



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

JUL 22 1996

Robert W. Craig  
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 AMENDED RESPONSE TO DEFICIENCY REPORT (DR) YM-96-D-048  
RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD)  
AUDIT YM-ARC-96-10 OF U.S. GEOLOGICAL SURVEY (SCPB: N/A)**

The YMQAD staff has evaluated the amended response to DR YM-96-D-048. 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. Please send a copy of extension requests to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

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

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2179

Enclosure:  
DR YM-96-D-048

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  
D. G. Horton, OQA, NV

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**OFFICE OF CIVILIAN  
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U.S. DEPARTMENT OF ENERGY  
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8 ☐ Performance Report  
☒ Deficiency Report  
NO. YM-QAD-96-D048  
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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*  
Mary G. McDaniel  
3/29/96  
Date

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

10 Response Due Date  
20 Working Days From Issuance

11 QA Issuance Approval  
*[Signature]*  
QAR (PR)/AOCAM (DR)  
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 *Mary G. McDaniel*  
Date 7/2/96

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

23 Response Accepted

QAR Date

24 Response Accepted

AOQAM Date

25 Amended Response Accepted

QAR *Maurice D. [Signature]* Date 7/2/96

26 Amended Response Accepted

AOQAM *[Signature]* Date 7/19/96

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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**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

5/8/96  
Date

**BLOCK 22 Corrective Action Completion Due Date:**

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

**ISSUE 2:** complete with this response

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AMENDED RESPONSE FOR DEFICIENCY REPORT YMQAD-96-D048

The following information amends and supersedes the 8/9/96 response. To facilitate readability, the response now addresses each issue separately.

**ISSUE 1: Out-of-calibration conditions for analytical balances**

**BLOCK 12 Remedial Actions:** As recommended by the YMQAD letter dated 6/5/96, Nonconformance Report (NCR USGS-96-0002) has been initiated in accordance with YAP-15.1Q R2 to document that the vendor's calibration results indicated out-of-tolerance conditions for three balances (S/Ns: 37060137, 3502098, and K59633). The NCR disposition will include an evaluation of the associated technical procedure requirements and an evaluation of the acceptability of data obtained using these balances.

Additionally, the NCR includes the noted discrepancy between the vendor's calibration reports (showing failed to meet manufacturer specifications for 3 balances) and the calibration certification (indicating compliance with manufacturer specifications). As part of the actions necessary to satisfactorily resolve the NCR, Earth Science Investigations Program (ESIP) personnel will meet with the vendor to discuss the calibration certification process, associated problems and corrective actions. A course of action will be agreed upon to resolve this issue and will be described in the NCR disposition.

**BLOCK 13 Remedial Action Response by:**

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

*6/28/96*  
Date

**BLOCK 14 Remedial Action Due Date:** NCR USGS-96-0002 has been initiated (copy attached).

**BLOCK 18 Investigative Actions:** The vendor's 5/16/95 calibration of 4 analytical balances [S/N 37060137, 3502098, K59633, and 2709142] was witnessed as part of YMP-USGS Quality Assurance supplier verification USGS-95039 (Certified Balance Service [CBS]). The QA supplier verification report is missing and associated actions for the missing record are part of YMQAD-96-D051. The vendor-supplied calibration documentation includes calibration certification with calibration reports for the 4 balances. Calibration report results for 3 of the 4 balances indicated calibrations "failed" to meet manufacturer specifications. Initial indications were that although the balances indicated "failed" the readings were still within the work tolerances of the associated technical procedures. Therefore, Quality Deficiency Report QDR-95056-2 was initiated as a result of the QA verification activity, and it was determined that an additional deficiency document (NCR) would not be needed. The calibration certification documentation was not annotated with a reference to QDR-95056, therefore, there was no traceability to the identification of an associated deficiency document during YMQAD Audit ARC-96-10, and the lack of the supplier verification report (USGS-95039-SV) hampered the efforts to retrieve the necessary information during the YMQAD Audit. However, as noted in the 6/5/96 YMQAD letter to R.W.Craig, the QDR did not accurately document or resolve the deficiency involving 3 balance calibrations that failed to meet manufacturer specifications, and the QDR did not adequately resolve whether the nonconforming conditions were within the allowable tolerances of the technical procedures. An NCR now has been initiated to provide for documentation of the nonconforming conditions and resolution of the problems including the evaluation of associated technical procedure requirements and the evaluation of possible impact on associated data.

**BLOCK 19 Root Cause Determination:** An NCR was not generated at the time the nonconforming calibration condition was noted because personnel mistakenly thought the NCR to be redundant to the QDR. However, QMP-12.01 R6 did require an NCR for this situation.

**BLOCK 20 Actions to Preclude Recurrence:** The requirement to initiate NCRs has been re-emphasized via the corrective actions for YMQAD-96-D049. Additionally, key personnel have been reminded of the requirement for NCRs as they work with the response to this DR and the disposition for NCR USGS-96-0002.

**BLOCK 21 Response by:**

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

*6/28/96*  
Date

**Block 22 Corrective Action Completion Due Date:** DR actions completed with this response. Calibration-related actions will be handled in accordance with NCR USGS-96-0002.

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AMENDED RESPONSE FOR DEFICIENCY REPORT YMQAD-96-D048 continued

The following information amends and supersedes the 6/9/96 response. To facilitate readability, the response now addresses each issue separately.

**ISSUE 2: No closing calibration for fission-track equipment**

**BLOCK 12 Remedial Actions:** 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 appropriate closing calibration information. If we are unable to substantiate the closing calibration, an NCR will be initiated to evaluate the acceptability of the data obtained [as identified in Technical Data Information Form (DTN GS950483117452.001)] using the fission-track equipment. The affected data records package will be annotated based upon the NCR disposition.

**BLOCK 13 Remedial Action Response by:**

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

6/28/96  
Date

**BLOCK 14 Remedial Action Due Date:** July 31, 1996 (obtain documented calibration or initiate USGS NCR).

**BLOCK 18 Investigative Actions:** 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 (reduction in force) 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 the needed 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.

**BLOCK 19 Root Cause Determination:** 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 non-conforming condition.

**BLOCK 20 Actions to Preclude Recurrence:** 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

6/28/96  
Date

**Block 22 Corrective Action Completion Due Date:** complete with this response

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT  
NONCONFORMANCE REPORT

*Amu White*  
1. Initiator Name: Ardell M. Whiteside Organization: YMPB-ESIP-Climate/Isotope Hydrology Date: June 17, 1996

## 2. Description of Non-Conformance:

WBS#: 1.2.3.6.2.2SCP Activity: 6.3.1.5.2.1.3 & 5REQUIREMENT: QMP-12.01 R6. Instrument Calibration, paragraph 5.5.1 "Upon detection of a deficient condition aNonconformance Report (NCR) shall be prepared in accordance with YAP-15.1Q... o Equipment found to be or suspected to be out-of-calibration..." Continued on page 2

Job Package/

☒ Hold Tag Applied No. of Hold Tags Applied 2 (see Note on pg.2) Test Planning Package No. NA3. ☐ Validation☐ Invalidation☐ Q ☐ Non-Q

Name: \_\_\_\_\_ Organization: \_\_\_\_\_ Date: \_\_\_\_\_

## 4. Disposition Evaluation

☐ Rework☐ Repair☐ Use-As-Is☐ Conditional Release☐ Reject/Scrap☐ Limited Use☐ DiscardJustification/Comments:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

INFORMATION COPY

## 5. Disposition by:

Name: \_\_\_\_\_ Organization: \_\_\_\_\_ Date: \_\_\_\_\_

## 6. QA Concurrence With Disposition:

Corrective Action:

☐ No ☐ Yes No \_\_\_\_\_☐ Reportable ☐ Non-Reportable

Name: \_\_\_\_\_ Organization: \_\_\_\_\_ Date: \_\_\_\_\_

## 7. Completion of Disposition:

☐ Hold Tag Removed

No. of Hold Tags Removed \_\_\_\_\_

Name: \_\_\_\_\_ Organization: \_\_\_\_\_ Date: \_\_\_\_\_

## QA/QC Concurrence:

Name: \_\_\_\_\_ Organization: \_\_\_\_\_ Date: \_\_\_\_\_

## 8. Final Review:

Name: \_\_\_\_\_ Organization: \_\_\_\_\_ Date: \_\_\_\_\_



**BLOCK 2 Description of Non-Conformance (continued from page 1)**

**NONCONFORMING CONDITION(S):** A review of calibration documentation from a vendor (Certified Balance Service [CBS]) indicates deficient calibration conditions (ref.YMQAD-96-D048). Calibration documentation from the CBS's 5/16/95 calibration of 4 balances indicates out-of-manufacturer specification conditions for 3 balances [S/N 37060137, 3502098, and K59633]. Additionally, the CBS calibration certificate was issued to accompany the calibration reports for the 3 balances with out-of-tolerance conditions yet the calibration certificate states "...found to be within manufacturers specifications".

**NOTE:** Hold Tags for this NCR applied to: 1) original CBS 1995 calibration certification documentation on file with Isotope Hydrology personnel, and 2) Balance 3502098. CBS's 1996 calibration results for balance 37060137 and balance K59633 have been documented in NCR USGS-96-0003.

INFORMATION COPY