



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

FEB 08 1995

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 TO CORRECTIVE ACTION REQUEST (CAR)
YM-95-021 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION'S (YMQAD) AUDIT YM-ARP-95-04 OF U.S. GEOLOGICAL
SURVEY (SCPB: N/A)

The YMQAD staff has evaluated the response to CAR YM-95-021.
The response has been determined to be unsatisfactory for the
reasons stated in the enclosed CAR.

Please provide a response that addresses the cited condition
within ten working days from the date of this letter. Send
the original of your response to Deborah Sult, YMQAD/QATSS,
101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.
If an extension to the due date is necessary, it must be
requested in writing, with appropriate justification, prior to
that date.

If you have any questions, please contact either Robert B.
Constable at 794-7945 or Kenneth O. Gilkerson at 794-7738.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2051

Enclosure:
CAR YM-95-021

cc w/encl:

~~John G. Spraul~~, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
D. D. Porter, USGS/SAIC, Golden, CO
T. H. Chaney, USGS, Denver, CO
R. W. Craig, USGS, Las Vegas, NV

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Larry R. Hayes

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FEB 08 1995

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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

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CORRECTIVE ACTION REQUEST

1 Controlling Document QARD DOE/RW-0333P, Revision 1		2 Related Report No. YM-ARP-95-04	
3 Responsible Organization USGS		4 Discussed With G. LeCain/W. Rodman/B. Scavuzza	
5 Requirement: QARD DOE/RW-0333P, Revision 1 1) QARD Section 12.2.1 states that: "Measuring and test equipment shall be calibrated, adjusted and maintained at prescribed intervals...." 2) QARD Section 12.2.1C states that: "The methods and interval of calibration shall be defined, based on the type of equipment, stability requirements,...." 3) QARD Section 12.2.1E states that: "Calibrated measuring and test equipment shall be labeled, tagged, or otherwise marked or documented to indicate due date or interval of the next calibration."			
6 Adverse Condition: Contrary to the above statements: 1) A review of the April 1994 calibration data sheets for pressure transducers and thermisters used in the Air Permeability Testing of Borehole UZ 16 indicated no calibration intervals for the HP 3457A Digital Multimeter and Keithley 230 power sources used as standards for the calibration. 2) USGS personnel no longer calibrates these standards but utilizes only performance or operational checks in accordance with EP 270, Revision 2, resulting in no "end" calibration for the standards used. 3) The technical procedures used in this study to calibrate the pressure transducers and thermisters still require an annual calibration of these standards which is no longer being performed.			
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
13 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 type="checkbox"/> Root Cause Determination			
12 Recommended Actions: 1) Ensure that standards are calibrated and utilized within the calibration interval. 2) Review procedures and revise as required to meet program requirements. 3) Review usage of any out-of-calibration standards for impact on data.			
7 Initiator K. O. Gilkerson <i>K. O. Gilkerson</i>		14 Issuance Approved by: QADD <i>[Signature]</i> Date: <u>12-29-94</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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WASHINGTON, D.C.

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

5 Requirements (continued)

- 4) USGS technical procedures HP 251, Revision 0; HP 247, Revision 0; and HP 271, Revision 0; para(s) 5.0 all require the Hewlett Packard 3457A Digital Multimeter and the Keithly 230 Programmable Voltage Source to be calibrated annually.

6 Adverse Condition (continued)

DISCUSSION:

M&TE calibrations performed with the bench mounted standards with lapsed calibration intervals includes (but is not necessarily all inclusive):

Pressure Transducers

AK 31229
AK 31226
AK 319861
AK 319861
AK 319863
AK 319865

Thermistors

AKTH 001-AKTA sets

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95-21

- A. **REMEDIAL ACTION:** Discussions were held with Joe Rousseau, the PI responsible for HP-270. Joe was not available at the time of the audit. Gary LeCain, the PI responsible for the related technical procedures has been unavailable.

Because of the complexity of HP-270 and how the other procedures relate to it, and due to the brevity of the description of adverse conditions, Rousseau requests that appropriate YMQAD representatives schedule a meeting to further clarify the deficiencies. Based on the information provided in the CAR, the USGS is unable to provide an accurate response to the CAR until we are sure that the requirements and methods described in HP-270 as well as the concerns expressed during the audit are fully understood by all parties. The PI feels that, as written, HP-270 complies with all QA requirements but the related procedures may need to be revised to establish consistency.

- B. **EXTENT OF THE DEFICIENCY:** TBD

- C. **ROOT CAUSE DETERMINATION:** TBD

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

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.

1. YMQAD to schedule a meeting with Rousseau by March 15, 1995.

2. Rousseau to coordinate with G. LeCain, HRF Calibration Laboratory, ESIP QAIS, and QA Office.

3. RESPONSE APPROVED:

Thomas H. Chaney

for Thomas H. Chaney
YMP-USGS Quality Assurance Manager

1-26-95

Date

Larry R. Hayes

for Larry R. Hayes
Chief, Yucca Mountain Project Branch

1/26/95

Date

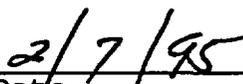
EVALUATION OF RESPONSE TO CAR YM-95-021

The response to CAR YM-95-021 response, dated 1/26/95, was found to be unacceptable for the following reasons:

- The documentation fails to provide a response to the identified problem (e.g. corrective action, action to preclude recurrence, dates, etc).
- Instead, the response requests a new meeting to discuss the issues that were already discussed during the audit with responsible personnel as part of the audit process. This response is neither responsive to the audit nor timely. It appears to be an attempt to extend the response due date to March 15, 1995. This deficiency was formally identified to USGS as a CAR on December 9, 1994 and discussed as an issue on December 5, 1994. This would appear to be more than adequate time to formulate the response.
- It should be noted that in discussions during the audit, the problem was clearly understood by both technical and QA personnel from USGS. USGS QA had also identified this problem as a CAR condition but had failed to issue this as a CAR prior to the YMQAD audit. A proposed response to the deficiency cited was presented by USGS personnel during the audit to resolve the issue.
- The requirement is clearly written and was understood by all during the audit. It is not clear to YMQAD two months after the audit why there is now a failure to comprehend the deficiency cited.

Please provide a response that addresses the cited condition within ten working days from the date of this letter.


Kenneth O. Gilkerson, QAR


Date