



## Department of Energy

Washington, DC 20585

QA: L

AUG 08 1997

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for Yucca Mountain Site  
Characterization Project  
TRW Environmental Safety Systems, Inc.  
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Las Vegas, NV 89134

**EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-048  
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) AUDIT  
LLNL/LBNL-ARP-97-16 OF LAWRENCE BERKELEY NATIONAL LABORATORY**

The OQA staff has evaluated the response to DR YM-97-D-048. 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-2034

Enclosure:  
DR YM-97-D-048

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

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☐ Performance Report  
☒ Deficiency Report

NO. YM-97-D-048

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**PERFORMANCE/DEFICIENCY REPORT**

**1 Controlling Document:**

DOE/RW-0333P Revision 5, QARD YMP-LBNL-QIP-SI3.0 Revision 1

**2 Related Report No.**

LLNL/LBNL-ARP-97-16

**3 Responsible Organization:**

M&amp;O- LBNL

**4 Discussed With:**

Don Mangold, Yvonne Tsang

**5 Requirement/Measurement Criteria:**

QARD SI3.2.2.B requires that Scientific Notebooks contain the following: "1. Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics. 2. Identification of method(s) and computer programs to be used. 3. Identification of any samples or measuring and test equipment used. 4. Description of work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries. 5. Descriptions of changes made to methods used, as appropriate."

QARD SI3.2.2.C also requires that notebooks are required to reviewed such that the investigation can be retraced and results confirmed without recourse to the originator.

YMP-LBNL-QIP-SI3.0 Rev 1 Mod 1 require first scientific notebook entries to address task description, objectives, equipment to be used, signatures for entries, procedures or methods to be used, etc. The procedure also requires that blank pages be annotated.

**6 Description of Condition:**

Scientific notebooks for ESF Thermal Tests do not comply with the requirements of LBNL's procedure and QARD requirements. Two scientific notebooks reviewed during the audit do not consistently meet these requirements. In Scientific Notebook YMP-LBL-3BH-1 adverse conditions include: (1) Objectives, project status, work to be performed, equipment, materials and procedures to be used, and signatures were not made *during the first entry* as required; (2) dates of when entries were made are questionable, i.e. an entry cut and pasted in the notebook for 10/15/96 as an initial entry actually came from a report that was generated 12/96 (3) the notebook entries are on the back of paper containing unrelated electronic media; (4) it is difficult to follow and understand the information being presented; and (5) the numbering of pages is not consistent. Issues relative to the master scientific notebook YMP-LBL-YWT-1 include: (1) no reference was made to the equipment to be used as required; (2) pages were blank and not annotated as required; (3) following the course of the investigation while possible was difficult and transitional information to subtler (field) notebooks were generally lacking. A review of other scientific notebooks (outside of the ESF Thermal Test Studies) disclosed similar inconsistencies. Actions were taken during the audit to address / correct some of the deficiencies cited.

**7 Initiator**

K. O. Gilkerson

Date 05/19/97

**8 Is condition an isolated occurrence?**

☐ Yes ☒ No ☐ Unknown; Must be Yes if PR

**10 Recommended Actions: (Not required for PR)**

1. Investigate through sampling or other methodological approach other Scientific Notebooks to determine the extent of the deficiency and to bound the problem.

2. Assure through training, briefings, etc. that PIs and Lab personnel responsible for maintaining notebooks share a methodology consistent with LBNL procedures and QARD requirements for the preparation, maintenance and review of notebooks.

3. To ensure some consistency and uniformity have an independent Technical Peer perform periodic reviews of scientific notebooks while the studies/tests are ongoing.

**11 QA Review**

QAR

Date 5/21/97

**12 Response Due Date**

Twenty working days from issuance

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

Printed Name DONALD G. HODSON

Signature

Date 6/2/97

**22 Corrective Actions Verified**

QAR

Date

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

AQQAM

Date

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

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Action  
See attached

15 Extent of Condition: (Not required for PR)  
See attached

16 Root Cause Determination: (Not required for PR) Required: ☐ Yes ☒ No

17 Action to Preclude Recurrence: (Not required for PR) Required: ☒ Yes ☐ No  
See attached

18 Corrective Action Completion Due Date:  
10/31/97

19 Response by: *David L. Friebe*  
Date 7/1/97 Phone 510-486 5610

20 Response Accepted

QAB *Michael S. Khan* Date 7/1/97

21 Response Accepted (N/A for PR)

DOQA *David L. Friebe* Date 8/4/97

Rev. 06/02/97

7/17/97 Mangold to Aostan

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Earth Sciences Division

**NUCLEAR WASTE DEPARTMENT**  
**YMP-LBNL QA OFFICE**  
**TEL. 510.486.4017 | FAX 510.486.6115**

July 1, 1997

Response to Deficiency Report YM-97-D-048:

#### **14 Remedial Actions:**

The specific deficiencies identified in the DR for notebook YMP-LBNL-YWT-1 are corrected during the audit. Some of the deficiencies identified for notebook YMP-LBNL-JBH-1 were corrected during the audit. Other concerns were indicated by the Technical Auditor. These concerns will be corrected by August 29, 1997.

#### **15 Extent of Conditions:**

In order to determine the extent of the deficiency, a selective sample of approximately 25 % (approx. 20 notebooks) of open scientific notebooks will be drawn from all WBS elements and examined to determine if these notebooks meet procedure requirements. If significant deficiencies are discovered during this review, additional notebooks will be sampled. This new sample will be based on the number of deficiencies found and WBS element of the deficient scientific notebook. If the number of significantly deficient notebooks exceeds 20 percent of the sampled notebooks (4 out of 20), another selective sample of 25 % (20 notebooks) of the entire population of open scientific notebooks will be reviewed unless the majority of significantly deficient notebooks are from a single WBS element or PI. If the majority of the deficiencies can be attributed to one WBS element or PI, then all of the WBS element or PI's notebooks will be reviewed. If the second sample of notebooks provides similar results to the first sample, then all open LBNL scientific notebooks will be reviewed.

The first 25 % of all open scientific notebooks will be reviewed by August 29, 1997 and remedial actions for newly discovered deficiencies completed by September 30, 1997. If significant deficiencies are found in more than 20 % of the first set of sampled notebooks, then an additional response will provide details of corrective measures and completion dates.

Note: A significant deficiency is considered a problem with a notebook that jeopardizes the repeatability of the work or traceability of data or equipment, for example missing initial entry information. It does not include minor errors like missing initials/dates on crossouts and similar errors.

An initial cause of this deficiency is determined to be inattention to detail and unfamiliarity with all the procedural requirements. If additional significant deficiencies are discovered during the investigative actions, a new cause and associated preventive actions may be proposed.

#### **17 Actions to Preclude Recurrence:**

To address the unfamiliarity with the procedural requirements, new training will be provided to PIs and technical staff responsible for the use and maintenance of scientific notebooks in the form of classroom and individual training. This training will be completed by October 31, 1997.

To address inattention to detail, periodic reviews of scientific notebooks by PI s and EA personnel will be conducted. LBNL will request that the OQA Site representative perform periodic surveillances of the implementation of scientific notebook procedure requirements as a specific

surveillance as well as part of surveillances of WBS element activities. The periodic review of notebooks by PI and EA is an ongoing activity that will commence after the completion of investigative actions.

The request for OQA to perform surveillances of scientific notebooks will be completed by July 25, 1997.