



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

QA: L

JUL 05 1994

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

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) YM-94-043 THROUGH
CAR YM-94-050 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT YMP-94-06 OF U.S. GEOLOGICAL SURVEY
(SCPB: N/A)

Enclosed are CARs YM-94-043 through YM-94-050 generated as a
result of YMQAD audit YMP-94-06.

Please identify the corrective actions to be taken and
implemented to correct the deficiencies. CAR Continuation
Sheets and instructions for completion have been provided. Send
the originals of your responses to Deborah Sult, YMQAD/QATSS,
101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.
Responses to the CARs are due 20 working days after the date of
this letter. Extensions to due dates must be requested in
writing, with appropriate justification, prior to the due dates.

If you have any questions, please contact either Robert B.
Constable at 794-7945 or Charles C. Warren at 794-7248.

R.E. Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4160

Enclosure:
CARs YM-94-043
through YM-94-050

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PDR WASTE PDR
WM-11

YMP-5

ADD: Bill Belke T759

Let. Encl.
1 1

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wm-11
NH03

Larry R. Hayes

-2-

JUL 05 1994

cc w/encl:

W. L. Belke, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. L. Badredine, M&O/TRW, Las Vegas, NV
T. H. Chaney, USGS, Denver, CO
R. W. Craig, USGS, Las Vegas, NV
D. D. Porter, SAIC, Golden, CO

cc w/o encl:

J. W. Gilray, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV



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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 CAR NO.: YM-94-043
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document
QARD, Revision 0

2 Related Report No.
YMP-94-06

3 Responsible Organization
USGS

4 Discussed With
L. Hayes

5 Requirement:
QARD Supplement III 2.2.A states: "Scientific investigations shall be performed using scientific notebooks, technical implementing documents, or a combination of both."

6 Adverse Condition:
Contrary to the above, Tectonic Modeling and Synthesis Activity 8.3.1.17.4.12 does not use a scientific notebook or technical implementing documents. Furthermore, YMP-USGS-ACS-G12328412-2, Revision 0, graded the requirement as not applicable to the activity.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Circle One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Circle One: A B C

3 Response Due Date:
20 Working Days From Issuance

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1. Provide for the use of a Scientific Notebook for Activity 8.3.1.17.4.12.
2. Investigate to identify any other cases of inappropriate grading.

7 Initiator
James Blaylock *C.L. Warren for*

14 Issuance Approved by:
QADD *[Signature]* Date 7-4-94

15 Response Accepted
QAR Date

16 Response Accepted
QADD Date

17 Amended Response Accepted
QAR Date

18 Amended Response Accepted
QADD Date

19 Corrective Actions Verified
QAR Date

20 Closure Approved by:
QADD Date

ENCLOSURE

REV. 2/14/94

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CAR NO. _____
PAGE: _____ OF _____
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

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OFFICE OF CIVILIAN
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INSTRUCTIONS FOR CORRECTIVE ACTION

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If it becomes apparent that any of the corrective action due dates cannot be met, a written request for extension must be provided to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

3. The response must include the dated signature of the Responsible Manager.

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GUIDELINES FOR ROOT CAUSE DETERMINATION

When it is established that an investigation to determine root cause is required, the following guidelines may assist in the determination:

- 1) Clarify the specific condition. Pertinent clarifying questions must be asked and answered as accurately as possible.
 - a) What happened?
 - b) Where did the condition occur?
 - c) When did the condition occur?
 - d) What was the extent of the condition?
 - e) Who was involved?
 - f) In what manner did it happen?
 - g) What reasons are given by knowledgeable personnel for why it happened?

- 2) Obtain information related to the identified condition.
 - a) Investigate, in detail, the specific condition adverse to quality.
 - b) Interview personnel.
 - c) Review pertinent documents.
 - d) Use quality tools (cause & effect diagrams, flowcharting, Pareto analysis, comparative analysis, etc.).
 - e) Identify and collect data needed to get to the root cause.

- 3) Most root causes fall into one or more of the following generic categories. Specific review of these areas may be useful in arriving at cause determination:
 - a) Procedures
 - b) Personnel
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8 CAR NO.: YM-94-044
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document
YMP-USGS-QMP-18.02, Revision 3

2 Related Report No.
YMP-94-06

3 Responsible Organization
USGS

4 Discussed With
T. Chaney/L. McInroy

5 Requirement:

Attachment I provides the surveillance report format. It requires a statement in the report summary on acceptability and effectiveness of the activity under surveillance.

6 Adverse Condition:

Contrary to the above, surveillance reports issued during FY 1994 do not contain a statement in the report summary on acceptability and effectiveness of the activity. The acceptability and effectiveness statement is contained in the surveillance report transmittal letter.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Circle One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Circle One: A B C

3 Response Due Date:
20 Working Days
From Issuance

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
Comply with procedure requirements.

7 Initiator
S. Maslar *C.C. Warren for*

14 Issuance Approved by:
QADD *R. Donahue* *for* Date *7-4-94*

15 Response Accepted
QAR Date

16 Response Accepted
QADD Date

17 Amended Response Accepted
QAR Date

18 Amended Response Accepted
QADD Date

19 Corrective Actions Verified
QAR Date

20 Closure Approved by:
QADD Date

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WASHINGTON, D.C.

CAR NO. _____
PAGE: _____ OF _____
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CORRECTIVE ACTION REQUEST (Continuation Page)

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| OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. | 8 CAR NO.: <u>YM-94-045</u> PAGE: <u>1</u> OF <u>1</u> QA |
|---|---|

CORRECTIVE ACTION REQUEST

| | |
|--|--|
| 1 Controlling Document YMP-USGS-QMP-3.03, Revision 4 | 2 Related Report No. YMP-94-06 |
|--|--|

| | |
|---|--|
| 3 Responsible Organization USGS | 4 Discussed With D. Gockel/M. Wallendorf |
|---|--|

5 Requirement:
 QMP-3.03, Paragraph 5.3.2.3 states in part: "Software user documentation... It shall include basic information such a installation procedures, hardware and software operating environments, input and output options, file formats and default parameters."

6 Adverse Condition:
 Contrary to the above, no objective evidence in the form of user documentation could be provided to reflect all of the information required to be addressed in the user documentation for MAIN 130/1.

| | | |
|--|--|--|
| 9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C D E | 10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C | 3 Response Due Date: 20 Working Days From Issuance |
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11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
 Either generate or obtain user documentation that addresses the information specified in QMP-3.03, Revision 4 for main 130/1.

| | |
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| 7 Initiator Richard L. Maudlin <i>C. C. Wann for</i> | 14 Issuance Approved by: QADD <i>RBO</i> for Date <u>7.4.94</u> |
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| 15 Response Accepted QAR _____ Date _____ | 16 Response Accepted QADD _____ Date _____ |
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| 17 Amended Response Accepted QAR _____ Date _____ | 18 Amended Response Accepted QADD _____ Date _____ |
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| 19 Corrective Actions Verified QAR _____ Date _____ | 20 Closure Approved by: QADD _____ Date _____ |
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CORRECTIVE ACTION REQUEST (Continuation Page)

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INSTRUCTIONS FOR CORRECTIVE ACTION

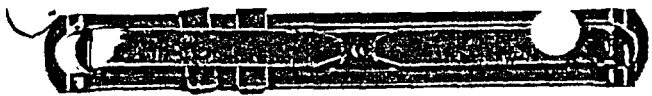
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8 CAR NO.: YM-94-046
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

| | | | |
|--|--|---|--|
| 1 Controlling Document QARD, Revision 0; YMP-USGS-QMP-16.04, Revision 0 | | 2 Related Report No. YMP-94-06 | |
| 3 Responsible Organization USGS | | 4 Discussed With T. Chaney | |
| 5 Requirement: QARD, Section 16.0 states: "A condition adverse to quality shall be identified when a QARD or implementing document requirement is not met." QMP-16.04, Section 5 states: "The identification of a condition adverse to quality shall be documented by the individual identifying the condition using a Quality Deficiency Report (QDR) or equivalent." | | | |
| 6 Adverse Condition: Contrary to the above requirements, during a review of USGS internal audit reports 94058-IA and 94031-IA, it appears that of 13 concerns identified, more than half of these concerns met the criteria of the QARD and QMP-16.04 for a conditional adverse to quality without QDRs or equivalent being issued to document these conditions. USGS, per internal memo dated 6/17/94, has defined/interpreted a condition adverse to quality a "a clean or very clear violation of a QMP or technical procedure." This is not in compliance with the QARD or QMP-16.04 definition of a condition adverse to quality in that it does not include noncompliance with quality program requirements other than those specified in procedures. | | | |
| 9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No <u> </u> If Yes, Circle One: A B C D E | | 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 | |
| 3 Response Due Date: 20 Working Days From Issuance | | | |
| 11 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 | | | |
| 12 Recommended Actions: 1) USGS should use the wording in the QARD and QMP-16.04 as the basis for determining conditions adverse to quality. 2) Previously identified and future concerns with the associated recommendation need to be formally tracked to insure acceptable closure to USGS-QA. | | | |
| 7 Initiator S. Maslar | | 14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>7/5/94</u> | |
| 15 Response Accepted QAR _____ Date _____ | | 16 Response Accepted QADD _____ Date _____ | |
| 17 Amended Response Accepted QAR _____ Date _____ | | 18 Amended Response Accepted QADD _____ Date _____ | |
| 19 Corrective Actions Verified QAR _____ Date _____ | | 20 Closure Approved by: QADD _____ Date _____ | |

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CAR NO. _____
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CORRECTIVE ACTION REQUEST (Continuation Page)

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GUIDELINES FOR ROOT CAUSE DETERMINATION

When it is established that an investigation to determine root cause is required, the following guidelines may assist in the determination:

- 1) Clarify the specific condition. Pertinent clarifying questions must be asked and answered as accurately as possible.
 - a) What happened?
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 - f) In what manner did it happen?
 - g) What reasons are given by knowledgeable personnel for why it happened?

- 2) Obtain information related to the identified condition.
 - a) Investigate, in detail, the specific condition adverse to quality.
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8 CAR NO.: YM-94-047
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document
QARD, Rev. 0

2 Related Report No.
YMP-94-06

3 Responsible Organization
USGS

4 Discussed With
T. CHANEY

5 Requirement:
DOE/RW/0333P QARD, Section 2.2.9c, states for Document Review: "The review shall be performed by individuals other than the originator."
QARD Section 2.2.9f states: "Mandatory comments resulting from the review shall be documented and resolved before approving the document."
QARD Supplement III, Section III 2.2.4 states: "The reviewer shall be independent from the collector."

6 Adverse Condition:

1. Contrary to the QARD Requirements, QMP-3.04 does not require review comment resolution with the independent technical reviewer. QMP-3.04, para. 5.4.3.2 and 5.4.4.4 requires the YMPB Program Chief to resolve comments. The YMPB Program Chief responsibilities of directing the work defeats the independence of the review.
2. Contrary to QARD an independent data review was not performed for Geologic Data DTN #G5920708314221.003:
 - The reviewer changed data without an independent review.
 - The Acting Program Chief GSP approved the review.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Circle One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Circle One: A B C

3 Response Due Date:
20 Working Days from Issuance

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1. Revised QMP 3.04 to be consistent with QMP 3.07 and meet QARD requirements.
2. Perform the actions indicated in block 11.

7 Initiator
T. SWIFT *C.C. Wanner for*

14 Issuance Approved by
QADD *[Signature]* Date 7.4.94

15 Response Accepted
QAR Date

16 Response Accepted
QADD Date

17 Amended Response Accepted
QAR Date

18 Amended Response Accepted
QADD Date

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QAR Date

20 Closure Approved by:
QADD Date

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CAR NO. _____
PAGE: _____ OF _____
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

OFFICE OF CIVILIAN
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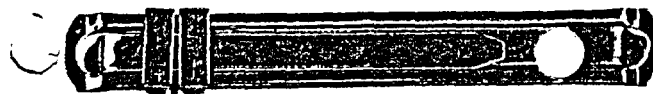
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 - b) Interview personnel.
 - c) Review pertinent documents.
 - d) Use quality tools (cause & effect diagrams, flowcharting, Pareto analysis, comparative analysis, etc.).
 - e) Identify and collect data needed to get to the root cause.

- 3) Most root causes fall into one or more of the following generic categories. Specific review of these areas may be useful in arriving at cause determination:
 - a) Procedures
 - b) Personnel
 - c) Management systems
 - d) Supervision
 - e) Training
 - f) Communications
 - g) Scientific investigation/design methods
 - h) Human factors
 - i) Reliability considerations
 - j) Miscellaneous or multiple areas



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8 CAR NO.: YM-94-048
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CORRECTIVE ACTION REQUEST

1 Controlling Document
YMP-USGS-QMP-18.01, Rev. 4

2 Related Report No.
YMP-94-06

3 Responsible Organization
USGS

4 Discussed With
T. CHANEY

5 Requirement:
YMP-USGS-QMP-8.01, R4 contains the QARD requirements for identification and control of samples.

6 Adverse Condition:
The QMP-8.01, R4 requirements have not been fully incorporated into many of the implementing technical procedures and scientific notebooks. Two examples of procedures not being updated to QMP-8.01, R4 are HP-200, R0 and HP-249, R0.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Circle One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Circle One: A B C

3 Response Due Date:

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1. Incorporate the QMP 8.01 requirements in the implementing documents.
2. Review the myriad of sample control procedures to identify interfaces and sequencing.
3. Remove what may be extraneous procedures.

7 Initiator
J. BLAYLOCK *C. C. Wann Jr*

14 Issuance Approved by:
QADD *[Signature]* for Date *7-4-94*

15 Response Accepted
QAR _____ Date _____

16 Response Accepted
QADD _____ Date _____

17 Amended Response Accepted
QAR _____ Date _____

18 Amended Response Accepted
QADD _____ Date _____

19 Corrective Actions Verified
QAR _____ Date _____

20 Closure Approved by:
QADD _____ Date _____

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CORRECTIVE ACTION REQUEST (Continuation Page)

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INSTRUCTIONS FOR CORRECTIVE ACTION

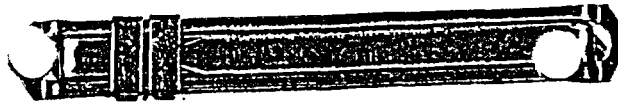
You are requested to provide a response to a Corrective Action Request (CAR) by the due date identified in block 13 of the CAR. If this due date cannot be met, provide a written request for extension to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

In order to develop the CAR response, perform investigative action (if required in block 11 of the CAR) to determine the extent of the deficiency and to identify root cause. Next, determine the actions required to correct the adverse condition. These actions include remedial action, and in the case of CARs that identify significant conditions adverse to quality, corrective action to preclude recurrence. A review of the recommended actions (if any) provided in block 12 of the CAR may assist in this determination. The response must include the following information:

1. Corrective Action Response for CAR # _____
 - A. Remedial Action - Describe actions required to correct the specific conditions noted. (Required for all CARs)
 - B. Extent of the Deficiency - Describe the investigative actions performed to determine the extent of the condition and the results of the determination. (Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA).
 - C. Root Cause Determination - Identify the root cause of the condition as determined through investigative action. (Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA).
 - D. Corrective Action to Preclude Recurrence - Identify the actions required to address the root cause of the condition in order to preclude recurrence. (Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA).
2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

If it becomes apparent that any of the corrective action due dates cannot be met, a written request for extension must be provided to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

3. The response must include the dated signature of the Responsible Manager.



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8 CAR NO.: YM-94-049
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CORRECTIVE ACTION REQUEST

1 Controlling Document
QARD, Rev. 0

2 Related Report No.
YMP-94-06

3 Responsible Organization
USGS

4 Discussed With
T. CHANEY

5 Requirement:
Section 5.2.2.D of the QARD states, in part: "Implementing documents shall include the following information as appropriate to the work to be performed: D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished."

6 Adverse Condition:
QMP 16.03, R3, provides no criteria as to what constitutes a trend, hence the rationale and conclusions of the trend reports for the time periods 10/1/93 - 12/31/93 and 1/1/94 - 3/31/94 are not substantiated by the information provided.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Circle One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Circle One: A B C

3 Response Due Date:

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1. Provide qualitative criteria in QMP 16.03.
2. Change the definition of adverse condition to be consistent with the QARD glossary.
3. Substantiate the trend reports for the time frame identified above.

7 Initiator
J. BLAYLOCK *C.C. Wynn for*

14 Issuance Approved by:
QADD *[Signature]* Date 7-4-94

15 Response Accepted
QAR _____ Date _____

16 Response Accepted
QADD _____ Date _____

17 Amended Response Accepted
QAR _____ Date _____

18 Amended Response Accepted
QADD _____ Date _____

19 Corrective Actions Verified
QAR _____ Date _____

20 Closure Approved by:
QADD _____ Date _____

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INSTRUCTIONS FOR CORRECTIVE ACTION

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

If it becomes apparent that any of the corrective action due dates cannot be met, a written request for extension must be provided to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

3. The response must include the dated signature of the Responsible Manager.

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8 CAR NO.: YM-94-050
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CORRECTIVE ACTION REQUEST

| | | | |
|--|--|---|--|
| 1 Controlling Document QARD DOE/RW/033P and YMP-USGS QMPs | | 2 Related Report No. YMP-94-06 | |
| 3 Responsible Organization USGS | | 4 Discussed With | |
| 5 Requirement: 1. QARD, Section 4.0, PROCUREMENT DOCUMENT CONTROL, Para. 4.2.1 states: "Procurement documents issued by each affected organization shall include the following provisions, as applicable to the items being procured." Para. 4.2.1.C.1:1s states: "...A requirement for the supplier to have a documented QA program that implements the applicable QARD requirements prior to the | | | |
| 6 Adverse Condition: Contrary to the above requirements: (1) The USGS procurement procedures fail to translate the QARD requirements into the work process which describes the methodology for accomplishing the activity or task and, (2) The implementation of the USGS procurement procedures have not provided assurance that the activity results in an acceptable product or service. The above deficiencies are supported by the following observations: Contrary to the QARD requirements, Section 5 Items 2,3,4,7,8 and 9: a) The procurement procedure YMP-USGS-QMP-4.01, Rev. 6, fails to identify the methodology for determining what QARD requirements apply to any given scope of work identified in the purchase document. The procurement documents fail to be specific as to what QA program requirements pertain to the procurement or specifically identify those USGS QA program procedures that apply. The Requisition Request and Purchase Orders reviewed, PO 164388-93, PO 162578-93, PO 164411-93, 4RQ4889-5738, | | | |
| 9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No <u> </u> If Yes, Circle One: A B C D E | | 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 | |
| 3 Response Due Date: 20 Working Days from Issuance | | | |
| 11 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 | | | |
| 12 Recommended Actions: 1. Revise USGS procedures to facilitate translation of QARD requirements into work processes. 2. Implement procedures to assure procurement activities result in acceptable product or services. | | | |
| 7 Initiator Donald Harris <i>C.L. Warren Jr</i> | | 14 Issuance Approved by: QADD <i>[Signature]</i> Date <i>7/5/94</i> | |
| 15 Response Accepted QAR Date | | 16 Response Accepted QADD Date | |
| 17 Amended Response Accepted QAR Date | | 18 Amended Response Accepted QADD Date | |
| 19 Corrective Actions Verified QAR Date | | 20 Closure Approved by: QADD Date | |

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CORRECTIVE ACTION REQUEST (Continuation Page)

5 Requirements (continued)

initiation of the work."

2. Para. 4.2.1C.3: "When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's quality assurance program provided the work is adequately addressed. In these cases, procurement documents shall specify that the purchaser's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to them."

3. Para. 4.2.2 (C) states in part: "Reviews shall assure that all applicable technical and quality program requirements are included."

4. QARD Section 7.0, CONTROL OF PURCHASED ITEMS AND SERVICES, Para. 7.2.1:

Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall:

- A. Identify procurement methods and organizational responsibilities.
- B. Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.
- C. Identify and document the sequence of actions and milestones needed to effectively complete the procurement.

5. Para. 7.2.3:

- A. The proposal/bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified organizations including the quality assurance organization. The evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:

- 1. Technical considerations
- 2. Quality assurance program requirements
- 3. Supplier personnel
- 4. Supplier production capability
- 5. Supplier past performance
- 6. Alternatives
- 7. Exceptions

- B. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.

6. Para. 7.2.4 (A) states in part: "The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance." Para. 7.2.4.A3: "...Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements."

7. QARD, Section 5.0, IMPLEMENTING DOCUMENTS, Para. 5.2.2 states: "Content of implementing documents shall include the following information, as appropriate to the work to be performed: (A) Responsibilities of the organizations affected by the document, (B) Technical and regulatory requirements, (C) states in part: Sequential description of the work to be performed, (D) Quantitative and qualitative acceptance criteria sufficient for determining the activities were satisfactorily accomplished, (E) Prerequisites, limits, precautions, process

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CORRECTIVE ACTION REQUEST (Continuation Page)

5 Requirements (continued)

parameters, and environmental conditions, (F) Quality verification points and hold points, (G) Methods for demonstrating that the work was performed as required, (H) Identification of lifetime and nonpermanent QA records generated by the implementing document and (I) Identification of associated items and activities."

8. QARD, Section 2.0, QUALITY ASSURANCE PROGRAM, Para. 6.2.3 states: "REVIEWING DOCUMENTS. Documents that specify technical requirements, quality requirements or prescribe work shall be reviewed for adequacy, correctness and completeness, according to the requirements of Section 2.0, prior to approval of issuance."
9. Para. 2.2.9 states: "Documents shall be reviewed to the following requirements and for any additional requirements specified by the applicable section of the QARD. (A) Review criteria shall be established before performing the review. These criteria shall consider applicability, correctness, technical adequacy, completeness accuracy, and compliance with established requirements, (B) Pertinent background information shall be made available to the reviewers by the organization requesting the review if information is not readily available to the reviewer, (C) The review shall be performed by individuals other than the originator, (D) Reviewers shall be technically competent in the subject area being reviewed, (E) The scope of the review shall consider all aspects of the document...."
10. QARD Section 18.0, AUDITS
- Para. 18.2.2C: "External audits for compliance shall be performed triennially as a minimum. Pre-award surveys, if applicable, may serve as the first triennial audit if the affected organization is implementing the same quality assurance program for other contracts that is proposed for the purchaser's contract."
11. QMP-7.04, Rev.1, CONTROL OF PURCHASED ITEMS AND SERVICES, Para. 5.2, states in part: "Suppliers on the Approved Suppliers List (ASL) shall receive an annual evaluation any time prior to the scheduled anniversary date at the discretion of the YMP-USGS QA Manager."

6 Adverse Condition (continued)

4RQ4889-5695, and 4RQ4889-5696 only identify that work is to be performed in accordance with either the supplier's QA program or in accordance with the USGS QA Program. (generally non-specific)

- b) YMQAD Corrective Action Request, CAR YM-93-053 was closed on 4/26/94, based on QMP-4.01, Rev. 6. The effectiveness of implementation of the QMP in appropriately passing the QARD requirements down to the Suppliers was not performed at CAR closure. The effectiveness of correction performed during the Audit reflected the following in process Requisition Requests and Requisitions 4RQ4889-5738, 4RQ4889-5695 and 4RQ4889-5695 failed to identify the appropriate QARD requirements.

(Reference DOE Letter YMQAD:RBC-1155, dated December 17, 1993, to Larry R. Hayes, from Richard E. Spence, Subject: Verification of Corrective Action Request (CAR) YM-93-053 Resulting from YMQAD Review)

Contrary to QARD requirements Section 5 Items 2,3,4,5,7,8 and 9:

- c) QMP-4.01, Rev. 6, PROCUREMENT DOCUMENT CONTROL, Paras. 5.4.1.2 and 5.4.1.3 in part states: "When a proposal is selected and meets all the requested requirements the Contracting Officer

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8 CAR NO.: YM-94-050
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CORRECTIVE ACTION REQUEST (Continuation Page)

6 Adverse Condition (continued)

(C.O.) shall forward the document to the Requester and QA Manager for review to ensure the procurement document include the appropriate provisions identified in Para. 5.4.1 (restatement of QARD requirements) and attachment 4. The procedure fails to provide the methodology for performing the reviews and attachment 4 is identified as 'Supplier Performance Evaluation' and does not contain information on Proposal evaluations.'

Contrary to QARD requirements, Section 5 Items 3,4,7,8 and 9:

- d) OMP-7.04, Rev. 1, CONTROL OF PURCHASED ITEMS AND SERVICES, Para.5.3, Source Verification, states in part: "YMP-USGS may accept an item or service by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called Source Verification. Attachment 2 (Source Verification Form) or equivalent shall be used. Para. 5.3.2 states: "Documented evidence of acceptance or rejection of source verified items or services shall be furnished to the requester, the supplier and included in the procurement records package." The procedure fails to contain any methodology for planning source inspections, determining what quantitative and qualitative acceptance criteria to include or on the actual performance of the source inspection. Currently two source inspections have been performed utilizing a Source Verification Plan which does at least provide a description of what was inspected and the results. Attachment 2, Source Verification Form provides very limited information. The Source Verification Form or Source Verification Plan are not sent to the supplier as required by the procedure.

Contrary to QARD requirements, Section 5 Items 1,2,3,4,7,8 and 9:

- e) USGS QDR 93-011-2 was initiated against a series of procurement documents initiated by USGS Support Contractor. The QDR was dispositioned to require the QA implementation advisor to assure the deficiencies in the procurement documents are corrected by a change order. The inprocess Change Order R6028657, to PO 45-930092 generated only invokes that: "Work performed under this contract shall meet all YMP-USGS QA Program Requirements in effect for the duration of this Contract." This Change Order fails to identify specific requirements.

The existing contract fails to invoke any technical or quality requirement, therefore it would not stand the test of any judgement (law) against the supplier. Subsequently a letter was generated on 9/5/90, essentially specifying USGS QAPP-01, Rev. 5, Section 4, PROCUREMENT DOCUMENT CONTROL, Paras. 4.3.4. and 4.3.6 which were to be met, Right of Access Control and what constitutes a nonconformance. This letter failed to provide appropriate technical and quality assurance requirements or reference the Purchase Order.

- f) YMQAD evaluation of Security Archives Storage Facility (SAIC/USGS contractor) during Audit YMP-94-06 two deficiencies of Security Archives were found (i.e.: Security Archives instruction was not referenced in the purchasing document with Security Archives). The first related to penetrations through the vault. It was observed that a Halon pipe penetration through the vault was not sealed to as required. Secondly, the temperature and humidity strip recorder indicated for a seven week period that the temperatures in the vault were below the minimum set forth in the Security Archive instruction which is based on the manufactures

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CORRECTIVE ACTION REQUEST (Continuation Page)

6 Adverse Condition (continued)

recommendations. No corrective action documents were generated by USGS to address this condition. USGS had just performed a requalification audit of Security Archives (USGS-94052-SA) on May 24, 1994 and failed to identify these conditions. As a result of the audit, Security Archives was maintained as a supplier of services on the USGS ASL.

Contrary to QARD requirements, Section 5 Items 6 and 11:

- g) QDR 94-063, initiated 5/23/94, addressed the failure of USGS to perform their Annual Supplier Evaluations in accordance with QMP-7.04 which is the basis for retention on the ASL. These suppliers were not suspended from the ASL. They are retained on a managerial risk basis.

Contrary to QARD requirements, Section 5 Items 1,2,3,4,6,7,8,9 and 10:

- h) YMP-USGS-QMP-7.04, Rev. 1, CONTROL OF PURCHASED ITEMS AND SERVICES, Para. 5.4, Triennial Audits in accordance with this paragraph is only three years after a supplier is placed on the ASL. The QMP fails to address the requirement or the methodology required by the QARD. The QARD requires that after qualification of a Supplier by History, Quality Records Review, or Survey when the supplier is using a QA program other than the QA program with requirements specifically required by USGS procurement document, an audit must be performed after commencement of USGS's work. This audit is used to set the triennial audit date and provides a degree of confidence the supplier is performing as required.

Contrary to QARD requirements, Section 5 Items 2,3,4,5,7,8 and 9:

- i) The contract 1434-93-C-40098 Desert Research Institute (DRI) Quality Assurance Agreement between DRI Quarternary Science Cetner and USGS Geological Survey for Yucca Mountain Project Data Collection. (approved by USGS3/94) fails to address: 1) what Ymp-USGS-QMPs DRI is responsible to implement; 2) allows DRI to generate written procedures for sample tracking and data collection without being performed in accordance to YMP-USGS-QMP-501; 3) fails to invoke a Document Control requirement, based on a statement of "Employee Awareness"; 4) fails to invoke YMP-USGS procedures QMP-2.08 PERSONNEL QUALIFICATION, QMP 6.01 DOCUMENT CONTROL, QMP 8.01 IDENTIFICATION AND CONTROL OF SAMPLES or QMP 16.04 CONTROL OF DEFICIENCY REPORTS (Note: based on the Attachment I statement It appears that DRI is augmented staff to USGS.)

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CORRECTIVE ACTION REQUEST (Continuation Page)

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INSTRUCTIONS FOR CORRECTIVE ACTION

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GUIDELINES FOR ROOT CAUSE DETERMINATION

When it is established that an investigation to determine root cause is required, the following guidelines may assist in the determination:

- 1) Clarify the specific condition. Pertinent clarifying questions must be asked and answered as accurately as possible.
 - a) What happened?
 - b) Where did the condition occur?
 - c) When did the condition occur?
 - d) What was the extent of the condition?
 - e) Who was involved?
 - f) In what manner did it happen?
 - g) What reasons are given by knowledgeable personnel for why it happened?

- 2) Obtain information related to the identified condition.
 - a) Investigate, in detail, the specific condition adverse to quality.
 - b) Interview personnel.
 - c) Review pertinent documents.
 - d) Use quality tools (cause & effect diagrams, flowcharting, Pareto analysis, comparative analysis, etc.).
 - e) Identify and collect data needed to get to the root cause.

- 3) Most root causes fall into one or more of the following generic categories. Specific review of these areas may be useful in arriving at cause determination:
 - a) Procedures
 - b) Personnel
 - c) Management systems
 - d) Supervision
 - e) Training
 - f) Communications
 - g) Scientific investigation/design methods
 - h) Human factors
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 - j) Miscellaneous or multiple areas