



Department of Energy

Washington, DC 20585

QA: L

SEP 11 1997

L. D. Foust, Technical Project Officer
for Yucca Mountain Site
Characterization Project
TRW Environmental Safety Systems, Inc.
1180 Town Center Drive, M/S 423
Las Vegas, NV 89134

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-036
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) AUDIT
SNL-ARP-97-014 OF SANDIA NATIONAL LABORATORIES

The OQA staff has evaluated the response to DR YM-97-D-036. 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 Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Kenneth O. Gilkerson at (702) 794-1486.

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2188

Enclosure:
DR YM-97-D-036

- cc w/encl:
- T. A. Wood, DOE/HQ (RW-55) FORS
- J. O. Thoma, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- B. R. Justice, M&O, Las Vegas, NV
- R. A. Morgan, M&O, Las Vegas, NV

- cc w/o encl:
- W. L. Belke, NRC, Las Vegas, NV
- K. O. Gilkerson, OQA/QATSS, Las Vegas, NV
- D. G. Sult, OQA/QATSS, Las Vegas, NV
- R. W. Clark, DOE/OQA, Las Vegas, NV

11
102.7
WM-11
RH 33

9709220020 970911
PDR WASTE
WM-11 PDR



Recip:



Printed with soy ink on recycled paper

130073

MMS/pahl

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

8 Performance Report
 Deficiency Report
NO. YM-97-D-036
PAGE 1 OF 2
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
DOE/RW 0333P, QARD Revision 5

2 Related Report No.
SNL-ARP-97-014

3 Responsible Organization:
M&O SPO

4 Discussed With:
Michael Brady, Larry Hayes

5 Requirement/Measurement Criteria:
Supplement III.2.5 A states: "Traceability to its [unqualified data] status as unqualified data shall be maintained."
Supplement III.2.3 A requires that "Data shall be identified in a manner that facilitates traceability to associated documentation."

Note that QARD Revision 6 Supplement III. 2.3 B states "Data shall be identified in a manner that facilitates traceability to its qualification status."

YAP SIII.3Q paragraph 5.2 requires that data be identified and tracked as *preliminary* if the acquired data has not received the confirmation of quality assurance. Paragraph 5.3 requires unqualified data to be identified as such on the TDIF.

6 Description of Condition:
Data was obtained from instrumentation installed in the ESF Alcove 5 for the Single Element Heater Test that was not calibrated and/ or not qualified as required by the OCRWM QA program elements 4, 7 and 12 resulting in the data not being "qualified"(see related DR 97-D-025 issued to the M&O). Additionally, the reports resulting from this data and the data submitted into the Technical Information Database are not flagged and identified as suspect or unqualified or preliminary. These instruments and equipment were procured by the M&O for installation by the labs. The M&O is responsible for coordinating the tests and data and DR responses (including corrective action) with the labs.
Discussion: It was noted during the audit of the M&O at SNL that the remedial action for DR 97-D-025 requires the PI to perform a review of data for impact of the instrumentation being installed without appropriate calibrations being performed. This review was not required to be performed, documented or submitted until August 1997; yet data has been collected and submitted on TDIFs as qualified data and two reports have been generated without flagging the data as unqualified or indeterminate (SNLs SLTR *Pre-Experiment Thermal Hydrological-Mechanical Analyses for the Single Heater Test- Phase 2* and the M&O document *Single Heater Test Interim Report*).

7 Initiator
K.O. Gilkerson Date 04/21/97

9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)
1. Review reports and TDIFs for similar conditions relative to other equipment being used that have open deficiency reports against them that would impact the integrity of the data.
2. Develop a system (similar to the M&Os TBV/TBD design methodology) for flagging data in reports for situations similar to the above, as well as with respect to dissemination of site characterization data from other than the Technical Database (TDB).

11 QA Review
QAR [Signature] Date 4/24/97

12 Response Due Date
Twenty Working Days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name DONALD G. HORTON

Signature [Signature]

Date 5/2/97

22 Corrective Actions Verified

QAR Date

23 Closure Approved by: (N/A for PR)

ADDAM Date

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

PR/DR NO. YM-97-D-036
PAGE OF
QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SNL has completed an investigation of the impact of DR YM-97-D-025 on the data collected and have identified no adverse impact. The current qualification status of Q on the TDIFs is accurate. The M&O report "Single Heater Test Interim Report" is identified as QA:N/A. No further remedial action is required for the two items originally identified in this DR.

15 Extent of Condition: (Not required for PR)

Twenty-eight TDIFs and reports applicable to this work were examined. One additional report titled "1st Quarter Thermal and Mechanical Results", DTN# SNF35110695001.003 was issued as Q prior to completing corrective action for DR YM-97-D-025. This oversight was corrected as noted in block 14 above. No other TDIFs/reports contained data incorrectly identified as Q due to outstanding DRs on instrumentation.

16 Root Cause Determination: (Not required for PR)

See attached.

Required: Yes No

17 Action to Preclude Recurrence: (Not required for PR)

Required: Yes No

1. The lead PI for thermal testing for LBNL, LLNL, and SNL and the SPO Thermal Manager will retrain to YAP-SIII.3Q by August 30, 1997.
2. Future corrective action responses submitted by the SPO Manager will be evaluated prior to submittal to ensure impact to data determinations are addressed in a timely manner starting August 8, 1997.
3. The SPO Manager will request an OQA audit/surveillance of the Department of Energy's technical data tracking system to determine the overall effectiveness of the program by August 10, 1997.

18 Corrective Action Completion Due Date:

08/30/97

19 Response by: Andrew Burningham

Andrew Burningham

Date 08/03/97

Phone 5-5070

20 Response Accepted

QAR

[Signature]

Date

8/12/97

21 Response Accepted (N/A for PR)

QOQA

[Signature]

Date

9/10/97

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Page 1 of 4

Refer to Subsection 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. Identify the adverse condition.
Data generated by M&TE with deficiencies documented in DRs were included in reports and TDIFs without the data being identified as suspect as required by YAP-SIII.3Q.

2. Indicate *Where* the condition was found.
Reports "Pre-Experiment Thermal Hydrological-Mechanical Analysis for the Single Heater Test - Phase 2" and "Single Heater Test Interim Report" were initially identified as locations where this data were not properly identified.

3. Note *When* the condition was first found.
This condition was documented by DR YM-97-D-036 on 5/21/97 and resulted from audit SNL-ARP-97-014.

4. Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)
Repository (Scientific Investigations) is affected by this condition.

5. Denote the specific area(s) or discipline(s) of the major program element the condition occurred.
(e.g., engineering, design, ES&H)
This condition is specific to data collected from the Thermal Test Facility in WBS element 1.2.3.14 by M&O personnel.

6. Determine if the condition is isolated or recurring.
See attached.

7. Determine if the condition is hardware (item) or programmatic (procedures, personnel) related or both.
The condition is programmatic in nature.

8. Denote what organizations are affected by this condition (M&O, USGS, Weston, OCRWM, etc.).
LBNL, LLNL, SNL and the SPO have generated reports/TDIFs with Single Heater Test data. This condition has the potential to affect any YMP participant who uses data from reports or other sources where the status of the data is not correctly identified.

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

9 Document the changes that have taken place that could have caused the condition.

No recent changes seem relevant to the cause of this condition.

10. Determine the need for sketches or photographs.

No sketches or photographs apply to this condition.

11. Determine the need for laboratory tests.

No laboratory tests apply to this condition.

12. Identify the physical evidence examined.

No physical evidence relates to this condition.

13. Note the relevant documents reviewed.

See attached.

14. Document any other information that may be pertinent to supporting the selection of the correct root cause.

N/A

15. Interviews conducted: Yes No

If Yes, refer to page 3 of this attachment.

RI or designee: (Print)
Andrew Burningham

Signature:



Date:

8/4/97

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

TELEPHONE OR PERSONAL INTERVIEW RECORD

Person Interviewed: (Print)

Title:

Organization/Location:

Telephone No.:

Date/Time:

CAR No./DR No.:

Interview Details:

N/A

Interviewer

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE**

Root Cause Code:
10 A (2Ab and 3Cb)

CAR No./DR No.:
YM-97-D-036

Root Cause:
Miscellaneous or Multiple Areas (Personnel - Lack of Attention to a Task and Oversight and Management System Corrective Action - Untimely corrective action.)

Justification or Rationale for Selected Root Cause:

Multiple causes resulted in this DR being issued. As indicated in the DR YM-97-D-036 another DR had already identified that calibrations of Measuring and Test Equipment (M&TE) were inadequate. In that DR, YM-97-D-025, the corrective action of the PI determining the impact on the data was grouped with the other corrective action as being due on August 30, 1997. As data had the potential to be reported prior to that date, the action to determine the impact to data should have been called out with a more timely corrective action deadline.

Regardless of when the determination on data was to be made, YAP-SIII.3Q requires preliminary data to be identified as such. It should be noted that, of the reports identified in the DR, "Pre-Experiment Thermal Hydrological-Mechanical Analyses for the Single Heater Test-Phase 2" was issued before DR YM-97-D-025 was issued, that the report does not contain data from the instruments identified in DR 025, and that the report is identified as "Information Only - Do Not Reference". In addition, the report titled "Single Heater Test Interim Report" is identified as QA:N/A. When the requirement to determine the adverse impact of DR YM-97-D-025 was initiated, personnel committed an oversight in not taking into account data already issued as Q.

Designee: (Print)
Andrew Burningham

Signature:



Date:

8/4/97

RI: (Print)
Larry Hayes

Signature:



Date:

8/4/97

Block 6 continued

A request for investigative action of similar situations in reports to lab leads and SPO technical leads identified one additional report, "Evaluate Measurements and Analyze Single Heater Test First Quarter Results" with data not appropriately qualified. The two reports cited in the DR were identified as QA:N/A or had the statement "For Information Only - Do Not Reference" thus indicating the non-qualified status of the data.

Twenty eight TDIFs related to the Thermal Alcove (Single Heater Test) were identified: 9 by LBNL, 15 by LLNL, and 4 by SNL. Based on responses from PI organizations, no deficiencies issued against instruments have impacted data identified as Q in the technical database. LBNL and LLNL have determined that DRs on instrumentation have had no impact to data and that the current identification of Q is correct. SNL has not yet collected data with thermocouples identified in YM-97-D-051. SNL has completed the corrective action task from DR YM-97-D-025 of identifying the impact of the adverse condition on the data. They have determined that the data were not affected.

Block 13 continued

Note that DR YM-97-D-036 was incorrectly identified as YM-97-D-037 in an initial correspondence resulting in the mislabeling of the subject DR in several of these correspondence.

- Quality Assurance Deficiency Log Application - electronic format.
- SPO Deliverables tracking database - electronic format.
- Technical Database - electronic format.
- YAP-SIII.3Q, R0 dated 5/6/96.
- Report "Pre-Experiment Thermal Hydrological-Mechanical Analyses for the Single Heater Test - Phase 2", dated 12/13/96.
- Report "Evaluate Measurements and Analyze Single Heater Test First Quarter Results", dated 1/17/97.
- Report "Single Heater Test Interim Report", dated February 1997.
- Memorandum Costin to Elkins dated 5/16/97.
- IOC Hayes to Distribution "Investigative Action Related to YM-97-D-037", dated 7/9/97.
- Electronic Correspondence Schelling to Burningham "Response to 7/9 Hayes Memo Re: YM-97-D-037", dated 7/11/97.
- Electronic Correspondence Mustard to Burningham "USGS Input into Investigative Actions", dated 7/17/97.
- Electronic Correspondence Hoxie to Burningham "Investigative Action Related to YM-97-D-037", dated 7/21/97.
- Electronic Correspondence Smith to Burningham "YM-97-D-037", dated 7/22/97.
- Electronic Correspondence Clevenger to Burningham "Deficient data or instrumentation", dated 7/23/97.
- Electronic Correspondence Peters to Burningham "1.2.3.14.2 Reports Related to DR YM-97-D-036", dated 7/24/97.
- Electronic Correspondence Monks to Burningham "DR-036", dated 7/31/97.