



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

WBS 1.2.9.3
QA

DEC 19 1990

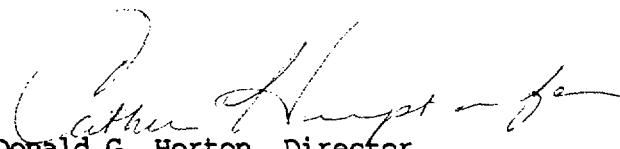
Carl P. Gertz, Project Manager, YMP, NV

EVALUATION OF RESPONSES TO CORRECTIVE ACTION REQUESTS (CARS) YM-91-005, YM-91-007, AND YM-91-011 RESULTING FROM THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT 90-I-01

The YMQAD staff has evaluated the responses to CARS YM-91-005, YM-91-007, and YM-91-011. The responses have been determined to be satisfactory. Verification of completion of the corrective actions will be performed after the effective dates provided.

Any extension to the effective dates must be requested in writing with appropriate justification prior to those dates.

If you have any questions, please contact either Catherine E. Hampton at 794-7973 or Stephen R. Dana of Science Applications International Corporation at 794-7176.


Donald G. Horton, Director
Yucca Mountain Quality Assurance Division

YMQAD:CEH-1282

Enclosure:
CARS YM-91-005, YM-91-007, and
YM-91-011

cc w/encl:
K. R. Hooks, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
M. J. Meyer, CER, Arlington, VA
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:
J. W. Gilray, NRC, Las Vegas, NV

YMP-5

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PDR WASTE
WM-11 PDR

FULL TEXT ASCII SCAN

ADD: KHooks

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NH03

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

14 CAR NO.: YM-91-005
DATE: 11/09/90
SHEET: 1 OF 1
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAPD, Revision 3	2 Related Report No. Audit No. 90-I-01
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3 Responsible Organization Quality Assurance Division	4 Discussed With Donald G. Horton
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10 Response Due 11/29/90	11 Responsibility for Corrective Action D. Horton	12 Stop Work Order Y or N N
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5 Requirement:

QAPD, Rev. 3, Para. 2.1.1 states in part:

"A matrix, which cross-references OCRWM procedures and the QAPD to the QARD requirements, is established and maintained by the Office of Quality Assurance."

6 Adverse Condition:

Documented evidence of a matrix that cross-references OCRWM procedures and the QAPD to the QARD requirements does not exist.

NOTE: The auditor was aware that this matrix was in the process of being developed based on the fact that the portion related to the YMPO was almost finished at the time of the Audit Exit Meeting. However, the document has not been approved as required by the implementing procedure.

7 Recommended Action(s):

Identify the remedial actions to be taken to correct the deficiency noted in Block 6.

8 Initiator Mario R. Diaz	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/>	13 Approved By: OQA <u>James Blaylock</u>	Date: <u>11/9/90</u>
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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CAR NO.: YM-91-005
DATE: 11/9/90
SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST
(continuation sheet)

CORRECTIVE ACTION RESPONSE:

Corrective Action For Deficient Condition #1

Remedial Action:

The matrix, which cross-references OCRWM procedures and the QAPD to Revision 4 QARD Requirements is in preparation. The matrix will be completed and submitted for approval by the Director, OQA by January 31, 1991.

Response Approved N. Coltura
Responsible Manager

12/4/90
Date

Response Accepted S. J. Davis
QAR

12/4/90
Date

Response Accepted Catherine J. Stender
Office of Quality Assurance

12-7-90
Date

**OFFICE OF CIVILIAN
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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**14CAR NO.: YM-91-007
DATE: 11/09/90
SHEET: 1 OF 2
QA
WBS No.: 1.2.9.3**CORRECTIVE ACTION REQUEST**

1 Controlling Document EDD-001, Rev. 0, and YMP/CM-007, Rev. 1		2 Related Report No. Audit 90-1-01	
3 Responsible Organization Engineering & Development Division		4 Discussed With G. Dymmel and J. Waddell	
10 Response Due 11/29/90	11 Responsibility for Corrective Action E. Petrie	12 Stop Work Order Y or N N	
5 Requirement: <p>QA Grading Report No. EDD-001, Page 4, Item F, states "The document shall cover all requirements necessary to establish the flowdown of requirements from source documents."</p> <p>Page I-1 of Technical Requirements for the Yucca Mountain Project (YMP/CM-0007) states in part, "This document defines a basis traceable from the Waste Management Systems Requirements Document..."</p>			
6 Adverse Condition: <p>The flowdown of requirements from the WMSR Volume IV to, respectively, the MGDS System Requirements (SR), Site Requirements Document (SRD), Test & Evaluation Planning Basis (T&EPB), and Surface-Based Testing Facilities Requirements Document (SBTFRD), as shown in Figure I-1 of YMP/CM-0007 is not apparent. Examples are as follows:</p> <ol style="list-style-type: none">1. Requirements in Section IV (SRD) should flow down from Section III (SR). Page IV-2 states, "All requirements in this section are based on the Site Characterization Plan..."2. Requirements in Section V (T&EPB) should flow down from Section IV (SRD). The only references in Section V are to Neal, 1985, and the SCP. However, Page V-1 says the two figures in Section V are based on inputs from Section III (SR) and page V-5 says requirements to control testing are based on "[NEV]."			
7 Recommended Action(s): Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar conditions to those listed on the CAR. Identify these deficiencies and provide the measures			
8 Initiator Marc Meyer	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <u>James Blaylock for</u> 11/9/90
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted: QAR _____ Date _____		17 Closure Approved By: OQA _____	

ORIGINAL
THIS IS A RED STAMP

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DATE: 11/09/90
SHEET: 2 OF 2

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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CAR NO. YM-91-007

DATE: 11/29/90

SHEET: 3 OF 5

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

CORRECTIVE ACTION RESPONSE

EXTENT OF DEFICIENCY:

The requirements document (CM-0007) is a unique, one-of-a-kind document that was prepared to temporarily take the place of portions of several higher tier documents that were or still are in preparation.

ROOT CAUSE:

An independent Root Cause Analysis disclosed the following root causes for the identified deficiencies:

1. Project documents addressing development of the Requirements Document (development criteria contained in the QA grading package and the Development Plan) lacked sufficient direction to preparers regarding format and methods of depicting flowdown.
2. Inadequate recognition by preparers of their responsibility and accountability for the quality of their document.
3. Fundamental purpose and scope of Project Office reviews not clearly defined by procedures for special cases where the Project Office is the preparer of the document (versus performing an acceptance review on a document that has been prepared under a Participant's QA program).
4. Project documents addressing development and review of the Requirements Document, including QMP-06-04, lacked sufficient information and criteria for reviewers regarding format, flowdown, and traceability.

REMEDIAL ACTION:

Additional regulatory, technical, management, and quality assurance reviews conducted in accordance with QMP-06-04 have been completed on YMP/CM-0007. The review criteria (see attached), under general guidance states in part:

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SHEET: 4 OF 5

CORRECTIVE ACTION REQUEST
(continuation sheet)

"Since this is a pruned set of requirements, the sub-tier does not need to be sufficient to satisfy the upper tier requirement. However, the requirement must be derivable from the upper tier requirement or requirements starting with WMSR IV and must be sufficient with respect to the activities titled Midway Valley/Calcite Silica."

Also, technical review criteria number 6 states: "Is there clear and unambiguous flow down and linkage among all requirements?"

In response to reviewer comments, numerous changes were made to clarify traceability. Clarifications were made to nearly all pages. This ensured that the flow down from WMSR IV was clarified, reviewed, and accepted.

The specific examples given in the CAR were corrected as follows:

1. Page IV-1 of Rev. 1 noted the two primary SR statements which lead to the need for testing of the site. As a result of the review comments several clarifications were made. For example, Figure II-1, Figure V-1, and Figure V-2 were changed to give more explicit references. In addition, page IV-2 now states: "All requirements in this section are consistent with the Site Characterization Plan...."
2. The TEPB flows from sections III and IV. Explanation of this has been added. "NEV" references have been replaced with citations to upper tier requirements which formed the basis.

Please note that on page 1 of the Review Instructions it states that a hold on the completion of verification of H&N design products until the new revision of the requirements document was completed. That hold was never assigned. The document was released for use on November 28, 1990 and the verification of the design products is not scheduled for completion until the first week of December. Therefore, the hold is no longer necessary.

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CORRECTIVE ACTION REQUEST
(continuation sheet)

CORRECTIVE ACTION TO PREVENT RECURRENCE:

As stated previously, CM-0007 is a unique, one-of-a-kind document. Even though there are no plans to prepare additional, similar documents, we have taken or are taking the following actions to ensure the quality of other types of documents that may be prepared by the Project Office in the future. The actions are numbered to coincide with the root causes that they address.

1. QMP-06-04 will be revised to provide additional guidance regarding the specificity of instructions that should be provided to the preparers of documents.
2. QMP-06-04 will be revised to include more specific direction to document preparers regarding their responsibility for the quality of the documents they prepare.
3. QMP-06-04 will be revised to be more specific regarding the purpose and scope of Project Office reviews in those special cases where the Project Office acts as the preparer of a document as opposed to reviews of documents prepared by Participants.
4. BTP-EDD-002 has been issued to provide more specific review criteria for document reviewers in the EDD. In addition, when the uniqueness of a document requires it, we will exercise additional care in identifying more specific supplemental guidance to the assigned reviewers.

The revisions to QMP-06-04 will be completed by 1/30/91 (Petrie/Alderson).

Edgar A. Petrie 11/30/90
RESPONSIBLE MANAGER DATE

Response Accepted [Signature] 12/5/90
Date

Response Accepted [Signature] 12-10-90
Office of QA Date

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

14CAR NO.: YM-91-011
DATE: 11/09/90
SHEET: 1 OF 2
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QMP-06-04, Revision 1		2 Related Report No. Audit No. 90-I-01	
3 Responsible Organization Regulatory & Site Evaluation Division		4 Discussed With Ram Murthy	
10 Response Due 12/03/90	11 Responsibility for Corrective Action D. Dobson		12 Stop Work Order Y or (N)
<p>5 Requirement:</p> <p>QMP-06-04, Para 3.3 states:</p> <p>"A minor change is an alteration to an approved document such as an organizational title change; a change to the alpha-numeric identifier of the document; minor wording changes for clarity; editorial, typographical, grammar, punctuation, or spelling corrections; where the basic content of the document does not change."</p> <p>NOTE: Any other change is considered major.</p>			
<p>6 Adverse Condition:</p> <p>Contrary to the above, the following ICNs were classified as being a minor change when in fact they do not meet the definition of a minor change. ICN #1 to BTP-QRB-001, ICN #2 to AP-5.28Q, and ICN #4 to AP-5.28Q.</p>			
<p>7 Recommended Action(s):</p> <p>Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Investigate the program, process, activities, or documentation to determine the extent and depth of similar conditions to those listed on the CAR. Identify these deficiencies and provide the measures</p>			
8 Initiator John S. Martin	Date: 10/26/90	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <u>James B Langford</u> for <u>11/9/90</u>
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted:		17 Closure Approved By:	
QAR _____ Date _____		OQA _____	

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CAR NO.: YM-91-011
DATE: 11/09/90
SHEET: 2 OF 2

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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CAR NO. YM-91-011

DATE: 12/3/90

SHEET: _____ OF _____

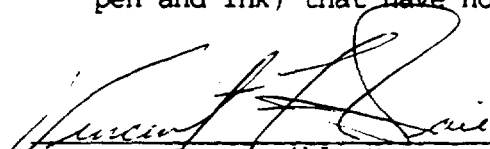
CORRECTIVE ACTION REQUEST
(continuation sheet)

- A. Investigative action performed was a review of all unincorporated ICNs to BTPs, QMPs and APs (see enclosure 1) to determine if any ICNs, including those referenced in the CAR, inadvertently classified changes as minor which were actually major in nature.


The investigation revealed that there were ICNs to the following procedures classifying changes as minor which should have been major.

AP-1.5Q
AP-5.28Q
BTP-QRB-001
BTP-SMF-001
BTP-SMF-002
BTP-SMF-005
BTP-SMF-006
BTP-SMF-008

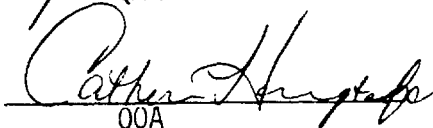
- B. The causes of the deficiency was the result of a too liberal interpretation of the procedure definition of "minor" change.
- C. The procedures noted have all been revised to incorporate outstanding ICNs and were submitted for formal review so that all ICNs were reviewed in context with the entire procedure.
- D. AP-6-04 has been revised to limit ICN use to very minor changes (usually pen and ink) that have no impact on procedural content.


Responsible Manager

12/4/90
Date

Response Accepted 
QAR

12-10-90
Date

Response Accepted 
OQA

12-10-90
Date