



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

MAY 18 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

VERIFICATION OF CORRECTIVE ACTION OF 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 verified the corrective action to CAR
YM-95-021 and determined the results to be unsatisfactory
because of reasons stated in the enclosed CAR.

Your response, indicating the appropriate corrective action
completion date, is required to be submitted to this office
within ten working days of the date of this letter.
Concurrence, as requested also in the enclosed CAR, is
required. 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 794-7945 or Kenneth O. Gilkerson at 794-7738.

Robert B. Constable

YMQAD:RBC-3328 Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

Enclosure:
CAR YM-95-021

cc w/encl:

~~C. G. Spraul~~, 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:

D. G. Sult, YMQAD/QATSS, Las Vegas, NV
W. L. Belke, NRC, Las Vegas, NV

YMP-5

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PDR WASTE PDR
WM-11

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**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 HP 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>12-23-94</u>	
15 Response Accepted QAR <i>[Signature]</i> Date <u>2/28/95</u>		16 Response Accepted QADD <i>[Signature]</i> Date <u>n/a</u>	
17 Amended Response Accepted QAR <i>[Signature]</i> Date <u>2/28/95</u>		18 Amended Response Accepted QADD <i>[Signature]</i> Date <u>3-2-95</u>	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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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

Thermisters

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

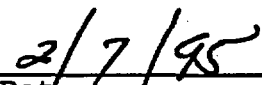
The response to CAR YM-95-021 response, dated 1/26/95, was found to be unacceptable for the following reasons:

- 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

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WASHINGTON, D.C.

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CORRECTIVE ACTION REQUEST (Continuation Page)

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

A. REMEDIAL ACTION: Calibration documentation for the six pressure transducers and one thermistor identified will be reviewed to ensure that the system (bench) used in support of their calibration is identified and that the system calibration data (currently referred to in HP-270, R2 as a "check") is included with the calibration documentation. Reference to CAR No. YM-95-21 will be added to calibration documentation as required by QARD requirement 12.2.6G.

B. EXTENT OF THE DEFICIENCY:

- i) Calibration documentation for M&TE used in support of the Air Permeability Testing of Borehole UZ 16 (in addition to those specifically identified in the CAR) will be reviewed and amended as required, to ensure that calibrations performed are adequately documented (see Part A above).
- ii) Investigation of YMP-USGS technical procedures (in addition to those specifically identified in the CAR) will be conducted to identify those that interface with HP-270. Identified procedures will be reviewed and revised as required to ensure proper procedural interface with HP-270 (see Part D below) system calibration requirements.

C. ROOT CAUSE DETERMINATION: Not requested.

D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE:

- i) HP-270, R2 will be revised/modified as required to address QARD requirements identified in this CAR. This procedural modification/revision will:
 - Identify the current "Rack Diagnostics" and "System Check" as a "System Calibration;"
 - Include a specific time interval for documented performance of the system calibration;
 - Ensure labeling of each system (bench) with calibration sticker to indicate system calibration status; and
 - Identify individual pieces of equipment (serial number, model number, etc.) that are components of the calibration bench system on YMP-USGS-QMP-12.01 Calibration Status form.
- ii) USGS technical procedures HP-251, R0; HP-247, R0; and HP-271, R0 will be reviewed and modified as required to ensure proper procedural interface with HP-270 system calibration requirements.

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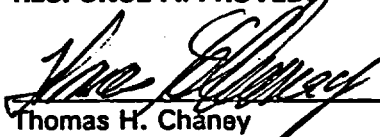
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2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

- | | | |
|---------|---|----------|
| 1.A. | G.D. LeCain, YMP-USGS Principal Investigator | 03/13/95 |
| 1.B.i) | G.D. LeCain, YMP-USGS Principal Investigator | 03/31/95 |
| 1.B.ii) | R. Scavuzzo, Quality Assurance Specialist | 05/01/95 |
| 1.D.i) | J.P. Rousseau, YMP-USGS Principal Investigator
R. Scavuzzo, Quality Assurance Specialist | 05/01/95 |
| 1.D.ii) | G.D. LeCain, YMP-USGS Principal Investigator
R. Scavuzzo, Quality Assurance Specialist | 05/01/95 |

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

2/28/95
Date

fr 

Larry R. Hayes
Chief, Yucca Mountain Project Branch

2/22/95
Date

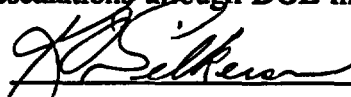
VERIFICATION OF CORRECTIVE ACTION FOR CAR YM-95-21

The corrective action to preclude recurrence was due to have been implemented by 5/1/95. It was determined that this verification would be performed in Denver the week of 5/8/95 during Audit YM-ARP-95-09. The key elements for resolution of this issue required:

- A change to USGS Procedure HP-270 to identify the current "Rack Diagnostics" and "Systems Checks" as a "system calibration; include a specific time interval for documented performance of the system calibration; ensure labeling of each system (bench) with calibration sticker to indicate system calibration status; and, identify individual pieces of equipment (serial number, model number, etc) that are components of the calibration bench system on YMP-USGS-QMP-12.01 Calibration Status Form.
- Review other USGS Technical Procedures that refer or interface with HP-270 for required changes and modify as necessary.

The modification to HP-270 had occurred as required but was never issued due to internal technical comments by USGS. On 5/11/95 USGS notified the YMQAD Representative assigned to this CAR that they now wished to change their previously accepted corrective action commitments and withdraw their procedure changes. Subsequently, the corrective action for CAR YM-95-021 is rejected due to the failure of USGS to implement the accepted corrective action proposals as agreed. The new proposal is required to be submitted formally to YMQAD with concurrence from the YMSCO AM for Scientific Programs. It should be noted that the resolution of these issues has not been timely and any further delays will result in additional escalations through DOE management.

Evaluation by



YMQAD/

QAR 5/12/95