Department of Energy
Washington, DC 20585

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APR 08 1998

D. R. Wilkins, Technical Project Officer
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EVALUATION OF RESPONSE TO UNSATISFACTORY VERIFICATION OF 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 unsatisfactory verification of 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 G. 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.

R.W. Cal
for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1461

Enclosure:
DR YM-97-D-048

cc w/encl:
T. A. Wood, DOE/HQ (RW-55) FORS
S. L. Wastler, NRC, Rockville, MD
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cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
K. O. Gilkerson, OQA/QATSS, Las Vegas, NV
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 ☐ 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&O- LBNL

4 Discussed With:
Don Mangold, Yvonne Tsang

5 Requirement/Measurement Criteria:
QARD SIII.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 SIII.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-SIII.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 subtier (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. HORTON Signature Date 6/2/97

22 Corrective Actions Verified
QAR Date

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

Exhibit AP-16.1Q.1 Rev. 07/15/96

ENCLOSURE

BERKELEY LAB
Earth Sciences Division

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

July 1, 1907

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 defieiencies 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

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One Cyclotron Road | Berkeley, California 94720 | Tel: 510.486.7071 | Fax: 510.486.5686

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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.

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PR/DR CONTINUATION PAGE

AMENDED RESPONSE TO DR YM-97-D-048

The amended response to DR YM-97-D-048 is to conduct a 100% review of the remaining active YMP-LBNL notebooks in order to discover deficiencies in either the planning aspect or the recording of necessary information for the repeatability of the work or traceability of data or equipment.

The Corrective Action Completion Due Date is April 30, 1998.

Revisions to procedure YMP-LBNL-QIP SIII.0, *Scientific Investigation*, to include periodic technical review of notebooks, will be the action to preclude recurrence.

If additional deficiencies are found in the above matters, new actions to preclude recurrence may be proposed.

2/23/98 Bodvarsson to Gilkerson

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Summary of LBNL Effort
Answering YM-97-D-048

To answer the problems found with our notebooks, we checked 25 notebooks to see whether there were any major problems with them. Our investigation showed that almost all the notebooks were in reasonable condition. One or two needed improvement in a stronger way, but the owners were very willing to make all the changes right away. Therefore, we felt that the notebooks at LBNL were ready for closing verification. The verification included notebooks not in the original sample and only two were found to be out of compliance, and the scientists were willing to solve the problems right away. Upon the OQA Representative's recommendation that more work was needed, we agreed and left the deficiency open in case the audit discovered something additional to what had been found. Nothing more was added due to the audit.

Concerning some of the issues raised about the scientific notebooks, we would like to mention the following:

- In LBNL's program, the planning for the scientific investigation is placed at the beginning of the scientific notebook because LBNL does not have Study Plans, Activity Plans, or Work Agreements. According to YMP-LBNL-QIP SI.0, Section 3.0.3, these plans have documented reviews.

- The notebooks are reviewed by our EA staff according to a three-page checklist to cover the major and many minor points of keeping scientific notebooks. All the Drift Scale Test Preparedness Assessment recommendations were included in the checklist. A copy is attached as an example. Our practice is to provide the owner of a reviewed notebook with a copy of our filled-n checklist with a memo summarizing the needed changes, often including page numbers where the changes need to be made. (See attached example copy.)

- We are revising our procedure YMP-LBNL-QIP SIII.0, *Scientific Investigation*, to include a periodic technical review of notebooks for work in progress, not merely waiting until the notebook is completed to review.

From the above points, we believe it is apparent that we have made a good faith effort to answer every aspect of the deficiency regarding our scientific notebooks. Our amended response is a further indication of how we are striving to raise up the standard of our program in every way.

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Scientific and Field Notebook Entries
YMP-LBL

Audit Recommendations

- ☐ **Cross referencing** between notebooks used in the same task (also reference to the notebooks used by the PI(s) and the technical staff working under your direction) would be very helpful to later reviewers.

- ☐ **Add more explanatory statements.** Opinions/thought processes/logic trains are the hardest thing to follow when trying to "retrace the investigation without recourse to the original investigator". For example, rather than just stating that air injection times were increased, state that "air injection times were increased because --- ."

- ☐ **Label any sketches,** as well as **the axes of any sketched graphs.** A hand drawn sketch of a borehole video log looks remarkably like a hand drawn sketch of a length of core and a label eliminates any possible confusion.

- ☐ State **testing requirements** such as needed equipment or environmental conditions.

- ☐ Quite often data and/or calculations are in computer files, be sure to **reference** where and how to access these files in the scientific notebook.

- ☐ **Limit** the use of **project jargon** and cryptic notations that require prior knowledge to understand. For example a notebook entry that indicates "the blue holes were tested" or "the red holes were tested" is not meaningful to a reviewer unless they have the color coded borehole layout from the TCO (and none of the notebooks examined included or referenced the color coded layout.)

Notes:

- ☐ Do not use the notebook pages as scratch paper or scratch paper as notebook pages.
- ☐ Do no use recycled computer print-outs unless both sides of the page contain information related to the notebook.
- ☐ Do not include personal notes or information (your dentist appointment belongs on your calendar!)

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Summary and Conclusion Entries

- ☐ Summarize the results of sub-tasks, tasks, and projects (ie. upon completion of a milestone).
- ☐ Provide descriptions of observations or results and their acceptability or non-acceptability.
- ☐ Provide interim conclusions drawn from the observations or results.
- ☐ Sign and date conclusions.

Notebook Duplication

- ☐ Duplicate notebooks that are in use for more than one year and submit the copy to the QA Office for duplicate storage.

ESD
Nuclear
Waste
Department

MEMO

YMP-LBNL-EA OFFICE

To: April James

Date: August 22, 1997

SAMPLE

From: Vivi Fissekidou VF

cc: G. S. Bodvarsson,
D. Mangold

Re: Scientific Notebook EA review.

In order to investigate the extent of deficiencies in scientific notebooks and to satisfy the requirements of the Deficiency Report issued during the last M&O/DOE audit, the Engineering Assurance (EA) office has started reviewing a sample of scientific notebooks.

Your scientific notebook (YMP-LBNL-YSW-ALJ-1, starting date 5/1/97) was reviewed strictly for EA procedural requirements and it met most of them; however, a few items need to be addressed:

1. Project status: A statement is needed and can be provided by the PI (page 1).

2. List computer programs: EOS9, a TOUGH2 qualified module, was used with out been listed on page 1 under numerical codes. Also, list any other modules you might have used.

3. Cross referencing between notebooks used in the same task is absolutely necessary and it would be very helpful to later reviewers. Do not just refer to investigators' names but the notebook ID number, since more than one notebook may be assigned to the same person. Also reference the notebooks used by your PI and the technical staff working with you.

4. You need to include more information about the Data tracking Number (DTN) and the Q-status of the source data. Listing the name of the person providing the data is not sufficient information.

5. You provided excellent reference of the location of your output files. You should maintain the files for future reference and/or review.

6. Corrections should be done by a single line through the mistake, date, initials, and the correct information within close proximity (YMP-LBNL-QIP-SIII.0 R1 MOD 0 3.3.5). Also, initial and date write-overs and do not scribble. An explanation to a correction of data or parameters would be helpful to future reviewers.

If you have any questions please contact me at X5610.

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