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

MAR 0 8 1995

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

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) RESULTING FROM U.S. DEPARTMENT OF ENERGY/HEADQUARTERS' QUALITY ASSURANCE DIVISION (HQQAD) AUDIT HQ-ARC-95-04 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (SCPB: N/A)

Enclosed is CAR YM-95-028 generated as a result of HQQAD Audit HQ-ARC-95-04.

Please identify the corrective action to be taken and implemented to correct the deficiency. A CAR Continuation Sheet and instructions for completion have been provided. Send the original of your response to Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109. Response to the CAR is due 20 working days from the date of this letter. Any extension to due date must be requested in writing, with appropriate justification, prior to the due date.

If you have any questions, please contact either Robert B. Constable at 794-7945 or John F. Pelletier at 794-7538.

R E. Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2368

Enclosures:
1. CAR YM-95-028
2. CAR Continuation Sheet
and Instructions

NH03
WM-11
102.7

YMP-5

cc w/encls:
T. A. Wood, HQ (RW-14) FORS
T. L. Badredine, M&O, Las Vegas, NV
J. G. Sprath, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. L. Robertson, M&O, Vienna, VA
Richard Jiu, M&O, Las Vegas, NV
R. P. Ruth, M&O, Las Vegas, NV
D. G. Horton, OQA (RW-3) NV
W. E. Barnes, YMSCO, NV

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

ORIGINAL
THIS IS A RED STAMP

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CORRECTIVE ACTION REQUEST

1 Controlling Document	2 Related Report No.
OCRWM QARD DOE/RW-0333P, Revision 1	Audit HQ-ARC-95-04
3 Responsible Organization	**4 Discussed With**
CRWMS M&O	A. Segrest

5 Requirement:

QARD Section 17.0

Paragraph 17.2.2B: "Individuals creating quality assurance records shall ensure that the quality assurance records are legible, accurate, and complete."

Paragraph 17.2.2C: "Individuals handling quality assurance records shall protect them from damage or loss until the records are submitted to the records management system."

Paragraph 17.2.3E3: "QA Records shall be indexed to ensure retrievability. The indexing system shall include identification of the item or related activity to which the QA records pertain."

6 Adverse Condition:

Contrary to the above requirements, records and record packages associated with drawings, specifications, and analysis are not being properly authenticated for accuracy, and appropriate to the work accomplished, completeness, nor are they being turned over to the LRC reasonably contemporaneous with completion of the individual records and record packages, or protected from deterioration, loss, or damage until turned over to the LRC. Additionally, indexing of records does not adequately provide a cross reference to the documentation or the associated activity.

Examples:

The following represent examples only. A comprehensive review is required to determine the extent and impact of the deficiencies.

Records segment package (LRC-114) for the BAB000000-1717-6300-02341, Revision 02, Steel Sets and Accessories Subsurface (Specification) does not contain a copy of the specification review summary.

9 Does a Significant Condition Adverse to Quality exist? Yes X No ___ If Yes, Check One: ☒A ☐B ☐C ☐D ☐E	10 Does a stop work condition exist? Yes ___ No X ; If Yes - Attach copy of SWO If Yes, Check One: ☐A ☐B ☐C	13 Response Due Date: 20 Working Days From Issuance

11 Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

12 Recommended Actions:

1) Recommend that a performance based surveillance be conducted to determine the extent and impact of the deficiencies.

2) Recommend that record process improvements be communicated through extensive training.

7 Initiator John F. Pelletier 3/1/95	14 Issuance Approved by: QADD Date 3/1/95
15 Response Accepted QAR Date	16 Response Accepted QADD Date
17 Amended Response Accepted QAR Date	18 Amended Response Accepted QADD Date
19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date

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5 Requirements (continued)

M&O QAP-17-1, Revision 3, PO 4

Paragraph 3.2, Authentication: "The act of attesting that the information contained within a record is legible, accurate, complete, and appropriate to the work accomplished."

Paragraph 5.3, Protection of Records and Records-In-Process: "Responsible management and Record Sources shall ensure that records/records-in-process are protected from deterioration, loss, or damage."

Paragraph 5.4.3A: "Records sources shall authenticate individual records and record packages immediately following creation and shall turn them over to the LRC reasonably contemporaneous with completion...individual records and record packages shall be turned over to the LRC no later than 20 working days after completion."

QAP-3-9, Revision 4, Paragraph 6B: "The following QA records generated as a result of this procedure shall be submitted by the LDE to the LRC in accordance with QAP-17-1: Design Analysis Review Summary."

NLP-3-24, Revision 1, Paragraph 5.1.1d: "The drawing or specification Originator shall forward the completed IL to the LDE for transmittal to Local Records Center in accordance with QAP-3-8 or QAP-3-10, after the output (drawing or specification) is approved."

QAP-3-10, Revision 4, Paragraph 6.0: "The following QA Records are generated as a result of this procedure and shall be submitted by the LDE to the Local Records Center in accordance with QAP-17-1:

A. Approved Drawings (which will be or are baselined)
B. Drawing Input List
C. Drawing Review Summary"

6 Adverse Condition (continued)

The TS North Ramp Ground Support Scoping Analysis DI: BAB000000-1717-0200-00010, Revision 01, and Material Dedication Rockbolts, Shotcrete and Accessories DI: BAB000000-1717-00009, Revision 1 have not been sent to the LRC for records processing.

Records package BABEAB000-01717-0200-0002, Structural Steel Sets Analysis, Revision 01 does not contain the Design Analysis Review Summary.

Records packages BABEAB000-01717-6300-02165, Revisions 05 and 06 have not been sent to the LRC for processing.

Records packages were not cross-referenced to the related records packages for proper indexing and ease of retrievability:

BAB000000-01717-6300-01501, "Subsurface General Construction," 2/16/95

Records package for Design Package ID 90% Design Review QA Record Package, 11/28/94

Integrated Data and Control System 90% Design Review QA Record, 1/12/95

The following drawings and the related documentation were not submitted to the LRC as required by NLP-3-24, Revision 1, and QAP-3-10, Revision 4:

Drawings listed by Document Number Description:

BABEAB000-01717-2100-40151, Revision 1, TS North Ramp Ground Support Master Elevation and Sections

BABEAB000-01717-2100-40161, Revision 1, TS North Ramp Alcoves Rockbolts and

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6 Adverse Condition (continued)

Shotcrete Sections

BABEAB000-01717-2100-40162, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Plan and Sections

BABEAB000-01717-2100-40163, Revision 1, TS North Ramp Alcoves Rockbolts and Shotcrete Plan, Sections and Elevation

BABEAB000-01717-2100-41101, Revision 3, TS North Ramp Steel Sets and Lagging Elevation

BABEAB000-01717-2100-41102, Revision 3, TS North Ramp Steel Sets and Lagging Sections and Details

BABEAB000-01717-2100-41103, Revision 3, TS North Ramp Steel Sets and Lagging Sections and Details

13 Recommended Action(s) (continued)

3) Recommend that the entire records process be studied and reengineered, both at Las Vegas and Vienna.

4) Recommend that indexing methods and structures be devised that allow retrievability of all records pertaining to a given work effort.

5) Recommend that the M&O concepts of authentication and validation be evaluated in light of the deficiencies.

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INSTRUCTIONS FOR CORRECTIVE ACTION

You are requested to provide a response to a Corrective Action Request (CAR) by the due date identified in block 13 of the CAR. If this due date cannot be met, provide a written request for extension to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

In order to develop the CAR response, perform investigative action (if required in block 11 of the CAR) to determine the extent of the deficiency and to identify root cause. Next, determine the actions required to correct the adverse condition. These actions include remedial action, and in the case of CARs that identify significant conditions adverse to quality, corrective action to preclude recurrence. A review of the recommended actions (if any) provided in block 12 of the CAR may assist in this determination. The response must include the following information:

1. Corrective Action Response for CAR # _____

   A. **Remedial Action** - Describe actions required to correct the specific conditions noted. **(Required for all CARs)**

   B. **Extent of the Deficiency** - Describe the investigative actions performed to determine the extent of the condition and the results of the determination. **(Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA)**

   C. **Root Cause Determination** - Identify the root cause of the condition as determined through investigative action. **(Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA)**

   D. **Corrective Action to Preclude Recurrence** - Identify the actions required to address the root cause of the condition in order to preclude recurrence. **(Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA)**

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

   If it becomes apparent that any of the corrective action due dates cannot be met, a written request for extension must be provided to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

3. The response must include the dated signature of the Responsible Individual.

ENCLOSURE 2

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WASHINGTON, D.C.

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GUIDELINES FOR ROOT CAUSE DETERMINATION

When it is established that an investigation to determine root cause is required, the following guidelines may assist in the determination:

1) Clarify the specific condition. Pertinent clarifying questions must be asked and answered as accurately as possible.

   a) What happened?
   b) Where did the condition occur?
   c) When did the condition occur?
   d) What was the extent of the condition?
   e) Who was involved?
   f) In what manner did it happen?
   g) What reasons are given by knowledgeable personnel for why it happened?

2) Obtain information related to the identified condition.

   a) Investigate, in detail, the specific condition adverse to quality.
   b) Interview personnel.
   c) Review pertinent documents.
   d) Use quality tools (cause & effect diagrams, flowcharting, Pareto analysis, comparative analysis, etc.).
   e) Identify and collect data needed to get to the root cause.

3) Most root causes fall into one or more of the following generic categories. Specific review of these areas may be useful in arriving at cause determination:

   a) Procedures
   b) Personnel
   c) Management systems
   d) Supervision
   e) Training
   f) Communications
   g) Scientific investigation/design methods
   h) Human factors
   i) Reliability considerations
   j) Miscellaneous or multiple areas