Department of Energy
Washington, DC 20585

QA: QA

JUL 19 2002

Bruce Parks, Acting Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
P.O. Box 25046, M/S 421
Denver, CO 80225

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT (DR) USGS-01-D-105 RESULTING FROM THE OFFICE OF QUALITY ASSURANCE (OQA) AUDIT USGS-ARC-01-011

The OQA staff has evaluated the corrective action of DR USGS-01-D-105 and determined the results to be satisfactory. As a result, the DR is considered closed.

Out-of-calibration reports initiated as a result of this DR indicate that there was no impact on data.

If you have any questions, please contact James Blaylock at (702) 794-1420.

Ram B. Murthy, Acting Director
Office of Quality Assurance

OQA:JB-1421

Enclosure:
DR USGS-01-D-105

Printed with soy ink on recycled paper

NMSSO7
WM-11

cc w/encl:
James Blaylock, DOE/OQA (RW-3), Las Vegas, NV
N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV
S. W. Lynch, State of Nevada, Carson City, NV
Engelbrecht von Tiesenhausen, Clark County, Las Vegas, NV
M. H. Mustard, USGS, Denver, CO
W. B. Scott, USGS, Las Vegas, NV
D. J. Sinks, BSC, Denver, CO
A. M. Whiteside, BSC, Denver, CO
R. W. Andrews, BSC, Las Vegas, NV
G. K. Beall, BSC, Las Vegas, NV
Ken Hess, BSC, Las Vegas, NV
S. H. Horton, BSC, Las Vegas, NV
R. P. Keele, BSC, Las Vegas, NV, M/S 280
D. T. Krisha, BSC, Las Vegas, NV
T. J. Wall, BSC, Las Vegas, NV
D. M. Kunihiro, BSC, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
D. H. Coleman, DOE/YMSCO, Las Vegas, NV
J. R. Dyer, DOE/YMSCO, Las Vegas, NV
C. E. Hampton, DOE/YMSCO, Las Vegas, NV
D. G. Horton, DOE/YMSCO, Las Vegas, NV
J. M. Replogle, DOE/YMSCO, Las Vegas, NV
B. M. Terrell, DOE/YMSCO, Las Vegas, NV

NMSS 07
WM 11

ORIGINAL

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

8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION REPORT

NO. USGS-01-D- 105

PAGE 1 OF

QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document:
AP-12.1Q / Rev. 0 / ICN 1

2. Related Report No.: Audit
USGS-ARC-01-011

3. Responsible Organization:
US Geological Survey

4. Discussed With:
P Stiffler, M. Mustard, P. Motyl

5. Requirement:
(1) ¶ 5.2.1 in part requires the Measuring and Test Equipment (M&TE) Custodian maintain and be responsible for an up-to-date list of M&TE...

(2) ¶ 5.3.1c)1) and 2) states in part that for M&TE calibrated internally that procedures are developed and maintained for the calibration or the calibration is documented in a scientific notebook, and the documentation address the following: Detailed description of calibration method. Identification of tolerances and range of use.

(3) ¶ 5.7.1a)5) states that M&TE is out of calibration if, during recalibration, it is found to be out of allowed specification tolerances.

6. Description of Condition:
Contrary to (1) and (2) above Scientific Notebook SN-0099, V1, pages 68-80 record the calibration of seventeen heat dissipation probes (HDP). None of the HDPs appear on the master M&TE list. The documentation of the HDP does not clearly reference the calibration procedure nor describe the tolerance or range of use. In addition there is an extensive overdue calibration list for M&TE with an Active status. Most of the overdue M&TE are assigned to a single USGS PI.

Contrary to (3) above, Satorius balance #3404009 was calibrated on 6/29/99 and 12/7/00 and found to exceed the manufacturer's tolerances for the "as found" condition. Neither on Out-of-Calibration Report nor a Nonconformance Report was initiated.

7. Initiator:
James Blaylock
James Blaylock Date 3 July 2001

9. Does a stop work condition exist? (Not required for a DR)
☐ Yes ☒ No
If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:
NONE

11. QA Review:
QAR JAMES BLAYLOCK James Blaylock Date 7/17/01

12. Response Due Date:
10 Working Days From Issuance

13. DOQA Issuance Approval:
Printed Name Robert W. Clark Signature James Blaylock Date 7/18/01

22. Corrective Actions Verified:
QAR JAMES BLAYLOCK James Blaylock Date 6/26/02

23. Closure Approved by:
DOQA James Blaylock Date 6/26/02

Exhibit AP-16.1Q.1 Rev. 12/20/1999

TYPE RESPONSE:
☒ Initial
☒ Complete
☐ Amended

ORIGINAL

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

DR/CAR NO. USGS-01-D-105
PAGE OF
QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Action:
None needed.

Compliance Date:

14. Remedial Actions:
Conditions 1 and 2: Upon completion of the investigative actions, the USGS M&TE List will be updated to include all active M&TE and to reclassify any M&TE that will not be used any longer for YMP data collection. The seventeen cited HDPs will be entered into the USGS M&TE List with a reference to this DR. An explanation referencing this DR will be added to the Scientific Notebook SN-USGS-SCI-099-V1 record package. This explanation will include a more detailed description of the calibration method and provide the range, tolerance, and standards used for the calibration of HDPs recorded on pages 68-80 in a more organized manner. The explanation will be submitted to RPC by 09/30/2001.
(Continued on next page)

15. Extent of Condition:
Extent:

Conditions 1 and 2: The USGS PI with most of the overdue M&TE is no longer active on the YMP USGS project for data collection. Some of his work was terminated and some transitioned to another PI who has since left the project completely. A third PI has now inherited all his active work. The third PI is doing an equipment inventory to identify status and location of the equipment that he has inherited. From the inventory, he will determine the disposition of the equipment. Any other M&TE listed as overdue for calibration will be investigated independently with the responsible PI or designee.

Pages 8-9 of Scientific Notebook SN-USGS-SCI-0099-V1 included a detailed description of calibration method as planned but not as performed. Range was also provided on pages 8-9. The tolerances (errors) are provided on page 41. The calibration standards used for the probes cited are listed on page 69.

(Continued on next page)

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)
Conditions 1 and 2: Transition of responsibility occurred twice in a relatively short time and included personnel who were leaving the project. The check out system for personnel leaving the project did not address transitioning this responsibility and the close-out process for terminated work (i.e., closing calibrations) was not adequately planned or funded.

Condition 3: Inattention to detail.

17. Action to Preclude Recurrence:
Conditions 1 and 2: The check out system for personnel leaving the project will include a coordination with the USGS M&TE Custodian to assure that the active M&TE is either properly inactivated or that the USGS M&TE List reflects transition to another active PI. In the future, when activities are completed or the Project decides to discontinue them, USGS will recommend that work scope be funded to provide an adequate close-out.

Condition 3: The cover letter for the next Quarterly USGS Status of Calibration report (scheduled for October 2001) will remind all responsible PIs with active calibrated M&TE to examine their vendor calibration certificates for acceptability of the as-found conditions.

18. Due Date: April 30, 2002
☐ For submittal of complete response
☒ For completion of corrective action

19. Response by: Robert W. Craig
Robert W. Craig
Date 08/07/2001 Phone (702) 295-5456

20. Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject
QAR James Blaylock Date 8/9/01

21. Concurrence:
DOQA James Blaylock for Date 8/9/01

Exhibit AP-16.1Q.1 Rev. 12/20/1999

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

8. ☒DR/CAR
☐ Stop Work Order

NO. USGS-01-D-105

PAGE OF

QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Block 14 Remedial Actions (continued):

Condition 3: USGS Out Of Calibration Reports (OCRs) USGS-2001-032 and USGS-2001–033 have been written to document the out of calibration conditions for Sartorius balance S/N 3404009 and Mettler balance E10807, respectively. Both OCRs were closed on 7/20/01.

Block 15 Extent of condition (continued):

Extent: (continued):

Condition 3: The three balances in the YMP USGS lab in Building 56 on the Denver Federal Center were investigated to identify any out of tolerance conditions noted on their calibration certificates. Per the governing technical procedure (YMP-USGS-HP-126), there were no out of tolerance conditions for Mettler balance S/N E20655. Out of calibration conditions were noted on the 6/9/99 calibration and the 12/7/00 calibration for Sartorius balance S/N 34040009 (as identified in block 6) and on the 6/29/01 calibration for Mettler balance S/N E10807.

Impact:

Conditions 1 and 2: There is no lasting impact due to the lack of appropriate tracking of the M&TE. When the investigative actions are complete, all equipment will have been appropriately accounted for.

Condition 3: The impact of these conditions were evaluated on the OCRs. Both OCRs indicated that there was no impact on data.

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

8. ☒ DR/CAR
☐ Stop Work Order

NO. USGS-01-D-105

QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

REQUEST FOR EXTENDED PROCESSING

Actions that will not be complete within Normal Processing:

Normal Processing will be over on October 19, 2001. The equipment inventory and the equipment disposition and the subsequent updating of the USGS M&TE List will not be complete within Normal Processing.

Justification for the additional time required:

Additional time (beyond Normal Processing) is required to complete the equipment inventory and equipment disposition due to the unplanned and unfunded nature of this work. Personnel currently working on this task are funded for other activities with deadlines that cannot be disregarded. Funding into next fiscal year is currently uncertain but, assuming funding for the close-out during FY2002, the actions should be complete by April 30, 2002.

Impacts:

There is no negative impact on data due to the extended processing of these actions because, as the need is identified, closing calibrations will be performed. The USGS M&TE List will remain a reliable tracking system except for M&TE assigned to personnel IDs 86, 157, 1106, and 1176.

Responsible Individual:

Robert W. Craig — 8/1/01

Robert W. Craig, Chief, Yucca Mountain Project Branch — Date

TYPE RESPONSE:
☐ Initial
☒ Complete
☒ Amended

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

DR/CAR NO. USGS-01-D-105
PAGE OF
QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Action:
None needed.

Compliance Date:

14. Remedial Actions:
Conditions 1 and 2: Upon completion of the investigative actions, the USGS M&TE List will be updated to include all active M&TE and to reclassify any M&TE that will not be used any longer for YMP data collection. The seventeen cited HDPs will be entered into the USGS M&TE List with a reference to this DR. An explanation referencing this DR will be added to the Scientific Notebook SN-USGS-SCI-099-V1 record package. This explanation will include a more detailed description of the calibration method and provide the range, tolerance, and standards used for the calibration of HDPs recorded on pages 68-80 in a more organized manner. The explanation will be submitted to RPC by 10/26/2001.
(Continued on next page)

15. Extent of Condition:
Extent:
Conditions 1 and 2: The USGS PI with most of the overdue M&TE is no longer active on the YMP USGS project for data collection. Some of his work was terminated and some transitioned to another PI who has since left the project completely. A third PI has now inherited all his active work. The third PI is doing an equipment inventory to identify status and location of the equipment that he has inherited. From the inventory, he will determine the disposition of the equipment. Any other M&TE listed as overdue for calibration will be investigated independently with the responsible PI or designee.

Pages 8-9 of Scientific Notebook SN-USGS-SCI-0099-V1 included a detailed description of calibration method as planned but not as performed. Range was also provided on pages 8-9. The tolerances (errors) are provided on page 41. The calibration standards used for the probes cited are listed on page 69.

(Continued on next page)

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)
Conditions 1 and 2: Transition of responsibility occurred twice in a relatively short time and included personnel who were leaving the project. The check out system for personnel leaving the project did not address transitioning this responsibility and the close-out process for terminated work (i.e., closing calibrations) was not adequately planned or funded.

Condition 3: Inattention to detail.

17. Action to Preclude Recurrence:
Conditions 1 and 2: The check out system for personnel leaving the project will include a coordination with the USGS M&TE Custodian to assure that the active M&TE is either properly inactivated or that the USGS M&TE List reflects transition to another active PI. In the future, when activities are completed or the Project decides to discontinue them. USGS will recommend that work scope be funded to provide an adequate close-out.

Condition 3: The cover letter for the next Quarterly USGS Status of Calibration report (scheduled for October 2001) will remind all responsible PIs with active calibrated M&TE to examine their vendor calibration certificates for acceptability of the as-found conditions.

18. Due Date: April 30, 2002
☐ For submittal of complete response
☐ For completion of corrective action

19. Response by: Robert W. Craig
Robert W. Craig
Date 09/27/2001 Phone (702) 295-5456

20. Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject
James B Blaylock
QAR James B. Blaylock Date 10/3/01

21. Concurrence:
DOQA James B Blaylock for Date 10/4/01

Exhibit AP-16.1Q.1 Rev. 12/20/1999

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	8. ☒ DR/CAR ☐ Stop Work Order NO. USGS-01-D-105 PAGE OF QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Block 14 Remedial Actions (continued):

Condition 3: USGS Out Of Calibration Reports (OCRs) USGS-2001-032 and USGS-2001–033 have been written to document the out of calibration conditions for Sartorius balance S/N 3404009 and Mettler balance E10807, respectively. Both OCRs were closed on 7/20/01.

Block 15 Extent of condition (continued):

Extent: (continued):

Condition 3: The three balances in the YMP USGS lab in Building 56 on the Denver Federal Center were investigated to identify any out of tolerance conditions noted on their calibration certificates. Per the governing technical procedure (YMP-USGS-HP-126), there were no out of tolerance conditions for Mettler balance S/N E20655. Out of calibration conditions were noted on the 6/9/99 calibration and the 12/7/00 calibration for Sartorius balance S/N 34040009 (as identified in block 6) and on the 6/29/01 calibration for Mettler balance S/N E10807.

Impact:

Conditions 1 and 2: There is no lasting impact due to the lack of appropriate tracking of the M&TE. When the investigative actions are complete, all equipment will have been appropriately accounted for. Use of data without associated closing calibrations is controlled through the TDMS and the TBV systems. Data collected with calibrated M&TE are considered non-Q until the closing (after-use) calibrations have been performed or the situation has been evaluated under an Out-of-Calibration Report (except for non-retrievable M&TE which does not require after-use calibration). Any Q use of data associated with the overdue M&TE is tracked using the AP-3.15Q TBV system (except input data that are considered QVL-2 and therefore are not required to be verified.) Impacts will be evaluated on a case-by-case basis with the initiation and disposition of OCRs, as needed.

Condition 3: The impact of these conditions were evaluated on the OCRs. Both OCRs indicated that there was no impact on data.

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

8. ☒ DR/CAR
☐ Stop Work Order

NO. USGS-01-D-105

PAGE OF

QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

REQUEST FOR EXTENDED PROCESSING

Actions that will not be complete within Normal Processing:

Normal Processing will be over on October 26, 2001. The equipment inventory and the equipment disposition and the subsequent updating of the USGS M&TE List will not be complete within Normal Processing.

Justification for the additional time required:

Additional time (beyond Normal Processing) is required to complete the equipment inventory and equipment disposition due to the unplanned and unfunded nature of this work. Personnel currently working on this task are funded for other activities with deadlines that cannot be disregarded. Funding into next fiscal year is currently uncertain but, assuming funding for the close-out during FY2002, the actions should be complete by April 30, 2002.

Impacts:

There is no negative impact on data due to the extended processing of these actions because, as the need is identified, closing calibrations will be performed. Impacts will be evaluated on a case-by-case basis with the initiation and disposition of the associated OCRs. Status of data is controlled through the AP-3.15Q TBV system and the TDMS system. The USGS M&TE List will remain a reliable tracking system except for M&TE assigned to personnel IDs 86, 157, 1106, and 1176.

Responsible Individual:

Robert W. Craig 09/27/2001

Robert W. Craig, Chief, Yucca Mountain Project Branch Date

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

8. ☒DR/CAR
☐ Stop Work Order

NO. USGS 01-D-105

PAGE OF

QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

APPROVAL SIGNATURES FOR REQUEST FOR EXTENDED PROCESSING FOR DR USGS-01-D-105 (EXTENDED PROCESSING REQUESTED UNTIL 4/30/02)

DOE Project Manager

10/4/01
Date

Acting Director, Office of Quality Assurance

10/5/01
Date

Submittal Page 1 of 1

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

☒ DR/CAR/QO
☐ SWO

No: USGS-01-D-105

Page ___ of ___

QA: QA

CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

VERIFICATION OF CORRECTIVE ACTION FOR DEFICIENCY REPORT (DR) USGS-01-D-105

The Scientific Notebook, SN-USGS-SCI-0099-VI, was amended to describe the calibration heat dissipation probes (HDP), reference to the range, tolerance, and standards used for calibration was recorded in a more organized manner, and the seventeen (17) HDPs were added to the M&TE Master List. The SN records package was amended to reference USGS-01-D-105.

The M&TE list was examined. No examples were identified of active M&TE not being on the current list. In addition, the overdue calibration list had a total of three (3) items of which two pieces on the overdue list had been placed on the list the week before the verification activity was initiated.

Out-of-calibration reports (OCR) were initiated for the Sartorius balance (SN 34040009) for which two calibration certificates indicated an out-of-calibration condition for the as found condition. The documentation for the OCRs included an impact on the data generated by the use of the Sartorius balance.

J Blaylock 6/26/02
Ja[illegible] [illegible]laylock, QAR

The Quarterly Calibration Report dated Oct. 16, 2001, reminded PIs to review calibration certificates for completeness to include as found calibration information.

James Blaylock
6/26/02

Template AP161-2

Rev 3/25/02