



Department of Energy

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

JUN 05 1996

Robert W. Craig
Acting Technical Project Officer
for Yucca Mountain
Site Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 4, Room 423, M/S 423
Las Vegas, NV 89134

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YMQAD-96-D048
RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD)
AUDIT YM-ARC-96-10 OF U.S. GEOLOGICAL SURVEY (USGS) (SCPB: N/A)

The YMQAD staff has evaluated the response to DR YMQAD-96-D048. The response has been determined to be unsatisfactory due to reasons as follows:

Quality Deficiency Report QDR-95056-2 cited by USGS as addressing the out of tolerance condition of analytical balances K59633 and 37060137 does not accurately document the condition or document determination of acceptability of data obtained using the equipment. A Nonconformance Report (NCR) will need to be generated to address the out of tolerance condition of analytical balances K59633 and 37060137 and the evaluation of the acceptability of the data obtained using these balances. QDR-95056-2 identified that a third balance was also found to be out of tolerance; this balance will need to be identified in the USGS response to this DR and data obtained using the balance evaluated for acceptability in the Nonconformance Report. Action to be taken to address the discrepancy between the calibration reports and the calibration certification regarding compliance with manufacturer specifications will also need to be addressed in the USGS response to this DR.

If the USGS is not able to substantiate the closing calibrations for the fission-track system identification numbers GCP-08-FT-A and GCP-08-FT-Z, a NCR will need to be generated to evaluate the acceptability of the data obtained using this equipment. The USGS response to this DR will need to reflect this. It is not acceptable to simply change the data to unqualified and reference this DR.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

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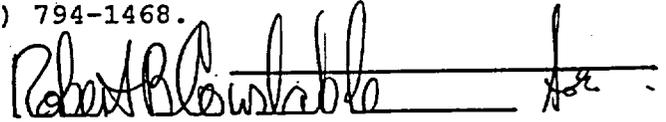
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Robert W. Craig

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If you have any questions, please contact either Robert B. Constable at (702) 794-5580 or Mary G. McDaniel at (702) 794-1468.

A handwritten signature in black ink, appearing to read "Robert B. Constable", is written over a horizontal line. To the right of the signature, there is a small, illegible mark.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1901

Enclosure:
DR YMQAD-96-D048

cc w/encl:
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
Records Processing Center

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

8 Performance Report
 Deficiency Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
YMP-USGS-QMP-12.01, Revision 6, Modification 2

2 Related Report No.
YM-ARC-96-10

3 Responsible Organization:
U.S. Geological Survey (USGS)

4 Discussed With:
W. Rodman / A. Whiteside / Z. Peterman

5 Requirement/Measurement Criteria:
USGS-QMP-12.01, Section 5.5.1, states: "Upon detection of a deficient condition, a Nonconformance Report (NCR) shall be prepared in accordance with YAP 15.1Q... Some of the items that constitute a deficient or nonconforming condition are as follows:

- Equipment found to be or suspected to be out-of-calibration (that is, beyond accepted tolerance established in technical procedures or in Scientific Notebooks) being used to collect data.
- No closing calibration per Paragraph 5.4.2."

6 Description of Condition:
Contrary to the above:
Issue 1: Documentation for calibrations performed for analytical balances K59633 and 37060137 on 5/16/95 indicate failure for both preliminary findings and final report. No NCR has been issued to document evaluations of the data obtained using this equipment, or justification for continued use of equipment.
Issue 2: No closing calibration has been documented for Fission-Track System id numbers GCP-08-FT-A and GCP-08-FT-Z and no NCR has been initiated.

7 Initiator: *Mary G. McDaniel* Date: *3/29/96*

9 QA Review
QAR: *Mary G. McDaniel* Date: *3/29/96*

10 Response Due Date
20 Working Days From Issuance

11 QA Issuance Approval
QAR (PRI/AOQAM (DR)) *[Signature]* Date: *4/10/96*

12 Remedial Actions:

13 Remedial Action Response By: *SEE ATTACHED RESPONSE* Date

14 Remedial Action Due Date
SEE ATTACHED RESPONSE Date

15 Remedial Action Response Acceptance
QAR Date

16 PR Verification/Closure
QAR *N/A* Date

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DEFICIENCY REPORT

17 Recommended Actions:

Issue 1: Issue NCR(s) to document out of tolerance conditions and evaluation of acceptability of data obtained using equipment.
Justify continued use of equipment; modify technical procedures as necessary.

Issue 2: Perform closing calibrations or issue NCR to document situation and evaluation of acceptability of data obtained using equipment.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response by:

SEE ATTACHED RESPONSE
Date

22 Corrective Action Completion Due Date:

SEE ATTACHED RESPONSE
Date

23 Response Accepted

QAR Date

24 Response Accepted

AOQAM Date

25 Amended Response Accepted

QAR Date

26 Amended Response Accepted

AOQAM Date

27 Corrective Actions Verified

QAR Date

28 Closure Approved by:

AOQAM Date

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RESPONSE FOR DEFICIENCY REPORT - YMQAD-96-D048

BLOCK 12 Remedial Actions:

ISSUE 1: None required. A Nonconformance Report (NCR) was not generated because a previously USGS deficiency document had identified a deficiency and effected resolution.

ISSUE 2: An NCR is not needed at this time because the actions are being taken in response to this DR. We are in contact with the person who performed the fission-track equipment calibrations and we anticipate obtaining the closing calibration information. If we are unable to substantiate the closing calibration, the Technical Data Information Form (DTN GS950483117452.001) in the affected data records package will be updated to reflect that the data are not qualified and to provide a reference to this DR.

BLOCK 13

Remedial Action Response by:



Bruce Parks, Associate Chief, Earth Science Investigations Program

5/9/96
Date

BLOCK 14 Remedial Action Due Date:

ISSUE 1: Not required.

ISSUE 2: June 28, 1996 (documented calibration or update data records package)

BLOCK 18 Investigative Actions:

ISSUE 1: The vendor's 5/16/95 calibration of analytical balances K59633 and 37060137 was witnessed as part of YMP-USGS Quality Assurance supplier verification USGS-95039 (Certified Balance Service [CBS]). Quality Deficiency Report QDR-95056-2 was initiated as a result of the verification activity. The QDR documents that although calibration results for several balances indicated readings did not meet manufacturer's specification, the out-of-tolerance conditions were within the technical procedure requirements for accuracy. Thus, there was no adverse impact on data. A Nonconformance Report would not have been needed because the QDR provided the necessary corrective actions.

ISSUE 2: This deficiency appears to be an isolated condition. Calibration documentation on file for fission-track equipment indicates GCP-08-FT-A was last calibrated on 10/6/94 and due for next calibration on 10/6/95; GCP-08-FT-Z was last calibrated on 11/17/94 and due for next calibration on 11/17/95. There is no evidence that the closing calibrations were conducted as scheduled because the personnel operating the equipment and conducting calibrations had been RIF'd by the USGS Geologic Division. The YMP-USGS Team Chief responsible for the fission-track activity was not aware that the employee was being RIF'd until after the fact. When the calibration reminder notice was issued, YMP-USGS personnel did not issue an NCR because they were trying to contact the RIF'd employee and obtain calibration information. A query of the ATDT indicates only one data records package included data acquired with the fission-track equipment after the last calibration. [DTN GS950483117452.001 includes data acquired from 10/6/94 to 3/4/95.] The fission-track equipment has not been used during FY96.

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⁸ Performance Report

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BLOCK 19 Root Cause Determination:

ISSUE 1: The calibration certification documentation was not annotated with a reference to this QDR, therefore, there was no traceability to the identification of a deficiency and subsequent resolution. The lack of the supplier verification report (USGS-95039-SV) hampered the efforts to retrieve the necessary information during the YMQAD Audit ARC-96-10.

ISSUE 2: An NCR was not initiated because efforts were still underway to contact the RIF'd employee and obtain the needed calibration documentation. Because we expected closing calibrations to be forthcoming, we did not view this as a deficient condition.

BLOCK 20 Actions to Preclude Recurrence:

ISSUE 1: The calibration certification documentation will be annotated with a reference to USGS QDR-95056. The problem involving the missing supplier evaluation report is being handled as part of YMQAD-96-D051.

ISSUE 2: The Isotope Hydrology Team Chief and Quality Assurance Implementation Specialist have been counseled through this DR to initiate NCRs when closing calibrations have not been performed or when calibration due dates have been exceeded.

BLOCK 21

Response by:

Bruce Parks
Bruce Parks, Associate Chief, Earth Science Investigations Program

5/9/96
Date

BLOCK 22 Corrective Action Completion Due Date:

ISSUE 1: 5/17/96 (annotate calibration documentation)

ISSUE 2: complete with this response