



**DEPARTMENT OF ENERGY**  
 Office of Civilian Radioactive Waste Management  
 Office of Geologic Disposal  
 Yucca Mountain Site Characterization Project Office  
 P.O. Box 98608  
 Las Vegas, NV 89193-8608

WBS 1.2.11  
 QA: N/A

**JAN 14 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

EVALUATION OF AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-93-053  
 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT  
 YMP-93-010 OF U.S. GEOLOGICAL SURVEY (SCP: N/A)

The YMQAD staff has evaluated the amended response to CAR YM-93-053. The amended response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Nita J. Brogan, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Richard L. Maudlin at 794-7290.

Richard E. Spence, Director  
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-1598

Enclosure:  
 CAR YM-93-053

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
- D. D. Porter, SAIC, Golden, CO

cc w/o encl:

- J. W. Gilray, NRC, Las Vegas, NV
- N. J. Brogan, YMQAD/QATSS, Las Vegas, NV

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 PDR WASTE  
 WM-11 PDR

ADD: Ken Hooks  
 Ltr. Encl.  
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102.7  
 WM-11  
 NHDZ

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

8 CAR NO.: YM-93-053  
DATE: 6/25/93  
SHEET: 1 OF 1  
QA

**CORRECTIVE ACTION REQUEST**

1 Controlling Document QAPP, Revision 5, QMP-4.01, Revision 4		2 Related Report No.	
3 Responsible Organization USGS		4 Discussed With J. Ziemra/A. Lykins/P. Rodriguz	
5 Requirement: QAPP, Revision 5, Subsection 4.3.3 states in part: "Procurement documents shall require that the suppliers have a documented QA program that implements either part or all of the requirements of this document."  QMP-4.01, Revision 4, Section 5.0, Paragraph 5.1 states in part: "The requester shall initiate a procurement action by the completion and submittal of a Requisition Request.... The following topics shall be considered and included as appropriate: o Scope of Work, o Technical Requirements, ... o Requirements...."			
6 Adverse Condition: Contrary to the above, P.O. 150669, dated 8/4/92 to "Colorado State Department of Agriculture," P.O. 162338-93, dated 6/1/93 to "Intertyme Metrology," and P.O. 162193-93, dated 5/19/93 to "VICI Metronics," do not include applicable QA program requirements such as: QA Element 2 (Personnel Qualifications), QA Element 5 (Procedures to Perform Calibrations), QA Element 12 (Calibration), and QA Element 17 (Control Records).			
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> 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 If Yes, Circle One: A B C D	
11 Response Due Date: 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: Review existing contracts and modify accordingly. Take the necessary action to evaluate the extent of the deficiency. Take action to preclude recurrence as the root cause. Revise QMP-4.01 to assure correct understanding and interpretation of application of QA requirements.			
7 Initiator R. L. Maudlin <i>Maudlin</i> Date <u>06/24/93</u>		14 Issuance Approved by: QADD <i>[Signature]</i> for <i>[Signature]</i> Date <u>07-01-93</u>	
15 Response Accepted QAR <i>Maudlin</i> Date <u>08/01/93</u>		16 Response Accepted QADD <i>[Signature]</i> Date <u>8/13/93</u>	
17 Amended Response Accepted QAR <i>Maudlin</i> Date <u>01/12/94</u>		18 Amended Response Accepted QADD <i>[Signature]</i> Date <u>1/13/94</u>	
19 Corrective Actions Verified QAR Date		20 Closure Approved by: QADD Date	

**ENCLOSURE**

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

CAR NO. YM-93-053  
DATE: 7/29/93  
SHEET: 2 OF 3

**CORRECTIVE ACTION REQUEST**  
(Continuation Page)

**1. CORRECTIVE ACTION RESPONSE FOR CAR #YM-93-053**

**A. REMEDIAL ACTION:**

There has been no impact on quality; and since the cut-off date for FY93 procurement is July 30, 1993, it would be inappropriate to take any remedial action on the procurements in process.

**B. INVESTIGATIVE ACTIONS:**

The majority of purchases from approved suppliers do not specify QA requirements. For all suppliers on the ASL, audits have been conducted which determined that the vendors are qualified to provide services to YMP-USGS. The audits were conducted in accordance with QMP 18.01 as well as QMP 7.01, which provide guidance in evaluating suppliers.

In addition to calibration traceability, the suppliers were evaluated in such areas as calibration capabilities, personnel qualifications, records maintenance, rights of access, and the documentation/certification of calibration services. Since these evaluations determined that the QA requirements were met, it was not required of the requestors of the calibration services to repeat the QA requirements on the Purchase Order. However, the scope of work in these procurement actions was calibration services, and documentation of the calibration as prescribed in QMP 12.01 was requested of the suppliers in the procurement documents.

**C. ROOT CAUSE DETERMINATION:**

The USGS has relied on vendor evaluation to verbally inform suppliers of the appropriate QA requirements. As a result, it has not been documented that the suppliers are aware of the QA criteria they are expected to meet.

**D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE:**

QMP-4.01 will be reworded to clarify and strengthen QA requirements and ensure they are incorporated into procurement documents.

*Str dttd 7/29/93 - Hayes to Spencer*

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

CAR NO. YM-93-053  
DATE: 7/29/93  
SHEET: 3 OF 3

**CORRECTIVE ACTION REQUEST**  
(Continuation Page)

**CORRECTIVE ACTIONS RESPONSE FOR CAR #YM-93-053 (Continued)**

**2. SCHEDULE OF ACTIONS:**

Complete by September 15, 1993. Alice Lykins will modify or revise QMP-4.01

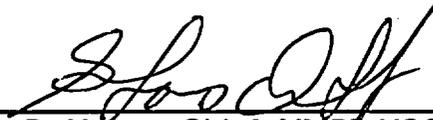
**3. RESPONSE APPROVAL:**



T. H. Chaney, YMP/USGS  
Quality Assurance Manager

7/30/93

Date



L. R. Hayes, Chief, YMPB-USGS

7/30/93

Date

For



**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

**DEC 17 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

VERIFICATION OF CORRECTIVE ACTION OF CORRECTIVE ACTION REQUEST (CAR) YM-93-053  
RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) REVIEW  
(SCP: N/A)

The YMQAD staff has verified the corrective action to CAR YM-93-053 and determined the results to be unsatisfactory because YMP-USGS-QMP-4.01, R5 does not adequately resolve the noted condition which requires U.S. Geological Survey (USGS) to appropriately pass down the applicable portions of the Quality Assurance Requirements Document (QARD) to its subtier suppliers.

Section 5.1 of Quality Management Plan/Procedure (QMP) 4.01 eludes to the pass down of applicable Quality Assurance (QA) requirements, but lacks any substance as to how this will be accomplished. Statements such as "subtier procurement" and "other applicable QA requirements from the QARD" are not defined statements. There is a major concern as to how someone responsible for implementing these requirements would accomplish the task.

There are fundamental requirements which would apply to almost any procurement, except where USGS requires the supplier to implement USGS procedures through the procurement documents. These fundamental requirements include, but are not limited to: Personnel Qualification and Training, Procurement Control, Procedures, Corrective Action, and QA Records.

It is understood that USGS is, at this point, primarily limited to procurement of calibration services at minimal costs; however, the fundamental requirements addressed above should already be implemented by the prospective supplier, so USGS, in essence, is not imposing any additional requirements on the supplier other than what the supplier is already implementing as a standard practice for all their work.

It should be understood failure of the procurement documents to adequately address the minimum QA requirements could place the quality of the product or service in question, and holding the supplier accountable to meet certain minimum requirements is not possible since the only contractual binding document is the procurement order.

Larry R. Hayes

-2-

DEC 17 1993

Please reevaluate your changes to QMP 4.01 and include controls which are well defined and can be adequately implemented by those responsible for generating purchase requisitions. A response to this evaluation is due within 10 working days of the date of this letter. Verification of completion of the required corrective action will be performed after the date provided.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Richard L. Maudlin at (702) 794-7290.

  
Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1155

Enclosure: .  
CAR YM-93-053

cc w/encl:

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  
N. J. Brogan, YMQAD/QATSS, Las Vegas, NV



United States Department of the Interior



GEOLOGICAL SURVEY  
BOX 25046 M.S. 425  
DENVER FEDERAL CENTER  
DENVER, COLORADO 80225

IN REPLY REFER TO:

WBS#: 1.2.11

QA: N/A

December 28, 1993

**QA RECEIVED**

JAN 3 1994

Richard E. Spence, Director,  
Quality Assurance Division  
Yucca Mountain Project Office  
U.S. Department of Energy  
P.O. Box 98608  
Las Vegas, NV 89193-8608

SUBJECT: Amended response to CAR 93-053

Reference your letter of December, 1993, subject: Verification of Corrective Action of Correction Action Request (CAR) YM-93-053 Resulting from Yucca Mountain Quality Assurance Division (YMQAD) review (SCP: N/A). QMP 4.01 is again being revised to include requirements as stated in the QARD. Anticipated completion date is January 31, 1994.

Sincerely,

*Wayne Redden*  
for T. H. Chaney, Quality  
Assurance Manager, Yucca  
Mountain Project

AEL/THC/aa

cc: L. R. Hayes, USGS, Denver, CO  
R. W. Craig, USGS, Las Vegas, NV  
A. E. Lykins, USGS, Denver, Co  
D. D. Porter, SAIC, Denver, CO  
J. W. Gilray, NCR, Las Vegas, NV  
N. J. Brogan, YMQAD/QATSS, Las Vegas, NV  
LRC File 3.16.01 (YM-93-053)