



Department of Energy
 Yucca Mountain Site Characterization
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WBS 1.2.11
 QA: N/A

JAN 29 1993

Larry R. Hayes
 Technical Project Officer
 for Yucca Mountain
 Site Characterization Project
 U.S. Geological Survey
 101 Convention Center Drive
 Suite 860
 Las Vegas, NV 89109

**EVALUATION OF RESPONSE AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR)
 YM-93-014 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD)
 AUDIT YMP-93-01 OF U.S. GEOLOGICAL SURVEY (USGS)**

The YMQAD staff has evaluated the response to CAR YM-93-014. The response has been determined to be satisfactory. The CAR has been closed for the following reasons:

YMQAD agrees that corrective actions dealing with the implementation of requirements, that will occur as a matter of course in the formal transition process to a QA program based on the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P, Revision 0), need not be independently undertaken outside of the transition process. That is, no revision of YMP-USGS-QMP-3.03, Revision 3, is necessary before it is brought into compliance with the new QARD. However, it should be noted that most, if not all, of the unimplemented requirements cited in this CAR can also be found in the new QARD (See QARD, Supplement I, Section 1.2.6.).

YMQAD also agrees that the lack of a review mechanism, such as a requirement matrix, is the root cause of the failure to incorporate all requirements into the procedure. Implementation of the QARD (Section 2.2.2, C) will fill this need. Therefore, USGS need not perform corrective action to prevent recurrence that is independent of the transition process.

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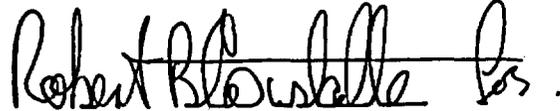
ADD: Ken Hooks

Encl.

102-7
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JAN 29 1993

If you have any questions, please contact either Robert B. Constable at 794-7945 or Thomas J. Higgins at 794-7173.



Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2248

Enclosure:
CAR YM-93-014

cc w/encl:

K. R. Hooks, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
R. W. Craig, USGS, Las Vegas, NV
R. L. Maudlin, MACTEC, Las Vegas, NV

cc w/o encl:

J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV
D. D. Porter, SAIC, Golden, CO

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WASHINGTON, D.C.

8 CAR NO.: YM-93-014
DATE: 10/23/92
SHEET: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document
Quality Assurance Program Plan, YMP-USGS-QAPP-01, R5, ICN-8

2 Related Report No.
YMP-93-01

3 Responsible Organization
USGS

4 Discussed With
D. Gockel & M. Wallendorf

5 Requirement:
The USGS QAPP, Section 6.1.2, "Implementation of Document Control", states in part:
"Implementation of Document control shall provide for:
* Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance....." (This is the third bullet as it appears in ICN-1 to the QAPP.)

6 Adverse Condition:
Contrary to this requirement, the reviews of both ICN-8 to the USGS QAPP, (YMP-USGS-QAPP-01, Revision 5) that made significant changes to Appendix H of the QAPP, and of Change M-1 to procedure YMP-USGS-QMP-3.03, Revision 3, failed to detect that some of the requirements established in ICN-8 were not carried down into procedure "QMP-3.03" that implements Appendix H. Both ICN-8 and M-1 were effective on March 12, 1992.
The identified, omitted requirements can be found in Appendix H (ICN-8), sections:
* 4.1 "Requirements Phase", items d and e
* 4.2 "Design Phase", items b and c
* 4.3.2 "Method of Software Validation", second paragraph.
An explicit statement of the omitted requirements is provided on page 2.

9 Does a significant condition adverse to quality exist? Yes ___ No X
If Yes, Circle One: A B C

10 Does a stop work condition exist? Yes ___ No X; 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: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

13 Recommended Actions:
1. Modify "QMP-3.03" to include all Appendix H requirements.
2. Review all Software Lifecycle Documents subject to the current Appendix H requirements to identify those failing to meet all requirements. Revise these lifecycle documents to bring them into compliance with Appendix H, ICN-8, including the conduct of additional testing if this is necessary for compliance. Continued.

7 Initiator
T. J. Higgins
Date 10-27-92

14 Issuance Approved by:
QADD [Signature] Date 11/3/92

15 Response Accepted
QAR [Signature] Date 1-25-93

16 Response Accepted
QADD [Signature] Date 1-20-93

17 Amended Response Accepted
QAR [Signature] Date 1-20-93

18 Amended Response Accepted
QADD [Signature] Date 01-28-93

19 Corrective Actions Verified
QAR [Signature] Date 1-21-93

20 Closure Approved by:
QADD [Signature] Date 01-28-93

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CORRECTIVE ACTION REQUEST (Continuation Page)

6 Adverse Condition (continued)

Omitted requirements from Appendix H (ICN-8):

* 4.1 REQUIREMENTS PHASE

A specification of software requirements shall be provided
This specification shall address the following:

- d. attributes - non-time-related issues of software operations such as portability, correctness, security, maintainability, etc.; and
- e. external interfaces - interactions with hardware, other software, and other participants.

* 4.2 DESIGN PHASE

In this phase the overall structure, This description shall address the following:

- b. A technical description of the software with respect to control flow, data flow, control logic, and data structure; and
- c. The allowable and tolerable ranges for inputs and outputs.

* 4.3.2 METHOD OF SOFTWARE VALIDATION

2nd paragraph: When testing is the selected method of software validation, test cases shall be developed and executed with inputs and conditions sufficient to invoke all elements of the code that represent implementation of the software requirements. These tests shall also identify boundary conditions, and provide a suitable benchmark.

13 Recommended Action(s) (continued)

- 3. Determine the reason that two related documents (Appendix H, ICN-8 and QMP-3.03, R3-M1), with identical effective dates, were reviewed and issued without identification and correction of the noted discrepancies. Propose suitable corrective action to prevent recurrence if such action is necessary.

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CAR NO. YM-93-014

DATE: _____

SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-93-014:

A. **Remedial Action:** No remedial actions are warranted specific to this CAR. QMP-3.03 will require review as part of a transition into the requirements of the OCRWM QARD. For the cited requirements, QMP-3.03, R3 is generally in line with the OCRWM QARD. Immediate modification of QMP-3.03 is not warranted; the modification would only address QAPP requirements that will be eliminated following issuance of the OCRWM QARD. Remedial actions under the DOE CARs YM-91-074 and -075 and preventative actions described below will be adequate to assure the identification and elimination of all QMP/QARD discrepancies. An evaluation of the impact of the issuance of the OCRWM QARD on previous implementation will be necessary as part of the transition into the requirements of the QARD. This evaluation and any actions required as a result of the evaluation are not specific to remediation of the condition identified in this CAR.

B. **Investigative Action:** A detailed comparison of the requirements that were cited by the CAR shows that the omissions are significantly less than described in Section 6 of the CAR. Specifically, attributes [4.1.d], which are referred to in QMP-3.03 as operation issues, are all carried down to the QMP except for correctness and security in section 5.4.3. External interfaces [4.1.e] are carried down to the QMP, as applicable, in sections 5.4.3 and 5.4.4. "Allowable and tolerable ranges for inputs and outputs" [4.2.c] are included in section 5.4.3 as "limitations of the expected inputs and outputs". The requirements for software testing [4.3.2] are adequately described within the QMP in section 5.4.6 and Attachment 5.

The Software Quality Assurance (SQA) requirements found in YMP-USGS QAPP-01, R5 and QMP-3.03 were recently updated in an effort to take advantage of learning associated with implementation and the improved understanding by the YMP and the USGS with respect to appropriate SQA requirements. These actions were undertaken in response in part to DOE CARs YM-91-074, -075, and -076. In an attempt to gain DOE YMQAD acceptance of the revised YMP-USGS SQA requirements prior to the issuance of DOE Quality Assurance Requirements and Description (OCRWM QARD), the SQA requirements in the YMP-USGS QAPP were adjusted to reflect the requirements of DOE/RW-0214, Quality Assurance Requirements Document, R4, Section 19. When DOE YMQAD acceptance was not attained, the YMP-USGS SQA requirements were implemented at risk.

One of the corrective actions for DOE CARs YM-91-074, -075, and -076 requires a review to be conducted of software quality assurance requirements against the requirements of OCRWM QARD, when issued. Subsequent actions are to be described in a supplemental response to these CARs following formal issuance of the OCRWM QARD. Draft OD has been transmitted to the USGS so that we may plan its implementation. The final version is expected to be approved and issued by December 1, 1992.

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DATE: _____
SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-93-014 (continued)

C. **Root Cause Determination:** Due to the circumstances described above, the QAPP was revised after the corresponding revision of the implementing procedure. A matrix to demonstrate that the requirements of the QAPP are met in the QMP was not required. Review of the implementing procedure was completed against QAPP requirements that were also in transition.

D. **Corrective Action to Preclude Recurrence:** Section 2.0 of draft 0D of the OCRWM QARD provides for the completion of a matrix to demonstrate that implementing procedures are in place to meet QARD requirements. The provision for this matrix is adequate to prevent recurrence of the isolated condition identified in this CAR. If the issued QARD substantially changes the requirements for this matrix, an evaluation will be completed and reported in a supplemental response within 10 days of the issuance of the OCRWM QARD.

2. For each action above, identify the name of the individual assigned responsibility for completion and the anticipated (or actual, if complete) completion date.

Not applicable.

3. Response Approved:



L. R. Hayes 12/1/92
Date
For Chief, Yucca Mountain Project Branch



T. H. Chaney 12/1/92
Date
YMP-USGS Quality Assurance Manager

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CAR NO. YM-93-014

DATE: 1/6/93

SHEET: OF

CORRECTIVE ACTION REQUEST
(continuation sheet)

CORRECTIVE ACTION RESPONSE:

1. CORRECTIVE ACTION FOR DEFICIENT CONDITION CAR No. YM-93-014

- A. **Remedial Action:** QMP-3.03 will require additional review and possible revision as part of a transition into the requirements of the DOE RW-0333P, Quality Assurance Requirements and Description, Revision 0 (OCRWM QARD). An evaluation of the impact of the issuance of the OCRWM QARD on previous implementation will be necessary as part of this QARD transition. Details of this evaluation will be provided in accordance with the USGS QARD Transition Plan which is currently scheduled to be submitted to the OCRWM Office of Quality Assurance by January 29, 1993. This evaluation and any actions required as a result of the evaluation are not specific to remediation of the condition identified in this CAR but will be tracked as a part of QARD implementation.

For the cited requirements, QMP-3.03, R3 is generally in line with OCRWM QARD. Immediate modification of QMP-3.03 to incorporate USGS QAPP Appendix H requirements is not warranted; the modification would only address QAPP requirements that are being eliminated following issuance of the OCRWM QARD. Corrective action for DOE CARs YM-91-074, -075, and -076 requires a review to be conducted of software quality assurance requirements against the requirements of OCRWM QARD, when issued. Subsequent actions are to be described in a supplemental response to these CARs following formal transmittal of the OCRWM QARD. Remedial actions under the DOE CARs YM-91-074 and -075 and preventative actions described below will be adequate to assure the identification and elimination of all QMP/QARD discrepancies. No remedial actions are warranted specific to this CAR.

- B. **Investigative Action:** A review of the discrepancies between USGS QAPP Appendix H and QMP-3.03, R3 indicates that no missing requirements exist that adversely impact the quality of the software being used by the USGS on YMP.
- C. **Root Cause Determination:** The Software Quality Assurance (SQA) requirements found in YMP-USGS QAPP-01, R5 and QMP-3.03 were recently updated in an effort to take advantage of learning associated with implementation and the improved understanding by the YMP and the USGS with respect to appropriate SQA requirements. These actions were undertaken in response in part to DOE CARs YM-91-074, -075, and -076. In an unsuccessful attempt to gain DOE YMQAD acceptance of the revised YMP-USGS SQA requirements prior to the issuance of the OCRWM QARD, the SQA requirements in the YMP-USGS QAPP were adjusted to reflect the requirements of DOE/RW-0214, Quality Assurance Requirements Document, R4, Section 19. When DOE YMQAD acceptance was not attained, the YMP-USGS SQA requirements were implemented at risk. Due to the circumstances described above, the QAPP was revised after the corresponding revision of the implementing procedure. Review of the implementing procedure was completed against

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(continuation sheet)

QAPP requirements that were also in transition. A matrix to demonstrate that the requirements of the QAPP are met in the QMP was not required to be completed or updated to support the review.

- D. **Corrective Action to Preclude Recurrence:** Section 2.0 of the OCRWM QARD provides for the completion of a matrix to demonstrate that implementing procedures are in place to meet QARD requirements. Incorporation of the requirement for this matrix into YMP-USGS QMP-5.03, or elsewhere as appropriate, will be accomplished according to the USGS QARD Transition Plan and the draft QARD Implementation Matrix which are currently scheduled to be submitted to the OCRWM Office of Quality Assurance by January 29, 1993. This action will be adequate to preclude recurrence of the isolated condition identified in this CAR.

2. NOT APPLICABLE.

3. RESPONSE APPROVED:


T.H. Chaney

1/6/93
Date

YMP-USGS Quality Assurance Manager


L.R. Hayes

1/6/93
Date

For
Chief, Yucca Mountain Project Branch

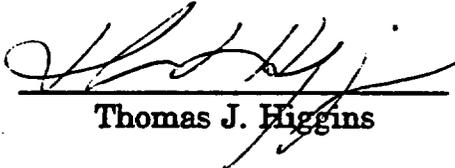
Verification of CAR YM-93-014

On review, the amended response has been found to be acceptable. This CAR has also been closed for the following reasons.

YMQAD agrees that corrective actions, dealing with the implementation of requirements that will occur as a matter of course in the formal transition process to a QA program based on the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P, Revision 0), need not be independently undertaken outside of the transition process. That is, no revision of YMP-USGS-QMP-3.03, Revision 3, is necessary before it is brought into compliance with the new QARD. However, it should be noted that most, if not all, of the unimplemented requirements cited in this CAR can also be found in the new QARD. (See QARD, Supplement I, Section 1.2.6.)

YMQAD also agrees that the lack of a review mechanism, such as a requirements matrix, is the root the cause of failure to incorporate all requirements into the procedure. Implementation of the QARD (Section 2.2.2, C) will fill this need. Therefore, USGS need not perform corrective action to prevent recurrence that is independent of the transition process.

Consequently this CAR is closed.

 1-21-93

Thomas J. Higgins