



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

To: Ken Hooks

WBS 1.2.9.3
QA

JUL 17 1991

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-91-053 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-91-05 OF U.S. GEOLOGICAL SURVEY

The YMQAD staff has evaluated the response to CAR YM-91-053. The 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, Science Applications International Corporation, Las Vegas, Nevada.

If you have any questions, please contact Catherine E. Hampton at 794-7973 or John S. Martin at 794-7881.

Catherine Hampton for

Donald G. Horton, Director
Yucca Mountain Quality Assurance Division

YMQAD:CEH-4610

Enclosure:
CAR YM-91-053

cc w/encl:
K. R. Hooks, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:
J. W. Gilray, NRC, Las Vegas, NV
D. D. Porter, SAIC, Golden, CO

ORIGINAL
THIS IS A RED STAMP

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

14 CAR NO.: YM-91-53
DATE: 5/30/91
SHEET: 1 OF 2
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document
YMP-USGS-QMP-12.01, R5

2 Related Report No.
Audit No. YMP 91-05

3 Responsible Organization
USGS

4 Discussed With
Wayne Rodman

10 Response Due
6/28/91

11 Responsibility for Corrective Action
L. R. Hayes, USGS TPO

12 Stop Work Order Y or N
N

5 Requirement:
YMP-USGS-QMP-12.01, R5, Para. 5.2.1, states in part, "calibrations performed by YMP-USGS or contractor personnel are to be recorded"

6 Adverse Condition:
Documentation of calibration for mass spectrometer No. 1-6 and 2-6 has not been accomplished as procedurally mandated.

7 Recommended Action(s):
Identify the remedial action(s) to be taken to correct the deficiencies noted in Block 6. Investigate the program process, activities or documentation to determine the extent and depth of similar deficient conditions on the CAR. Identify these deficiencies and

8 Initiator
J. S. Martin
Date: 5/30/91

9 Severity Level -
1 2 3

13 Approved By:
OQA *Colin Hayden*
Date: 5/30/91

15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted:
QAR _____ Date _____

17 Closure Approved By:
OQA _____

ENCLOSURE

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CAR NO.: YM-91-53
DATE: 5/30/91
SHEET: 2 OF 2

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

7 Recommended Action(s) (continued)

provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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CAR NO. YM-91-53
DATE: _____
SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

CORRECTIVE ACTION RESPONSE:

1. CORRECTIVE ACTION FOR DEFICIENT CONDITION (CAR No. YM-91-53):

A. Extent of Deficiency:

NBS #1 6-Inch Mass Spectrometer: Under technical procedure NWM-USGS-GCP-12, R2, the mass spectrometers were calibrated as part of a system calibration after a maximum of 30 samples using Rb and Sr laboratory standards. Calibrations for the NBS #1 mass spectrometer were being performed in accordance with this technical procedure. On July 16, 1990, Revision 3 of GCP-12 was approved and became effective. At this time Branch of Isotope Geology investigators decided to discontinue use of the NBS #1 mass spectrometer for Yucca Mountain Project work. A closing calibration was performed and the instrument was shut down on July 19, 1990. However, Notification of Calibration Status forms were not issued to the USGS QA Office as required by YMP-USGS-QMP-12.01, R5, paragraph 5.4. Therefore, the Calibration Record maintained by the QA Office did not reflect the updated status of the mass spectrometer as documented in the laboratory notebook.

NBS #2 6-Inch Mass Spectrometer: Revision 3 of NWM-USGS technical procedure GCP-12 was approved and became effective on July 16, 1990. Under this revision, the mass spectrometer calibration procedure and frequency changed from calibrations to be performed with Rb and Sr laboratory standards every 30 samples, to calibrations to be performed with NIST traceable SRM Rb and Sr standards on an annual basis. The changes in the frequency and procedure requirements within the revised technical procedure were substantial enough to have required a mass spectrometer calibration under GCP-12 R3 prior to instrument use. However, the Branch of Isotope Geology investigator performing the calibrations on the mass spectrometer had interpreted the annual calibration requirement to mean that once GCP-12 R3 became effective, the laboratory had until July 16, 1991, to perform a calibration with the newly specified set of standards.

On March 4, 1991, a calibration was performed on the mass spectrometer in accordance with the requirements of GCP-12, R3. Analyses of the standards revealed that the mass spectrometer met acceptable performance criteria. Prior to March 4, operational checks of the mass spectrometer using laboratory standards were performed in accordance with GCP-12 R3. The results of these checks were also within acceptable limits as specified within the technical procedure. However, Notification of Calibration Status forms were not issued to the USGS QA Office as required by YMP-USGS-QMP-12.01, R5, paragraph 5.4. Therefore, the Calibration Record maintained by the QA Office did not reflect the updated status of the mass spectrometer as documented in the laboratory notebook.

Ltr dtd 6/28/91 - Change to NBS #1

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CAR NO. YM-91-53
DATE: _____
SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

CORRECTIVE ACTION RESPONSE (continued):

B. Root Cause: Branch of Isotope Geology contributing investigators performing calibrations for the YMP misunderstood their documentation responsibilities pertaining to the reporting and tracking of equipment calibration status as required by QMP-12.01.

C. Remedial Action: The Geologic Division QA Implementation Specialists will coordinate with the QA Office to assure that the Calibration Record will reflect the appropriate status of calibration for each mass spectrometer (NBS #1 and #2) by July 31, 1991.

D. Corrective Action to Prevent Recurrence:

NBS #1 6-Inch Mass Spectrometer: The lack of a Notification of Calibration Status form had no adverse affect on the quality of data acquired with the mass spectrometer. Branch of Isotope Geology investigators responsible for calibrations for the YMP will be given one-on-one instruction by a Geologic Division QA Implementation Specialist to emphasize the requirements of QMP-12.01 (Calibration) concerning use of calibration status forms, calibration status stickers, and the purpose and operation of the calibration tracking system. The instruction attendance shall be documented and completed by July 31, 1991.

NBS #2 6-Inch Mass Spectrometer: The misinterpretation of the requirements for annual calibration is an isolated occurrence. The investigator performing the calibrations has become aware of the requirements through the resolution of the problem. Based on the results of the operational checks and the March 4, 1991, calibration, the documentation deficiencies had no adverse affect on the quality of data acquired with the mass spectrometer. No additional preventive actions are warranted for this condition.

RESPONSE APPROVED BY: _____

DATE: 6/28/91

RESPONSE ACCEPTED _____

7-2-91
Date

RESPONSE ACCEPTED _____

Date

[Handwritten signatures]
QAR

See amended response for acceptance
QQA

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CAR NO. YM-91-53
DATE: _____
SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

SUPPLEMENTAL CORRECTIVE ACTION RESPONSE:

1. CORRECTIVE ACTION FOR DEFICIENT CONDITION (CAR No. YM-91-53)

- A. **Extent of Deficiency:** It was determined through DOE Audit 91-05 and the follow-up DOE surveillance 91-20 that the extent of this deficiency is limited to a single Activity and has no impact on the YMP-USGS calibration program as a whole. A thorough investigation of the affected Activity has taken place and all deficiencies have been documented by the YMP-USGS.

Response Accepted:


QAR

7-9-91
Date

Response Accepted:


OQA

7-9-91
Date

RESPONSE APPROVED BY:



DATE:

7/3/91