



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

WBS 1.2.9.3
 QA

JAN 04 1991

Carl P. Gertz, Project Manager, YMP, NV

EVALUATION OF RESPONSES TO CORRECTIVE ACTION REQUESTS (CARs) YM-91-008 AND YM-91-009 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT 90-I-01

Reference: Letter, Petrie to Horton, dtd. 11/30/90

The YMQAD staff has evaluated the responses to CARs YM-91-008 and YM-91-009, submitted by the referenced letter. 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-1430

Enclosure:
 CARs YM-91-008 and 009

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

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

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WASHINGTON, D.C.**

14 CAR NO.: YM-91-008
 DATE: 11/09/90
 SHEET: 1 OF 2
 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document EDD-001, Revision 0	2 Related Report No. Audit 90-I-01
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3 Responsible Organization Engineering & Development Division	4 Discussed With G. Dymmel and J. Waddell
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10 Response Due 11/29/90	11 Responsibility for Corrective Action E. Petrie	12 Stop Work Order Y or N N
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5 Requirement:
 QA Grading Report No. EDD-001, Page 4, Items B and C states, "All inputs shall be documented. Use of inputs shall be documented and traceable."

6 Adverse Condition:
 Inputs in Revision 1 of YMP/CM-0007, "Technical Requirements for the Yucca Mountain Project (Midway Valley Trenching and Calcite/Silica Activities)" are not always traceable. *Examples are as follows:

1. The source of functional requirements on pages III-8, 10, and 11 is not apparent.
2. References on page IV-5 to Ross, 1987, and DOE, 1986, are not traceable.
3. Page IV-B-1 references 42USC9601 as the emergency planning and community Right-to-Know Act and a source of input. The reference is not traceable to the Act nor is it traceable to a requirement in Section III.
4. Page IV-B-1 references "N49602 Spang to Gertz 10/10/89" as a source of input. The letter does not exist. A letter dated 10/10/89 from Spang to the DOE Nevada Operations Office exists;

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>	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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6 Adverse Condition (continued)

however, the letter number is N48602.

5. None of numerous references to "[NEV]" are traceable because no such source of input exists.

6. Requirements in Section IV, Paragraph 2.8, are not traceable.

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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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 traceability.
2. Inadequate recognition by preparers of their responsibility and accountability for the quality of their document.
3. Fundamental purpose 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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"Since this is a pruned set of requirements, the sub-tier does not need to be sufficient to satisfy the upper tier requirements. 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.

Inputs developed under other QA programs must be determined to be acceptable. Successful resolution of any comments generated during this review will serve as the basis for acceptance of inputs developed under other QA programs."

Regulatory review criteria number 4 states: "Are the sources of information and data referenced and traceable?"

Technical review criteria number 1 states: "Are inputs and input sources current correct, and adequate for the intended use?"

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

Response to review comments have ensured that the input traceability was clarified, reviewed, and corrected when necessary.

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

1. Specific references to WMSR IV sections have been added to all functional requirements in this section.
2. These were secondary references which are given in the SCP sections which were referenced. These references have been added.
3. The "et seq." needed to be added to the references. The references have been corrected and reformatted for consistency.
4. This has been changed to the BLM references. Note this reference is now in Section V-B-1.

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5. "NEV" has been replaced with explicit citations to higher tier requirements.

6. The "site specific" constraints derive from the "general environmental constraints" provided in the prior sections. Specific citations are now provided. Note this was moved to Section V.

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.

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.

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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 H Petrie 11/30/90
RESPONSIBLE MANAGER DATE

S Jara 12/18/90
QAR DATE

Arthur H. Hopter 12-19-90
OQA DATE

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 DATE: 11/09/90
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 QA
 WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document QAPD, Revision 3; QMP-06-04, Revision 0		2 Related Report No. Audit No. 90-I-01	
3 Responsible Organization Engineering & Development Division		4 Discussed With Jon White and George Dymmel	
10 Response Due 11/29/90	11 Responsibility for Corrective Action E. Petrie	12 Stop Work Order Y or N N	
<p>5 Requirement:</p> <p>QAPD, Para. 3.1.6, states in part, "Technical reviews are performed by any competent individual(s) or groups..."</p> <p>QMP-06-04, Step 12, states, "Assign reviewer(s) by entering name(s) on Page 1 of DRS (name & discipline of the qualified, independent reviewer for technical reviews); provide reviewer(s) with review package and established review criteria. Attachment 7 provides examples for guidance in establishing criteria."</p> <p>QMP-06-04, Step 13, states in part, "Review document as instructed in the review package."</p>			
<p>6 Adverse Condition:</p> <p>The following conditions are associated with review of the Technical Requirements for the Yucca Mountain Project (YMP/CM-0007):</p> <ol style="list-style-type: none"> 1. The scope of expertise of the person who performed a technical review was not broad enough to cover the entire spectrum of characteristics requiring review. For example, the reviewer stated he did not perform a "flowdown" review because he had no systems engineering experience. The reviewer was unfamiliar with the fact that YMP/CM-0007 was to be based on WMSR requirements. 2. The reviewer was not familiar with technical review criteria in Attachment 7 to QMP-06-04. These were the only criteria provided the reviewer. <p>NOTE: The reviewer received no classroom instruction on QMP-06-04 and did not seek</p>			
<p>7 Recommended Action(s):</p> <p>Identify the remedial action(s) to be taken to correct the deficiencies noted in Block 6. Identify the condition and the planned action to prevent recurrence.</p>			
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</u> 11/9/90
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16 Corrective Action Completed and Accepted: QAR _____ Date _____		17 Closure Approved By: OQA _____	

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6 Adverse Condition (continued)

clarification on criteria during the course of his review.

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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 follow root causes for this deficiency:

1. 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).
2. 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.
3. Lack of feedback communications to inform management of questions and seek clarification regarding assigned tasks.

REMEDIAL ACTION:

Additional regulatory, technical, management, and quality assurance reviews conducted in accordance with QMP-06-04 have been completed on YMP/CM-0007.

Specific concern number 1: The further reviews conducted included reviewers from many disciplines. The technical areas covered (see attached for a list of reviewers and their specialties) were: engineering and construction, seismic, faulting hazards, sample management, environmental, systems, performance assessment, TE process, and testing linkage.

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The review criteria are attached.

Specific concern number 2: General review criteria was given to all reviewers (see attached). In addition, specific technical review criteria was provided to the technical reviewers (see attached). All reviewers were trained in the use of QMP-06-04 prior to performing the review.

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.

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 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.
2. 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.

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3. The Director, EDD will hold discussions with all EDD personnel to ensure that they understand that management wants, and it is their obligation to provide, feedback and seek clarification from their managers anytime they have questions regarding the scope, schedule or methods to be used in accomplishing assigned tasks.

The revisions to QMP-06-04 will be completed by 1/30/91 (Petrie/Alderson). The discussions with EDD personnel will be completed by 12/14/90 (Petrie).

Edgar H. Petrie
RESPONSIBLE MANAGER

11/30/90
DATE

S. Davis
QAR

12/18/90
DATE

Cather Alderson
OQA

12-19-90
DATE