



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

JUN 09 1995

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-95-028 RESULTING FROM U.S. DEPARTMENT OF ENERGY/HEADQUARTERS'
 AUDIT HQ-ARC-95-04 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT
 SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (SCPB: N/A)**

The Yucca Mountain Quality Assurance Division staff has evaluated the supplemental response to CAR YM-95-028. The response has been determined to be unsatisfactory because the response failed to adequately address preventive recurrence controls of the specific conditions adverse to quality cited in the CAR.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah G. Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

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

Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-3513

Enclosure:
 CAR YM-95-028

9506140295 950609
 PDR WASTE PDR
 WM-11

*NH03/11
 WM-11
 102.7*

L. Dale Foust

-2-

JUN 09 1995

cc w/encl:

T. A. Wood, HQ (RW-14) FORS
~~J. G. Spraul, 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 encl:

W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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

8 CAR NO.: YM-95-028
PAGE: 1 OF 3
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document OCRWM QARD DOE/RW-0333P, Revision 1		2 Related Report No. Audit HQ-ARC-95-04	
3 Responsible Organization CRWS M&O		4 Discussed With 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 <input checked="" type="checkbox"/> No <input type="checkbox"/> If Yes, Check One: <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
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		13 Response Due Date: 20 Working Days From Issuance	
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 <i>John F. Pelletier</i>		14 Issuance Approved by: QADD <i>RC. Sarno</i> Date <u>3/1/95</u>	
15 Response Accepted QAR <i>John F. Pelletier</i> Date <u>4/10/95</u>		16 Response Accepted QADD <i>RC. Sarno</i> Date <u>4/11/95</u>	
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-95-028
PAGE: 2 OF 3
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

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

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

8 CAR NO.: YM-95-028
PAGE: 3 OF 3
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

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.

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

⁸CAR NO. YM-95-028
PAGE 1 OF 3
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Remedial Action

The following are the examples listed in the CAR.

- A) BAB000000-01717-6300-02341 Rev 02...review summary missing from record package
- B) BAB000000-01717-0200-00010 Rev 01 and
BAB000000-01717-0200-00009 Rev 01...not in RPC
- C) BABEAB000-01717-0200-00002 Rev 01...review summary missing
- D) BABEAB000-01717-6300-02165 Rev 05 & 06...not in RPC
- E) BAB000000-01717-6300-01501...not cross referenced
ID 90% Review...not cross referenced
IDCS 90% Review...not cross referenced
- F) BABEAB000-01717-2100-40151 Rev 01...not in RPC
- G) BABEAB000-01717-2100-40161 Rev 01...not in RPC
- H) BABEAB000-01717-2100-40162 Rev 01...not in RPC
- I) BABEAB000-01717-2100-40163 Rev 01...not in RPC
- J) BABEAB000-01717-2100-41101 Rev 03...not in RPC
- K) BABEAB000-01717-2100-41102 Rev 03...not in RPC
- L) BABEAB000-01717-2100-41103 Rev 03...not in RPC

These actions listed below will correct all the examples listed above.

Examples B, D, F, G, H and I are complete and in the RPC.

Example A: BAB000000-01717-6300-02341 Rev 02...(Review Summary not in record package.)

Document was created under procedure QAP-3-8 Revision 3, which did not require a review summary and there is no evidence that one was later created to meet the requirements when the specification was actually approved. An IOC from lead with the above information will be added to the record package. This has been completed.

Example C: BABEAB000-01717-0200-00002 Rev 01...(Review Summary not in record package.)

Document was created under procedure QAP-3-9 Revision 3, which did not require a review summary and there is no evidence that one was later created to meet the requirements when the analysis was actually approved. An IOC from lead with the above information will be added to the record package. This has been completed.

Example J: BABEAB000-01717-2100-41101 Rev 03

Example K: BABEAB000-01717-2100-41102 Rev 03

Example L: BABEAB000-01717-2100-41103 Rev 03

Revision 3 of these documents are processed with revision 01 and 02 to keep the records easily retrievable. In compiling the records package Revision 01 (original) was not in EDC but was later located in the records center. The ID Review for Rev 02 of these documents is not available. At the time the ID review took place only the Review Summary sheet was a required record and it was not clear as to whether to keep a copy of the ID Review document. The only comments made were against -41101 by two reviewers who performed a management review and not a technical review. The other two drawings had no comments against them as written on the Review Summary Sheet. An IOC from lead with the above information will be added to the record packages. This has been completed.

Example E: BAB000000-01717-6300-01501; ID 90% Review and the IDCS 90% Review

A supplemental to add needed information to each record package to cross reference the different reviews and the baselining document will be completed. David Parker is the responsible individual for this example.

The completion date for the Remedial Action is May 10, 1995.

4/5/95 LV-ESSD.AMS. 4/95.062

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

8. CAR NO. YM-95-028
PAGE 2 OF 3
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Extent of Deficiency

M&O QA will conduct a surveillance (Recommendation No. 1) to provide more information that MGDS and IM will then evaluate for extent and impact. The surveillance will include record package completeness and submittal and will be complete by May 10, 1995. D.M. Franks is the responsible individual for this activity.

MGDS Development and IM will then evaluate the results and provide, as required, a supplemental Remedial Action and Extent of Deficiency. David Parker and Terry Mueller are the responsible individuals for this activity.

The following list of documents were verified to be in the records center. During the QA surveillance these record packages will be sampled for problems similar to those listed in the examples.

BABEAD000-01717-2100-40100 Rev 01
BABEAD000-01717-2100-40104 Rev 01
BABEAD000-01717-2100-40110 Rev 01
BABEAD000-01717-2100-40111 Rev 01
BABEAD000-01717-2100-40112 Rev 01
BABEAD000-01717-2100-40113 Rev 01
BABEAD000-01717-2100-40114 Rev 01
BABEAD000-01717-2100-40115 Rev 01
BABEAD000-01717-2100-40116 Rev 01
BABEAD000-01717-2100-40120 Rev 01
BABEAD000-01717-2100-40121 Rev 01
BABEAD000-01717-2100-40122 Rev 01
BABEAD000-01717-2100-40123 Rev 01
BABEAD000-01717-2100-40124 Rev 01
BABEAD000-01717-2100-40125 Rev 01
BABEAD000-01717-2100-40126 Rev 01
BABEAD000-01717-2100-40127 Rev 01
BABEAD000-01717-2100-40128 Rev 01
BABEAD000-01717-2100-40129 Rev 01
BABEAD000-01717-2100-40151 Rev 01
BABEAD000-01717-2100-40152 Rev 01
BABEAD000-01717-2100-40153 Rev 01
BABEAD000-01717-2100-40154 Rev 01
BABEAD000-01717-2100-40155 Rev 01
BABEAD000-01717-2100-40156 Rev 01
BABEAD000-01717-2100-40157 Rev 01
BABEAB000-01717-2100-40161 Rev 01
BABEAB000-01717-2100-40162 Rev 01
BABEAB000-01717-2100-40165 Rev 01
BABEAC000-01717-2100-41111 Rev 01
BABEAC000-01717-2100-41121 Rev 01
BABEAC000-01717-2100-41130 Rev 01
BAB000000-01717-6300-01500 Rev 00
BAB000000-01717-6300-01501 Rev 03
BAB000000-01717-6300-01600 Rev 01
BAB000000-01717-6300-01800 Rev 00
BABEAB000-01717-6300-02165 Rev 06
BABEAB000-01717-6300-03362 Rev 01
BABEAB000-01717-6300-03363 Rev 01

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

8.
CAR NO. YM-95-028
PAGE 3 OF 3
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Extent of Deficiency (Continued)

The QA surveillance will also include records packages from other M&O departments.

Root Cause and Action to Preclude Recurrence

Completion of Root Cause investigation must be postponed until after the surveillance to properly include all necessary information. Action to Prevent Recurrence will also be developed based on the root cause and will therefore be postponed until after the Root Cause Determination.

The QA surveillance will be completed by May 10, 1995. MGDS Development and IM will then evaluate the surveillance report for further extent of deficiency and impact. A supplemental response containing any additions to the Remedial Actions, Extent of Deficiency, a complete Root Cause and Actions to Preclude Recurrence will be sent to YMQAD by June 2, 1995.

This CAR contained five recommendations. Recommendation Number 1, the QA surveillance, is underway at this time. The other four recommendations will be reviewed based on the results of the surveillance and subsequent root cause determination.

Supplemental Response to CAR YM-95-028

Remedial Action:

Remedial actions committed by Letter No. LV.ESSD.AMS.4/95.062 and identified as Examples A through L have been completed.

Additional items identified by the surveillance conducted by M&O QA, R. B. Berlien: Table of Contents for LYNX version 3.06 did not include a QA designator and the page count was incorrect. The responsible individual is C. J. Houston.

The transmittal for DIPS version 3.1 included an incorrect page count. The responsible individual is N. Hodgson.

Documents in the DIPS package have the QA designator listed on page 2 rather than page 1. The RTN Matrix included in the records package for Revision 2 of QAP-16-1 did not include a QA designator. The responsible individual is G. S. Abend.

The RTN Matrix included in the records package for Revision 5 of QAP-2-4 did not include a QA designator. The responsible individual is P. R. Dahlberg.

All the identified deficiencies will be corrected and completed on or before July 14, 1995.

Investigation for Extent:

A surveillance was conducted by M&O QA, R. B. Berlien, April 17 through May 3, 1995, as requested by MGDS Development and Records Management. The purpose of the surveillance was to review 1) examples cited by the CAR, 2) additional records submitted to the Records Processing Center (RPC) as listed in the M&O initial response, and 3) records submitted by several M&O departments.

Quoting from the surveillance report (No. 95-NSS-24):

"The results are that the deficiencies identified in the CAR have been satisfactorily resolved except one item, which is scheduled to be completed by May 10, 1995. However, problems similar to those identified in the OCRWM CAR are routinely found with records from various M&O departments."

The following are deficient items identified as a result of the surveillance:

- 1) The records did not meet the requirement to submit them within 20 work days after completion (identified as "Examples D, F, G, H, and I").
- 2) Drawing packages typically stated there were two pages in the package; actually there were three; the third page was a Special Instruction Sheet. The practice of not identifying the Special Instruction Sheet on the Table of Contents is considered correct

by records personnel (this item was identified as a result of the review of additional records not cited in the CAR).

- 3) Block 9 of Special Instruction Sheet is not completed; instructions state that one of three entries is valid (this item was identified as a result of the review of additional records not cited in the CAR).
- 4) Record package for BABEAD000-01717-2100-40152 was compiled 3/31/95 and signed for 4/3/95 by RPC, but Table of Contents had not been authenticated (this item was identified as a result of the review of additional records not cited in the CAR).
- 5) Writeovers were obvious on Table of Contents for BABEAD000-01717-2100-40125 (this item was identified as a result of the review of additional records not cited in the CAR).
- 6) Baseline Change Proposals 02-95-0007, 0009, and 0017; Quality Program Status Reports and Trend Reports were requested from RPC: none was retrievable (these items were identified as a result of the review of other departments' records).
- 7) RPC is reviewing records submitted in November 1994. When current records are reviewed, it may be difficult to correct the problems identified because record sources may not be available to provide the corrections or explanations. In addition, because errors are not identified quickly, more errors are made before the source recognizes the mistake.
- 8) A signature on Table of Contents (block 11), Authenticated by, is clearly an act of authentication. Interviews of personnel indicated that the approving person does not consider the approval an act of authentication (this item was identified as a result of interviews with record sources and authenticators). The procedure is clear; it is not a matter of interpretation, but one of failure to comply with the procedure.
- 9) QAP-17-1, 5.3.D states the authenticator submits the record to the RPC. 5.4.2.E states the record source submits. In practice, records are submitted in a variety of ways including secondary distribution (this item was identified as a result of interviews with record sources and authenticators).
- 10) None of the authenticators interviewed understood the requirement of QAP-17-1, 5.3.C, that the authenticator must determine that the document being authenticated will

receive no more entries (this item was identified as a result of interviews with record sources and authenticators).

- 11) Protection of records and records-in-progress is not clear. The degree of protection is not specified (this item was identified as a result of interviews with record sources and authenticators).
- 12) Interpretation of "record segment" varies. CAR Example A had 19 separate documents as part of the records package. The 19 individual documents were submitted as a package. The first of these 19 documents was completed 3/94, yet the package was submitted 4/95 (this item was identified as a result of interviews with record sources and authenticators).
- 13) Procedures list lifetime and nonpermanent records; yet record packages typically contain additional records (this item was identified as a result of the review of other departments' records).
- 14) Consistency between organizations and within organizations: example, one person in RPC adds QA:N to transmittals. Another chooses not to add a QA designation to transmittals. (QAP-17-1 does not require identification with QA designator) (this item was identified as a result of the review of other departments' records).
- 15) Records packages for LYNX version 3.06 included Table of Contents without a QA Designator and page count was incorrect (this item was identified as a result of the review of other departments' records).
- 16) Transmittal for DIPS version 3.1 record package page count was wrong; documents in the package, such as Life Cycle Plan, have QA Designator on page 2 instead of page 1 (this item was identified as a result of the review of other departments' records).
- 17) Records packages for QAP-16-1 R2 and QAP-2-4 R5 included RTN record with no QA designator (this item was identified as a result of the review of other departments' records).

Root Cause

The above items 1) through 17) may be categorized and summarized as follows:*

2A-inadequate procedure: 4 cited [contributory causes]: Nos. 2, 3, 9, 11

3B-inattention to detail: 3 cited [contributory causes]: Nos. 15 through 17

3C-failed to follow procedure: 6 cited [root cause]: Nos. 1, 4, 5, 8, 10, 13

6A-inadequate administrative control: 2 cited [contributory causes]: Nos. 7 and 14

Nos. 6 and 12 are addressed below.

*All references to procedure relate to QAP-17-1, "Record Source Responsibilities for Inclusionary Records."

Action to Prevent Recurrence:

To address the cited causes for each item, the following preventive actions are indicated. Where applicable, each includes a completion date or scheduled completion date and responsible individual.

Items No. 1, 4, 5, 8, 10, 13, 15, 16, 17 are not significant if considered singly; however, taken together, they indicate a need to reemphasize the procedure for records sources to follow. Training to QAP-17-1 will be conducted when the QAP is revised. It is currently undergoing revision; completion is scheduled for September 1, 1995. Training on the revised QAP-17-1 will be completed by September 1, 1995. Responsible individuals are: Margaret A. Shepherd (revision of QAP-17-1); and Sandra Y. Bolden (training).

Items 2, 3, 9, and 11 are a result of unclear instruction as provided by QAP-17-1. Revising QAP-17-1 will prevent this problem from recurring. It is currently undergoing revision; completion is scheduled for September 1, 1995. The responsible individual is Margaret A. Shepherd.

Item 6 could not be retrieved because the records had not been submitted to the RPC in Vienna. These records need to be collected and submitted as required, on or before July 14, 1995. The responsible individual is R. Morgan. No further action will be necessary.

Item 7 resulted from inadequate resource allocation to control records in process. In the last several months, several new personnel have been acquired and assigned to the RPC. Records in process have been increasing, because the number of records input has been increasing. However, the addition of RPC personnel and the application of overtime is expected to mitigate records in process. No further action is required at this time.

Item 12 does not represent a deficiency. The 19 records were submitted in full compliance with requirements. A record segment may be held in storage for up to two years in compliance with QAP-17-1. This provision is needed to accommodate systems, components, etc. that take a long period of time from beginning to completion, and the records of which need to be considered part of a collected package. It is up to the record source to define what constitutes a record segment. No further action is necessary.

Item 14 represents the confusion caused by multiple procedures specifying QA designators for a multitude of different records. It is not, and should not, be the responsibility of the RPC staff to verify the correctness of QA designators, but only to verify that a QA designator exists on the first page of the record. The staff will be instructed not to change or add QA designators, but to question the record source when a question exists. The instruction will be documented; completion will be on or before June 9, 1995. The responsible individual is Laura M. Tate.