



Department of Energy
Yucca Mountain Site Characterization
Project Office
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Las Vegas, NV 89193-8608

WBS 1.2.11
QA: N/A

JUN 09 1993

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for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems
Bank of America Center, Suite P-110
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EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-93-036 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-93-07 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (SCP: N/A)

The YMQAD staff has evaluated the response to CAR YM-93-036. 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 Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Amelia I. Arceo at 794-7737.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4552

Enclosure:
CAR YM-93-036

cc w/encl:

Trudy Wood, HQ (RW-52) FORS

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S. W. Zimmerman, NWPO, Carson City, NV
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J. W. Gilray, NRC, Las Vegas, NV
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YMP-5

ADD: Ken Hooks

Wtr. Encl.
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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.**

8 CAR NO.: YM-93-036
DATE: 3/11/93
SHEET: 1 OF 3
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document CRWMS M&O QAP 5-1, Revision 1, PCN P01		2 Related Report No. Audit YMP-93-07	
3 Responsible Organization CRWMS M&O-Nevada		4 Discussed With R. Justice/T. Redding/F. Arth	
5 Requirement: QAP 5-1, Revision 1, PCN P01 1. Paragraph 5.3.2 states in part, "Each QAP/ILP shall be distributed by the responsible manager using an interoffice memo to the reviewing managers with a PRR. The PRR shall be completed with review instructions/criteria (see Attachment III, Standard Review Criteria) for performing the review...." Paragraph 5.2.1 of Revision 0 stated in part, "The development manager shall submit the draft procedure with review instructions/criteria to the manager of each interfacing organization...." (Continued on next page)			
6 Adverse Condition: The CRWMS M&O, Nevada Operations has not been implementing QAP 5-1. Example are: 1. There were no review criteria for the review of NSP-6-2, Revision 0, and NSP-17-1, Revision 0. The Document Review Records, "Review Instruction/Criteria Prepared by:" blocks were signed and dated; however, no review criteria were found in the records package. Furthermore, the review/instructions criteria was not identified on Block 7 of a Procedure Review Record for QLP-2-1, Revision 1. (Continued on next page)			
9 Does a significant condition adverse to quality exist? Yes <u>X</u> No <u> </u> If Yes, Circle One: A (B) C		10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	
11 Response Due Date: 20 Working Days from Issuance			
12 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 Recommended Actions: 1. Correct the examples identified. 2. Investigate to determine if there are similar deficiencies. 3. Determine root cause(s) and take action to preclude recurrence.			
7 Initiator <u>Amelia J. Arceo</u> A. J. Arceo Date <u>3/15/93</u>		14 Issuance Approved by: QADD <u>[Signature]</u> Date <u>3/15/93</u>	
15 Response Accepted QAR <u>Amelia J. Arceo</u> Date <u>6-1-93</u>		16 Response Accepted QADD <u>[Signature]</u> Date <u>6/8/93</u>	
17 Amended Response Accepted QAR <u> </u> Date <u> </u>		18 Amended Response Accepted QADD <u> </u> Date <u> </u>	
19 Corrective Actions Verified QAR <u> </u> Date <u> </u>		20 Closure Approved by: QADD <u> </u> Date <u> </u>	

ENCLOSURE

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CORRECTIVE ACTION REQUEST (Continuation Page)

5 Requirements (continued)

2. Paragraph 5.3.10 states in part, "The responsible manager shall finalize training requirements and the effective date of the QAP/ILP on the QAP/ILP Training Coordination Sheet. If formal classroom training is required, the Training Manager shall be consulted concerning the effective date... If formal classroom training is not required, the training recommendation shall be documented by the responsible manager on the QAP/ILP Training Coordination Sheet and sent to the Training Manager for tracking."
3. Paragraph 5.5.2.A states in part, "Changes in the QAP/ILP revision shall be designated by change bars in the retyped QAP/ILP...."
4. Paragraph 5.5.4.C states, "The Document Control Center shall distribute the cancellation notice and a revised Table of Contents in accordance with QAP 6-1."

Paragraph 5.7.3 states in part, "After approval, the PCN shall be given to the Document Control Center for distribution to all manual holders in accordance with QAP 6-1. The PCN shall be distributed with an updated Table of Contents...."
5. Paragraph 5.8.5 states in part, "Memos documenting the QAP/ILP review due to changes in upper documents shall be submitted to the LRC in accordance with QAP 17-1."
6. Section 6 states in part, "Documents generated as a result of this procedure shall be collected and maintained in accordance with QAP 17-1... As a minimum, the following shall be considered program records and shall be submitted through the Local Records Centers Program Records: Procedure Review Records and non-mandatory comments with distribution memo and a copy of the draft submitted for review...."

6 Adverse Condition (continued)

2. a. There was no QAP/ILP Training Coordination Sheet for NSP-6-2, Revision 0, "Nevada Site Document Tracking."

b. The QAP/ILP Training Coordination Sheet for QLP-2-1, Revision 1, "Certification of QC Inspectors"
 - 1) was not signed and dated by the Responsible Manager in the Preliminary Training Requirements Determination block, and
 - 2) the Final Determination of Training Requirements block was not filled in.

NOTE: Item b. was resolved on 3/2/93 by resubmitting corrected QAP/ILP Training Coordination Sheet to MNA.921105.0037 records package.

3. Changes to NSP-6-1, Revision 1, and NSP-17-1, Revision 1 were not indicated by change bars. The CRWMS M&O had decided that change bars were not needed when the revision was so extensive that the revision constituted a complete revision; however, the CRWMS M&O had not revised QAP 5-1 to reflect current practice.
4. The Document Control Center distributes Cancellation Notices and Procedure Change Notices without Table of Contents. There is no Table of Contents for implementing procedures.
5. There was no documented evidence indicating that ILPs were reviewed for impact when upper-tier documents are changed.
6. a. Records packages for the development of implementing procedures NSP-6-1, Revision 1, "Yucca Mountain Site Office: Document and Records Center: Document Control Operations" and NSP-17-1, Revision 1, "Yucca Mountain Site Office: Document and Records Center: Records Services Operations" were not submitted to the LRC.

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6 Adverse Condition (continued)

- b. Record package for QLP-2-1, Revision 1 did not contain the draft procedure submitted for review.

NOTE: Item a. was resolved on 3/3/93 by transmittal of records packages to the LRC and Item b. was resolved on 3/8/93 by transmittal of the draft procedure to the LRC.

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CORRECTIVE ACTION REQUEST (Continuation Page)

12. Required Actions; Response to CAR YM 93-036

12.1 Adverse Condition was: No review criteria for M&O ILP/NSP-17-1, Revision 0.

- A. Review criteria for M&O NSP-17-1, Revision 0, block 7, was amended and corrected prior to incorporation of records package into the Records Management System.
- B. Investigations concluded that this occurred to only one other document and it was also corrected.
- C. This occurred do to personnel inexperience and oversight.
- D. Any new or revised document will be reviewed by trained personnel using QAP-5-1.

12.2 Adverse Condition was: NSP-6-2, Revision 0 had no review criteria and no QAP/ILP Training Coordination Sheet.

- A. Could not be performed (see B).
- B. This CAR identified a deficiency in NSP-6-2, Revision 0 (i.e. review criteria was not identified on the document review record, and there was no training sheet). Revision 0 was reviewed during the audit as part of the case history of NSP-6-2. But, prior to the audit, the procedure was revised in its entirety and Revision 1 was created (effective 2/22/93). Although the deficiencies identified in Revision 0 cannot be corrected for the revision, the Revision 1 records package includes the necessary review criteria and training sheet.
- C. This occurred do to personnel inexperience and oversight.
- D. Additional training has been enforced for those people initialing procedures.

Ltr dtd 4/14/93 - LV, QA, BRJ. 04/93-079

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12.3 Adverse Condition was: Changes to M&O ILP/NSP-6-1 and NSP-17-1, Revisions 1, were not identified by change bars.

- A. Change bars to NSP-6-1, PCN's 1 and 2 were in place. Change bars to NSP-17-1, PCN 1, (which changed NSP-17-1 from revision 0 to revision 1) were completed as a "line through and initial", thus change bars were not included. A memorandum was included in the records package of NSP-6-1 revision 1 and 17-1, revision 1, which explained that both NSP's were complete rewrites and change bars were not incorporated into the revisions.
- B. Investigations concluded that the response indicated in paragraph A, is correct.
- C. Root cause was the interpretation of QAP-5-1, paragraph 5.5.2.A
- D. Closer attention to detail in the procedure will be done. QAP-5-1, revision 2, now states that change bars should be used, but no longer makes them mandatory.

12.4 Adverse Condition was: Document Control Center issued Cancellation Notices without issuing a Table of Contents.

- A. Non-compliance with this requirement was identified by the DCC prior to the audit. An Expedited Procedure Change Notice (PCN#2) was initiated and submitted to M&O Vienna for QA approval. This PCN was returned, and not approved because the issue was resolved, and will be changed in the next revision of QAP-5-1.
- B. Our investigation concluded that we were not in compliance and that all draft variations of QAP-5-1, Rev. 2 (issued soon) made issuing a Table of Contents "if applicable".

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12.4 (cont.)

- C. The M&O in Las Vegas controls individual documents, thus eliminating the need to include a Table of Contents. The Controlled Document Information System (CDIS) is the computerized index of controlled documents. This computerized index pertains to all M&O controlled documents issued by the DCC and maybe used by end users as an electronic Table of Contents.
- D. This change to QAP-5-1, has been distributed on April 12, 1993. QAP-5-1, revision 2, has deleted the requirement to distribute a Table of Contents.

12.5 Adverse Condition was: No documented evidence that ILP's were reviewed for impact when upper-tier documents are changed.

- A. This requirement was completed but not documented.
- B. During our investigation the above mentioned results were obtained.
- C. The root cause determination is due to personnel inexperience and oversight.
- D. The documentation was included as a records supplement to the records package on 4/14/93.

12.6. Adverse Condition was: Records Packages for NSP-6-1 and NSP-17-1 not submitted to LRC.

- A. Records packages for both NSP's were submitted within the ten day time frame after being authenticated, as required by QAP-17-1. Each package was authenticated during the course of the audit and forwarded to the LRC.
- B. During our inquiry, these were the only two documents in question and the M&O is confident that it was consistently met the requirements of QAP-17-1.

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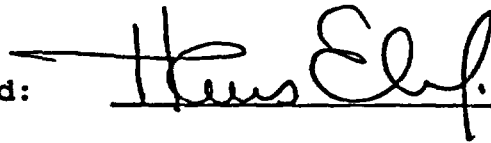
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12.6 (cont.)

- C. The cause of this was the interpretation of the procedure that states that records packages will be submitted within ten working days of authentication. The M&O believes we were and are in compliance and this is a non-issue.
- D. We will recommend a change to the M&O QAP-17-1 to require submittal of procedures to the LRC within 10 days of the effective date of the procedure.

Response Approved:



Date: 4/14/93

Hans Ebner
Document Control Manager



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

WBS 1.2.11
QA: N/A

MAY 13 1993

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EVALUATION OF RESPONSES TO CORRECTIVE ACTION REQUEST (CAR) YM-93-036 AND CAR YM-93-037 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-03-07 OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (CRWMS M&O)/TRW ENVIRONMENTAL SAFETY SYSTEMS, INC. (SCP: N/A)

The YMQAD staff has evaluated the responses to CARs YM-93-036 and YM-93-037. The responses have been determined to be unsatisfactory for the following reasons:

YM-93-036

This CAR indicated that there were numerous examples of failure to properly implement CRWMS M&O Quality Assurance Procedure (QAP) 5-1. Instead of addressing the condition adverse to quality as a general problem with implementation of the procedure, the CRWMS M&O response addresses each example provided in the CAR as a separate, unrelated condition adverse to quality.

The following is keyed to the six examples of the deficiency listed in the CAR:

1. The response fails to address the deficiencies regarding National Siting Plan (NSP) 6-2 and Quality Line Procedure 2-1. The response also fails to explain why, since there were no review criteria, there was no need to rereview the procedures. Simply adding review criteria after the review does not address the problem. Furthermore, the stated root cause "This occurred do (sic) to personnel inexperience and oversight" is not addressed in preventative action. Since March 8, 1993, has there been a training course given to personnel who implement QAP 5-1? YMQAD is having difficulty in understanding why CRWMS M&O management would assign the important task of writing/reviewing procedures to "inexperienced" personnel.

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2. The response addresses the Example 1 deficiency regarding NSP 6-2 but does not address example Deficiency 2 "No Quality Administrative Procedure (QAP)/Implementing Line Procedure (ILP) Training Coordination Sheet for NSP 6-2."
3. Investigative action fails to indicate what other procedures were reviewed for proper revision bar indicators. QAP 5-1, Revision 1, paragraph 5.5.2.A, was quite clear and not subject to misinterpretation; therefore, the root cause as stated is not acceptable.
4. The corrective action taken to revise QAP 5-1 to eliminate the requirement for a Table of Contents to be issued with each Procedure Change Notice (PCN) or cancellation notice is acceptable.
5. The response fails to provide specifics. Which ILPs were reviewed for impact? How was it determined that the impact was accomplished when it was not documented? Which records packages were supplemented?

The response fails to address actions taken to prevent recurrence that relate to root cause.

6. Both NSP 6-1 and NSP 17-1 were approved in December 1992, with an effective date of January 4, 1993. All "records" except the Table of Contents for the record package were completed on or before January 4, 1993. It should not take 56 days to generate two Table of Contents. Clearly, not having a record copy sent to the Local Record Center by March 1, 1993, is far too long. Furthermore, the response does not state when QAP 17-1 will be revised to clarify timeliness of submittals.

The CRWMS M&O needs to reassess their response and address this CAR as six examples of failure to implement QAP 5-1.

YM-93-037

The response to this CAR indicated that there were several examples of inadequate ILPs and indicated that ILPs did not address Office of Civilian Radioactive Waste Management Yucca Mountain Site Characterization Project (YMP) administrative procedures (AP). The response is unacceptable because the response addressed only the specific examples that were provided. There was a commitment to revise NSP 6-1 and NSP 17-1 by May 15, 1993; however, the response failed to address APs and an overall root cause has not been determined.

Amended responses are required to be submitted to this office within ten working days of the date of this letter. Send the original of your responses to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

MAY 13 1993

L. Dale Foust

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If you have any questions, please contact either Robert B. Constable at 794-7945 or Richard E. Powe at 794-7749.

Robert B. Constable for .

YMQAD:RBC-4146

Richard E. Spence, Director
Yucca Mountain Quality Assurance

Enclosures:

1. CAR YM-93-036
2. CAR YM-93-037

cc w/encls:

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S. W. Zimmerman, NWPO, Carson City, NV
R. J. Brackett, M&O/TRW, Vienna, VA
R. L. Robertson, M&O/TRW, Vienna, VA
J. A. Jackson, M&O/TRW, Las Vegas, NV

cc w/o encls:

J. W. Gilray, NRC, Las Vegas, NV
~~N. J. Brogan~~, SAIC, Las Vegas, NV

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Amended Response to CAR YM-93-036

A. Remedial Action

1. The review criteria for NSP-17-1, Rev. 0 have now been included in the records package. Procedures NSP-6-2 and QLP-2-1 have since been revised and review criteria were identified and provided for the reviewers. The procedures identified as not having review criteria included in the records package are acceptable as currently filed. Any review conducted without specific review criteria allowed persons to provide any comments without restriction which had to be resolved prior to procedure approval. In the case of NSP-6-1 and QLP-2-1, the procedures have since gone through an entire revision and comment cycle with review criteria specified.

2. The procedure NSP-6-2, Rev. 0 identified has already been revised. The Training Coordination Sheet was not in the records package. Revision 1 to this procedure included the Training Coordination Sheet with reading identified as the appropriate training for this procedure. Part B to this condition was identified as corrected during the audit.

3. Procedures NSP-6-1, Revision 1 and NSP-17-1, Revision 1 were both completely rewritten and sidelines not specifically identified. A memorandum was included in both the records packages to explain why change bars were not included. Procedure Change Notices (PCNs) to both procedures did include sidelines with the change pages.

4. Implementing procedures are distributed as individual documents and as such do not include a table of contents. The procedure which governs the preparation of Implementing Line Procedures has been revised and this requirement removed.

5. Procedure QAP-5-2, Preparation of ILPs, now requires compliance reviews be conducted when upper tier documents change. In addition to the corrective required, all M&O procedures are currently undergoing reviews to comply with the new QARD DOE/RW/0333P.

6. The records packages for procedures NSP-6-1 and NSP-17-1 were submitted to the LRC 3/3/93.

Lh 171 5/26/93 - LV. QA. PMS. 05/26/93

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B. Extent of Deficiency

A review of all ILP records has been conducted to determine if similar problems as those identified above exist. Records packages for MGP-3-8, MGP-3-9, and MGP-7-1 had not yet been submitted to the LRC. The records packages for these procedures have now been submitted to the LRC.

C. Root Cause

The cause of these deficiencies was due to inattention to the details in procedure QAP-5-1, Revision 1. In addition, QAP-5-1 described the process for handling the preparation and revision of both Quality Administrative Procedures (QAPs) and Implementing Line Procedures (ILPs). Although the processes were similar, they were not identical and this further contributed to the difficulty of effectively implementing QAP-5-1.

D. Action to Preclude Recurrence

Personnel who revise procedures need to be trained in the procedures which govern that activity. QAP-5-1 has been revised to separate the processes for preparation and revision of procedures. Two procedures were generated, QAP-5-1, Rev. 2 for QAPs and QAP-5-2, Rev. 0 for ILPs. This separation of activities should eliminate the confusion created by describing both processes in the same procedure.

Additionally, since it is impractical to train people on past revisions of a procedure, additional training on QAP-5-1, Rev. 1 is not required. However, since a new revision exists, personnel shall be trained in the new procedure prior to performing work. The procedure author of QAP-5-2 determined that only reading was required for this procedure. In addition to reading, we will prepare classroom instruction for QAP-5-2 (since this is the process we use in Las Vegas) and present it to potential procedure authors. This class will then be available on an as requested basis. This classroom training will be available by June 11, 1993.

Response Approved:

Robert Justice Jr.
Responsible Manager

Date: 5/26/93