> 8-3-94		14 Issuance Approved by: QADD <i>[Signature]</i> Date 8/5/94	
15 Response Accepted QAR <i>[Signature]</i> Date 8/30/94		16 Response Accepted QADD <i>[Signature]</i> Date 9-1-94	
17 Amended Response Accepted QAR _____ Date _____		18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8 CAR NO.: YM-94-065
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

5 Requirements (continued)

(Attachment 1) and that the design output is reasonable compared to the design input. QAP-3-10, Paragraph 5.2.4 requires that drawings are checked for completeness and technical adequacy utilizing Attachment 1 as appropriate. Additional requirements are detailed in Paragraph 5.2.4b through 5.2.4f to ensure that the relevant design parameters have been incorporated into the drawing, i.e., design inputs, assumptions were adequately described, the appropriate design method was used, and design input and verification requirements for interfacing organizations were specified.

- 2) QAP-3-9, Paragraph 5.2 requires that the checker shall check the design analysis for completeness and technical adequacy. Also, the checker must utilize the Design Analysis Outline (Attachment 1) to ensure the design analysis has been developed to the necessary detail. The checker must also ensure that the design output is reasonable as compared to the design input.
- 3) QAP-3-8, Paragraph 5.2.4 requires that the checker use Attachment 1 of the procedure to assure completeness and technical adequacy. Attachment 1 details checkpoints that are directly associated with the corresponding design analysis. QAP-3-10, Paragraph 5.2.4 details steps that require information taken directly from the associated design analysis.
- 4) QAP-3-9, Paragraph 5.24 requires that the checker document all comments clearly on the check copy.

6 Adverse Condition (continued)

- 4) The check copy of the electrical cable tray support design analysis was not available for review. The audit team was informed that it was not considered a QA record by the M&O and could therefore be discarded. The audit team is concerned that any OCRWM related documentation that could substantiate the design process, would be considered as disposable.

13 Recommended Action(s) (continued)

- 3) Re-evaluate procedural requirements detailing how reviews and checks are documented.

RESPONSE TO CAR NO. YM-94-065

ADVERSE CONDITION:

A. Remedial Action: All Items

1. All 2C design products containing errors (or where objective evidence that structural checks were performed does not exist) will be revised and will be rechecked in accordance with current QAPs. Interdiscipline reviews will be conducted as appropriate in accordance with QAP requirements. All Q-related drawings and specifications will be rechecked for errors. A review topic checklist will be filled out for each Q-related product rechecked. These checklists will be objective evidence that the checking process was followed. These checklists will not be QA records.
2. The MGDS Development Manager will issue a memo instructing MGDS that check copies of documents are Federal records and cannot be discarded. The records that were misplaced were for non-Q (electrical) design products.
3. Review with other M&O offices to determine if problem exists will be completed by 9/30/94.

Item 1 Responsible Individual: Robert Saunders
Date of Completion: 9/30/94 (Anticipated Release of 2C)

Item 2 & 3 Responsible Individual: Alden Segrest
Date of Completion: 9/30/94

Investigation: All Items

1. Preliminary copies of Design Analysis (structural) were used by checkers to verify Design Inputs to Drawings and Specifications during the design process. The Design Analysis Cover Sheet was not signed by the Department Manager and therefore was not complete.
2. Six non-Q check copies of 2C Design Analysis (structural) were misplaced and assumed to be discarded. The note in Paragraph 5.2 of the current QAP's indicate that the check copy is not a QA record but will be used during the final check of the document. Although the check copy is not a QA record, it is a Federal record and should not be discarded.
3. Investigation will be made to ensure no other records have been discarded. Early release documents will have new check copies.

4. Item 2 occurred when the design inputs were being developed parallel and were not completed prior to the drawings and specifications being developed.

Root Cause: All Items

1. The Design of the package was started in accordance with Revision 3 of the QAP's and completed in accordance with Revision 4 of the QAP's. In addition, NLP-3-14, R00, P03 was superseded by the contents of QAP-3-10 Revision 4, and QAP-3-8 Revision 4. Change in procedures caused confusion as to which revision was the governing document for Package 2C. The procedures were not followed and documents clearly identified when preliminary data was used as input. Design inputs were being developed parallel and were not completed prior to the drawings and specifications being developed.
2. There are no procedural guidelines for handling Federal records.
3. The checking process (and interdiscipline review) in the current Design Control Process precedes the 90% Design Review. Many discrepancies being identified indicate they are a result of incorporating 90% design review comments.
4. The actual checking process is not well documented.
5. Direction was not provided to designers for the storage of all records.
6. Personnel did not always follow checking and interdiscipline review requirements contained within procedures. The checking process described by the checklists (Review Topics) contained in QAP-3-8 and QAP-3-10 are not very clear to those who use them.

Action to Preclude Recurrence: All Items

1. A training session covering checking and interdiscipline reviews will be provided for all design personnel.
2. MGDS will request guidelines for the submittal of Federal records from the Records Management Organization. Appropriate procedures will be revised to incorporate instructions on how to process Federal records.
3. The M&O will review the current design control process, placing emphasis on improving the discipline checking and inter-discipline review steps. The design control process will be revised to move the discipline checking and interdiscipline reviews until after the 90% design review. The revised design control process will require that design inputs (analyses and the DIE) be

approved prior to the initiation of checking and interdiscipline reviews taking place. All designers will be trained to the revised process upon approval of necessary procedure revisions.

4. A review team will be established to review the checking process. Consideration will be made to document the actual checking process more formally by the use of checklists. MGDS management will be provided recommendations. The checking process will be revised accordingly. All designers will be trained to the revised checking process upon approval of necessary procedure revisions.
5. Direction has been provided that instructs the designers to submit all records to Engineering Document Control. See correspondence LV.ESSB.GH.7/94-691.

Responsible Individual: Alden Segrest
Date of Completion: 1/31/95



8/17/94