



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

JUL 12 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 AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST  
(CAR) YM-95-041 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE  
DIVISION'S (YMQAD) AUDIT YM-ARP-95-09 OF U.S. GEOLOGICAL SURVEY  
(SCPB: N/A)

The YMQAD staff has evaluated the amended response to CAR  
YM-95-041. 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 that date.

If you have any questions, please contact either Robert B.  
Constable at 794-7945 or Donald J. Harris at 794-7356.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-3905

Enclosure:  
CAR YM-95-041

cc w/encl:

~~J. 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:

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

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

B. CAR NO. YM-95-041  
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**CORRECTIVE ACTION REQUEST**

1. CONTROLLING DOCUMENT: QARD, DOE/RW-0333P, Revision 2	2. RELATED REPORT NO.: YM-ARP-95-09
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3. RESPONSIBLE ORGANIZATION: U.S. Geological Survey	4. DISCUSSED WITH: T. Chaney, B. Parks
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5. REQUIREMENT:  
SECTION 4.0, "Procurement Document Control," Paragraph 4.2.1 C.1, states in part, "a requirement for the supplier to have a documented Quality Assurance Program that implements applicable QARD requirements prior to the initiation of work."

6. ADVERSE CONDITION:  
Contrary to the cited requirement:

- Geometrics Incorporated performed calibration of magnetometer for USGS with past due Annual performance evaluation and the Triennial audit. The calibrations were performed and witnessed by USGS on surveillance 95002 SV (11/2/94) and 95027 SV (3/15/95) for Purchase Orders (PO) 1434 CR-94-PO-0331, 1434 CR-95-SA-0930, and 1434 CR-95-SA-0958.
- PCI Sales (unapproved supplier) performed calibration of MICROMETER Model MW-506 Flowmeter for USGS with USGS witnessing of the calibration on surveillance 95035 SV (4/13/95) for PO 1434 CR-95-SA-1048.

9. Does a Significant Condition Adverse to Quality exist? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No; 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
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11. Required Actions:  Remedial  Extent of Deficiency  Preclude Recurrence  Root Cause Determination

12. Recommended Actions:

7. Initiator: Donald J. Harris <i>Donald J. Harris</i> 5-15-95	14. Issuance Approved by: QADD <i>[Signature]</i> Date 5-17-95
15. Response Accepted QAR _____ Date _____	16. Response Accepted QADD _____ Date _____
17. Amended Response Accepted QAR <i>[Signature]</i> Date 7/10/95	18. Amended Response Accepted QADD <i>[Signature]</i> Date 7-13-95
19. Corrective Actions Verified QAR _____ Date _____	20. Closure Approved by QADD _____ Date _____

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

**1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95-041**

Background - This approach was undertaken to provide a method that supplement suppliers programs that are weak in the area of formal quality program documentation. It is the USGS position that Paras. 4.2.1 c 3 and 7.2 4 a of the QARD, as well as NQA-1 and 10 CFR 50, Appendix B, allow for this flexibility in selecting suppliers by responsibly managing and planning the overall procurement process.

This approach was developed because it is occasionally necessary for the USGS to obtain unique services from suppliers that do not maintain fully documented quality programs. In some situations, the service is one-time-only or very infrequent, or a very low dollar amount, for which there is little or no incentive for the supplier to invest in a more formal quality program. In other circumstances, the service is so unique that the number of suppliers is extremely limited.

The USGS plans to exercise this option on a limited basis, and to normally select suppliers with fully documented quality programs. To implement a more rigid approach would severely compromise the USGS's ability to provide a product that meets our technical standards.

**A. REMEDIAL ACTION:** Both of the instances identified, Geometrics and PCI/Micrometer, fit the circumstances described in the background information.

Geometrics had been maintained by the USGS as an Approved Supplier since 1989. As a result of CAR YM-94-050, the USGS removed Geometrics from the Approved Suppliers List (ASL) in November of 1994. Geometrics declined to develop a formal QA program citing that our work with them is extremely limited and it would not justify the expense. At this time, the USGS is unaware of other suppliers who can calibrate the magnetometers which were manufactured by Geometrics. However, it is the USGS position that the comprehensive Source Verification (copy attached) performed by the USGS demonstrated that the calibration work performed by Geometrics was completed with adequate quality.

PCI Sales/Micrometer - PCI Sales is merely the local (Denver area) representative for Micrometer, the company who manufactured the flow meter and performed the calibration. The flow meter was borrowed from REECO only to learn just before the flow test was to be performed, that it had not been calibrated. The meter was returned to the manufacturer for calibration. Again, the comprehensive Source Verification (copy attached) performed by the USGS demonstrates that the calibration was completed with adequate quality.

Certified Balance Services, Inc. (CBS) - Although not identified in the CAR, investigative action identified CBS as a supplier that does not have a documented quality program and that Source Verification was used to accept CBS work. CBS has been on the USGS ASL since 1991, but as a result of CAR YM-94-050, CBS will be deleted from the ASL. As a matter of note, CBS calibration standards are traceable to National Institute of Standards and Technology (NIST) through the Colorado Department of Agriculture. Also, NIST certifies the Colorado Department of Agriculture for the State of Colorado. All work in this one-man shop is done to manufacturer's procedures.

*initials* *Handwritten*

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

As a result of the comprehensive Source Verifications performed on the suppliers during their performance of the work, it is not believed that any Remedial Action is required. In all cases, it has been demonstrated that the work was performed in an adequate manner.

- B. **EXTENT OF THE DEFICIENCY:** As noted above, one additional Source Verification, beyond those identified in the CAR has been performed. See Attachment A for all Source Verifications performed by the USGS. Only those identified as Quality Related are subject to this CAR.
- C. **ROOT CAUSE DETERMINATION:** The root cause of the identified condition relates to the manner in which the QARD has been interpreted by the USGS and incorporated into Revision 7 of QMP-4.01.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** As noted in the Background Information, the approach to supplier selection and procurement planning is a planned process developed and implemented in a responsible manner. It is therefore the USGS position that no Corrective Action is required to preclude recurrence.

**NOTE:** If it is determined from the planned workshop with the DOE that the USGS approach is totally unsatisfactory, the flexibility provided by Revision 7 of QMP-4.01 will be removed. Alternatives to the approach have not yet been evaluated.

- 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.

None.

3. RESPONSE APPROVED:

Martha H. Mustard  
for Thomas H. Chaney  
YMP-USGS Quality Assurance Manager

6-15-95  
Date

Robert W. Craig  
for Larry R. Hayes  
Chief, Yucca Mountain Project Branch

6/15/95  
Date

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

**1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95-041**

As a result of discussions held with YMQAD representatives on June 27, 1995, it is necessary to amend our response to CAR YM-95-041. This meeting resulted in the consensus that using alternate procurement acceptance methods identified in the CAR, such as source verification, laboratory quality control plans and comprehensive receipt inspection to supplement incompletely documented QA programs is not provided for in the QARD. As a result, the USGS will submit to YMQAD a justification for using these methods in support of an exception to QARD requirements. The USGS will also provide specific criteria for their applications.

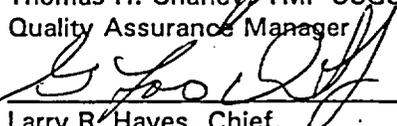
**2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.**

1. L.L. McInroy/T.H. Chaney                      7/30/95

**3. RESPONSE APPROVED**

  
\_\_\_\_\_  
Thomas H. Chaney, YMP-USGS  
Quality Assurance Manager

6/28/95  
Date

  
\_\_\_\_\_  
Larry R. Hayes, Chief,  
Yucca Mountain Project Branch

6/28/95  
Date

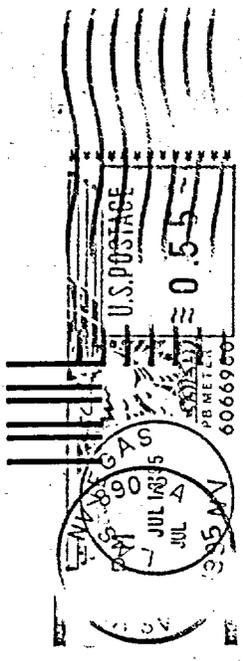
*120100                      Thomas H. Chaney*

United States Department of Energy  
Yucca Mountain Site Characterization  
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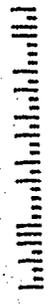
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**J. SPRAYL**

ARC  
DOCUMENT CONTROL DESK  
WASHINGTON DC 20555



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