



**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

L. Dale Foust  
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 for Yucca Mountain  
 Site Characterization Project  
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 101 Convention Center Drive  
 Las Vegas, NV 89109

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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ADD: Ken Hooks

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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.

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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

Richard E. Spence, Director  
Yucca Mountain Quality Assurance

YMQAD:RBC-4146

Enclosures:

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

cc w/encls:

Trudy Wood, HQ (RW-52) FORS  
K. R. Hooks, NRC, Washington, DC  
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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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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

**CORRECTIVE ACTION REQUEST**

|   |  |   |  |
|---|--|---|--|
| 1 Controlling Document<br>CRWMS M&O QAP 5-1, Revision 1, PCN P01  |  | 2 Related Report No.<br>Audit YMP-93-07   |  |
| 3 Responsible Organization<br>CRWMS M&O-Nevada  |  | 4 Discussed With<br>R. Justice/T. Redding/F. Arth   |  |
| 5 Requirement:<br>QAP 5-1, Revision 1, PCN P01<br><br>1. Paragraph 5.3.2 states in part, "Each QAP/IIP 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...."<br><br>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...."<br><br>(Continued on next page) |  |   |  |
| 6 Adverse Condition:<br>The CRWMS M&O, Nevada Operations has not been implementing QAP 5-1. Example are:<br><br>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.<br><br>(Continued on next page)  |  |   |  |
| 9 Does a significant condition adverse to quality exist? Yes <u>X</u> No ___<br>If Yes, Circle One: A (B) C   |  | 10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO<br>If Yes, Circle One: A B C D |  |
| 11 Response Due Date:<br>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:<br><br>1. Correct the examples identified.<br>2. Investigate to determine if there are similar deficiencies.<br>3. Determine root cause(s) and take action to preclude recurrence.  |  |   |  |
| 7 Initiator <u>Arceco I. Arceo</u> <u>3/15/93</u><br>A. I. Arceo Date   |  | 14 Issuance Approved by: <u>[Signature]</u> Date <u>3/15/93</u><br>QADD Date  |  |
| 15 Response Accepted<br>QAR Date  |  | 16 Response Accepted<br>QADD Date   |  |
| 17 Amended Response Accepted<br>QAR Date  |  | 18 Amended Response Accepted<br>QADD Date   |  |
| 19 Corrective Actions Verified<br>QAR Date  |  | 20 Closure Approved by:<br>QADD Date  |  |

**ENCLOSURE**

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QA

**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 NNA.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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**CORRECTIVE ACTION REQUEST (Continuation Page)**

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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QA

**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.

*Str del* 4/14/93 - LV, QA, BRJ. 04/93-079

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

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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**CORRECTIVE ACTION REQUEST (Continuation Page)**

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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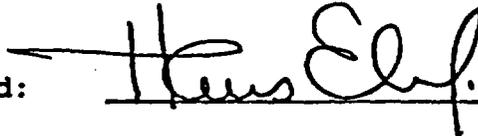
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**CORRECTIVE ACTION REQUEST (Continuation Page)**

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

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8 CAR NO.: YM-93-037  
DATE: 3/12/93  
SHEET: 1 OF 2  
QA

**CORRECTIVE ACTION REQUEST**

|  |  |   |  |
|--|--|---|--|
| 1 Controlling Document<br>CRWMS M&O QAPD, Revision 3   |  | 2 Related Report No.<br>Audit YMP-93-07   |  |
| 3 Responsible Organization<br>CRWMS M&O-Nevada   |  | 4 Discussed With<br>L. D. Foust, J. Jackson   |  |
| 5 Requirement:<br>CRWMS M&O QAPD, Revision 3, Section 5.1 states in part:<br><br>"....The M&O Quality Administrative Procedures (QAPs) and Implementing Line Procedures (ILPs) incorporate the committed requirements from the applicable sections of the QARD. QA ensures that all applicable quality assurance requirements are addressed prior to approval...."   |  |   |  |
| 6 Adverse Condition:<br>The CRWMS M&O Implementing Line Procedures (ILPs) do not meet some of the requirements of the CRWMS M&O QAPD and in some instances do not reflect current practice. Examples of ILPs that are inadequate or do not reflect current practice that were found during Audit YMP-93-07 are:<br><br>1. NSP-6-1, Revision 1, PCNs P01 and P02, Yucca Mountain Site Office: Document Control and Records Center: Document Control Operations<br><br>Paragraph 5.1.6.1 states, "Upon receipt of an approved master of a design document revision, the DRC staff shall destroy all hard copies of the superceded or obsolete (old) documents, including applicable incorporated change documents."<br><br>CRWMS M&O personnel were not destroying the hard copies of the superceded or obsolete document. Instead they are marking the copies as obsolete and keeping them for reference by field personnel. The documents are removed once the activity associated with the Job Package is completed and the Job Package is submitted to the Central Records facility. The ILP needs to be revised to reflect this current practice. |  |   |  |
| 9 Does a significant condition adverse to quality exist? Yes <u>X</u> No ___<br>If Yes, Circle One: A <u>(B)</u> C   |  | 10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO<br>If Yes, Circle One: A B C D |  |
| 11 Response Due Date:<br>20 work 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:<br>1) Correct the deficiencies identified; 2) Screen other ILPs to determine the extent of the deficiency; 3) determine if M&O personnel are sufficiently trained regarding working to approved procedures and what to do if a procedure needs to be revised; 4) determine root cause(s); and 5) take action to prevent recurrence.  |  |   |  |
| 7 Initiator <u>J. Blaylock/Rj Powe</u><br>Date <u>3/15/93</u>  |  | 14 Issuance Approved by:<br><u>R. Spruce</u><br>Date <u>3/15/93</u>   |  |
| 15 Response Accepted<br>QAR Date   |  | 16 Response Accepted<br>QADD Date   |  |
| 17 Amended Response Accepted<br>QAR Date   |  | 18 Amended Response Accepted<br>QADD Date   |  |
| 19 Corrective Actions Verified<br>QAR Date   |  | 20 Closure Approved by:<br>QADD Date  |  |

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

6 Adverse Condition (continued)

2. NSP-17-1, Revision 1, Yucca Mountain Site Office: Document and Records Center; Record Services Operations

a. CRWMS M&O QAPD, Revision 3, Section 17.6 states in part, "Records are controlled from the time they are completed until they are stored in predetermined locations that meet the requirements of the OCRWM QARD. The storage procedure includes:

.....  
f. The method for maintaining control of and accountability for records removed from the storage area...."

NSP-17-1, Revision 1, does not provide a method for controlling documents in temporary storage that are returned to the Record Source.

b. NSP-17-1, Revision 1, paragraph 5.1.8.1 states in part, "....The DRC records vault complies with applicable QA requirements to prevent loss, damage from moisture, temperature, pressure, excessive light, electromagnetic fields, and other hazards.

NSP-17-1 does not provide acceptance criteria for the prevention measures required, e.g. there is no criteria for what constitutes excessive light, electromagnetic fields, or other hazards.

3. General, all ILPs

CRWMS M&O QAPD, Revision 3, Section 2.1.2 states in part, "This QAPD details the M&O organizational structure, quality-affecting responsibilities, interfaces...." and Section 2.1.4 states in part, "M&O Implementing Line Procedures are used to control quality-affecting activities where detailed implementing instructions are restricted to an M&O geographic location or individual functional area...."

M&O ILPs do not reference interfacing Yucca Mountain Site Characterization Project Office Administrative Procedures such as AP 3.5Q and AP 6.17Q.

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

12. Required Actions; *Response* to CAR YM 93-037  
*Response*  
*mc 4/1/93*
- 12.1. Adverse Condition was: The DRC was not destroying the hard copies of superseded or obsolete documents, until the next revision of the document.
- A. The initial intent of the procedure was to make room for other obsolete documents. The procedure is due to be changed to no longer reflect this requirement.
  - B. A review of this revealed that Quality Assurance work was not affected.
  - C. Root cause of this was storage requirements, however, the staff of the DRC has occasionally referred to the obsolete documents for historical purposes.
  - D. The procedure will be changed by 5/15/93 to modify the requirement as previously identified in paragraph "A" above.
- 12.2a Adverse Condition was: M&O ILP/NSP-17-1 does not provide a means of controlling records in temporary storage, that have been returned to the record source.
- A. A modification to the form used by the DRC Staff to account for records stored in the vault, was made on the spot during the audit to document this action. The procedure will be modified to reflect the new process.
  - B. A search of the requirement revealed that no records segments were requested or returned in the past, however, we do recognize the need for such action and will modify NSP-17-1 to govern it.
  - C. Root Cause of the situation was the procedure did not provide for an action which had not yet occurred.
  - D. Corrective action is being taken as previously stated. The form used for records accountability has been modified and the procedure will be revised to provide.

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

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

12.2b Adverse Condition was: NSP-17-1 does not provide a single storage records vault.

- A. The condition of non-compliance is non-existent. Sub-paragraph 5.1.8.1, NSP-17-1 states, "The DRC staff shall store and protect QA records that have been received at the DRC, in a temporary storage records vault."
- B. Investigation concluded the audit team focused on a "Note" below the above mentioned sub-paragraph. This "Note" will be removed to avoid any further confusion.
- C. Root cause was difference of interpretation between the originator/users and the audit team, of the before mentioned subparagraph and the "Note".
- D. This "Note" will be removed from the procedure no later than 5/15/93.

Response Approved:



Date:

4/7/93

Hans Ebner  
Document Control Manager