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

SEP 25 1995

Robert W. Craig
Acting 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 AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-95-021 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-APR-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 satisfactory. As a result, the CAR is considered closed.

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

R. E. Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4647

Enclosure:
CAR YM-95-021

cc w/encl:
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
D. D. Porter, SAIC, Golden, CO

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

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ORIGINAL
THIS IS A RED STAMP

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8 CAR NO.: YM-95-21
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CORRECTIVE ACTION REQUEST

1 Controlling Document	2 Related Report No.
QARD DOE/RW-0333P, Revision 1	YM-ARP-95-04
3 Responsible Organization	**4 Discussed With**
USGS	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 X If Yes, Check One: ☐A ☐B ☐C ☐D ☐E	10 Does a stop work condition exist? Yes___ No X ; If Yes - Attach copy of SWO If Yes, Check One: ☐A ☐B ☐C	13 Response Due Date: 20 Working Days from Issuance

11 Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☐ 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 20Dec94	14 Issuance Approved by: QADD for Date 12.23.94
15 Response Accepted QAR Date 2/28/95	16 Response Accepted QADD n/a Date
17 Amended Response Accepted QAR Date 2/28/95	18 Amended Response Accepted QADD for Date 3.2.95
19 Corrective Actions Verified QAR Date 9/19/95	20 Closure Approved by: QADD Date 9/25/95

Exhibit QAP-16.1.1 Rev. 06/27/94

ENCLOSURE

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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	Thermisters
AK 31229	AKTH 001-AKTA sets
AK 31226	
AK 319861	
AK 319861	
AK 319863	
AK 319865	

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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:**

Martha H. Mustard for 1-26-95
Thomas H. Chaney — Date
YMP-USGS Quality Assurance Manager

[signature] 1/26/95
Larry R. Hayes — Date
for Chief, Yucca Mountain Project Branch

1/26/95 HAYES TO SPENCE

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 2/7/95

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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.

2/22/95 HAYES TO SPENCE

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CORRECTIVE ACTION REQUEST (Continuation Page)

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 — Date 2/22/95
YMP-USGS Quality Assurance Manager

for Larry R. Hayes — Date 2/22/95
Chief, Yucca Mountain Project Branch

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 K. Silkeson YMQAD QAR 5/12/95

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CORRECTIVE ACTION REQUEST (Continuation Page)

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

Reason for Amended Response: After the modification to HP-270, as proposed in the CAR response dated 2/22/95, a technical review was performed. During the review process it became apparent that the electronic diagnostic check was not intended to be a calibration. Many of the electronic diagnostic checks are simply checks that indicate problems, a need for cleaning or that a calibration is needed. As stated in the technical review, "At no time is an individual instrument calibrated and no attempt is made to reproduce the manufacturer's instructions for calibration of the instrument." In addition, the forms produced by these checks would not be sufficient to meet the requirements of section 5.2.1 of QMP-12.01 without substantial modifications of the software.

Therefore, the PI and his technical staff have opted for a 5 year calibration interval used in conjunction with the electronic diagnostic checks already being used in the technical procedures. The maximum interval of calibration would be 5 years. The electronic diagnostics would indicate if a calibration is required sooner. The 5 year interval was based on the reliability of the instruments and the experience of the technical staff using the instruments. The new 5 year calibration interval applies to the HP3457, the Keithley 220/263 and Keithley 181/182. Other instruments are already covered by specific intervals in HP-270 and other technical procedures. The five year calibration, in conjunction with the electronic diagnostic checks, which in many cases are more strict than manufacturer's specifications, will result in minimal risk to the data.

A. REMEDIAL ACTION: Calibration documentation for the six pressure transducers and one thermistor identified will be reviewed to ensure that the instruments used in support of their calibration are identified and that an explanation of 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 the 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: The root cause was not requested, although a discussion of the root cause is necessary to understand the issues involved. The original wording in HP-251, requiring an annual calibration (LeCain's procedure) was necessary because the air permeability group went to the field before HP-270 (Rousseau's procedure used to calibrated the bench in HP-271, 251 and 247) was in place in the calibration lab. The intention was to keep the requirements

6/2/95 Hayes to Spence

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CORRECTIVE ACTION REQUEST (Continuation Page)

at a one year calibration and then use HP-270 when it was approved. As an oversight, the Cal Lab personnel tested the pressure rack as they normally did without referring to HP-251 and did not check the calibration dates of the HP3457 and Keithley 220 in the rack, as required in HP-251.

D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE:

I. After technical review of the modification of HP-270, R2 per the corrective action (Part 1.D.i) proposed in the "Amended Corrective Action Response for CAR No. YM-95-21", dated 2/22/95, an alternative response has been proposed. The electronic diagnostic checks shall remain in place as diagnostic checks. The following instruments shall be calibrated at 5 year intervals or sooner if indicated by the electronic diagnostic checks: HP3457 multimeter, Keithley 220 current generator, Keithley 263 calibrator (if used), and Keithley 181/182 nanovoltmeters. There may be additional calibrations required due to the results of the electronic diagnostic checks in HP-270. Therefore, the following technical procedures shall be reviewed and modified as necessary to reflect the 5 year (or as required per HP-270) calibration requirement for equipment:

HP-270, "Electronic Diagnostic Testing for Calibration and Instrumentation DAS Racks, Unsaturated Zone Borehole Instrumentation and Monitoring Program"

HP-14, "Method for Calibrating Peltier-Type Thermocouple Psychrometers for Measuring Water Potential or Partially Saturated Media"

HP-138, "Method for Calibrating Pressure Transducers for Measuring Absolute Pneumatic Pressures in Unsaturated Zone Boreholes"

HP-162, "Method for Calibrating Thermistors for Measuring Absolute Temperatures in Unsaturated Zone Boreholes"

HP-137, "Operation of UZ Borehole Instrumentation Sites"

HP-189, "Method for an Operational Check of the Performance Status of a Standard Platinum Resistance Thermometer"

HP-244, "Method for Stemming and Instrumenting Unsaturated-Zone Hydro-Instrumented Boreholes"

HP-251, "Calibration of Pressure Transducers Used for Pneumatic Testing of Unsaturated Zone Boreholes"

HP-247, "Calibration of Thermistors Used for Pneumatic Testing of Unsaturated Zone Boreholes"

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CORRECTIVE ACTION REQUEST (Continuation Page)

HP-271, "Gas Flow Rate Calibration Procedure for Unsaturated Zone Borehole Testing Program"

The procedure review will ensure that all revisions or modifications include labeling of each instrument with a calibration sticker to indicate the 5-year calibration status; and identify individual pieces of equipment (serial number, model number, etc.) requiring periodic calibration status on the YMP-USGS-QMP-12.01 Calibration Status Form.

All instruments have been checked before and after each sensor calibration run (data collection) with the electronic diagnostic checks. For this reason, all sensor calibrations prior to when the modifications in the technical procedures take effect are considered valid and all data collected from these sensors are valid. The new calibration requirements, as proposed in this amended response, take effect when the modifications take effect. Any instruments requiring the 5 year calibration interval, which are more than 5 years out of calibration, will be recalibrated.

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. & 1.B.i)	LeCain, YMP-USGS Principal Investigator	11/01/95
1.B.ii)	G.D. LeCain, YMP-USGS Principal Investigator J.P. Rousseau, YMP-USGS Principal Investigator	COMPLETED 5/25/95
1.D.i)	J.P. Rousseau, YMP-USGS Principal Investigator (HP-270, 14, 137, 138, 162, 189, 244 only) G.D. LeCain, YMP-USGS Principal Investigator (HP-247, 251 and 271 only)	11/01/95

3. RESPONSE APPROVED:

Thomas H. Chaney — Date 6/2/95
YMP-USGS Quality Assurance Manager

Larry R. Hayes — Date 6/02/95
Chief, Yucca Mountain Project Branch

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CAR NO. YM-95-021

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CORRECTIVE ACTION REQUEST
(continuation sheet)

1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. YM - 95 - 021:

   A. Remedial Action: No change from 6/2/95 response.

   B. Extent of the Deficiency: No change from 6/2/95 response.

   C. Root Cause Determination: No change from 6/2/95 response.

   D. Corrective Action to Preclude Recurrence: No change from 6/2/95 response.

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.

   The following schedule amends and replaces the information provided in the 6/2/95 response:

1.A. & 1.B.i)	G.D.LeCain, YMP-USGS Principal Investigator	08/31/95
1.B.ii)	G.D.LeCain, YMP-USGS Principal Investigator J.P.Rousseau, YMP-USGS Principal Investigator	COMPLETED 5/25/95
1.D.i)	J.P.Rousseau, YMP-USGS Principal Investigator (HP-270, -14, -137, -138, -162, -189, -244 only) G.D.LeCain, YMP-USGS Principal Investigator (HP-247, -251, and -271 only)	08/31/95

3. RESPONSE APPROVED:

Martha N Mustard 6-7-95
for Thomas H. Chaney Date
YMP-USGS Quality Assurance Manager

[signature] 6/7/95
Larry R. Hayes Date
for Chief, Yucca Mountain Project Branch

6/7/95 Hayes to Spence

VERIFICATION OF CORRECTIVE ACTION FOR CAR YM-95-21

Verification of corrective action for CAR YM-95-21 was performed during the audit YM-ARP-95-20 of USGS while at the HRF Yucca Mountain. USGS Procedures HP-270 Rev 3 M1, HP-14 Rev 2 M1, HP-138 Rev 0 M2, HP-162 Rev 1 M1, HP-137 Rev 1 M1, HP-244 Rev 0 M3, HP-251 Rev 0 M1, HP-247 Rev 0 M1, and HP-271Rev 0 M1 were reviewed and determined to have been revised as required. Procedure HP-189 was determined not to require a revision to comply with the CAR commitments. Equipment in the laboratory was examined and found to have appropriate calibration stickers affixed denoting appropriate recall dates. Associated calibration documentation for the HP 3457 multimeters, Keithley 220 current generators, Keithley 263 calibrators and Keithley 181/182 nanovoltmeters were also examined. Based on the reviews and examinations, it is recommended that CAR YM-95-21 be closed.

Evaluation by _____ QAR 9/18/95