



Department of Energy

Washington, DC 20585

QA: L

007 08 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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORT (DR) YM-96-D-106 RESULTING FROM OFFICE OF QUALITY
ASSURANCE (OQA) REVIEW

The OQA staff has verified the corrective action to DR YM-96-D-106 and determined the results to be satisfactory. As a result, the DR is considered closed. This letter also acknowledges receipt and approval of your corrective action extension request.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Mary G. McDaniel at (702) 794-1468.

James Blaylock
Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0057

Enclosure:
DR YM-96-D-106

- cc w/encl:
- T. A. Wood, DOE/HQ (RW-55) FORS
- J. O. Thoma, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- M. J. Clevenger, M&O/LANL, Los Alamos, NM
- T.J. Hirons, M&O/LANL, Los Alamos, NM
- B. R. Justice, M&O, Las Vegas, NV
- R. A. Morgan, M&O, Las Vegas, NV
- J. A. Canepa, M&O, Las Vegas, NV
- L. R. Hayes, M&O, Las Vegas, NV
- L. E. Souza, OQA/LANL, Los Alamos, NM
- R. W. Clark, DOE/OQA, Las Vegas, NV

- cc w/o encl:
- W. L. Belke, NRC, Las Vegas, NV
- M. G. McDaniel, OQA/QATSS, Las Vegas, NV
- D. G. Sult, OQA/QATSS, Las Vegas, NV

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

Performance Report
 Deficiency Report
 NO. YM-96-D-106
 PAGE 1 OF 2
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: U.S. Department of Energy/RW-0333P, Quality Assurance Requirements and Description (QARD), Revision 5	2 Related Report No. YM-ARP-96-014
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3 Responsible Organization: Los Alamos National Laboratory (LANL)	4 Discussed With: Frank Perry/Greg Valentine/Mike Clevenger
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5 Requirement/Measurement Criteria:
 QARD, Section III.2.4, Data Review, states: "A documented independent review of acquired and developed data shall be performed to confirm technical adequacy."

6 Description of Condition:
 Contrary to the above, there is no objective evidence that an independent review of the following data was performed:
 Xenolith Abundance Data reported in Table 1 of Valentine and Groves (1996, The Journal of Geology, Volume 104, Pages 71-90; "Entrainment of Country Rock During Basaltic Eruptions of the Lucero Volcanic Field, New Mexico"). These data were derived from field measurements recorded in notebook TWS-ESS-5-6-93-01.
³He age determination for Lathrop Wells Center reported in notebook TWS-INC-03-93-06, Page 129.
 Interviews with the PIs for Study Plans 8.3.1.8.5.1 and 8.3.1.8.1.2 identified that the reviews of scientific notebooks conducted in accordance with LANL Quality Procedure-03.5 did not include verifying the accuracy of the calculations for LANL generated data.

7 Initiator Mary G. McDaniel Date 9/25/96	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Actions: (Not required for PR)
 Determine extent of condition. Perform and document independent review of data to confirm technical adequacy. Take necessary actions to ensure that such reviews are conducted for current and future scientific investigations.

11 QA Review: QAR <i>M. G. McDaniel</i> Date 9/30/96	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name <i>Richard E. Vance</i> Signature <i>[Signature]</i> Date <i>10/3/96</i>
--

22 Corrective Action Verified QAR <i>M. G. McDaniel</i> Date <i>4/30/97</i>	23 Closure Approved by: (N/A for PR) AOQAM <i>J. Blum</i> Date <i>10/15/97</i>
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

LANL YMP will perform and document an independent review of the data identified in the DR.

15 Extent of Condition: (Not required for PR)

The PI for volcanism studies will review the scientific notebooks for the LANL generated volcanism data to determine if an independent review has been performed and appropriately document. If it is determined that data have not been reviewed the PI will ensure that an independent review is performed and documented.

Completion Date: 12/27/96

16 Root Cause Determination: (Not required for PR)

Required

Yes

No

N/A

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

Required

Yes

No

The LANL TPO will generate a memo to all YMP PIs stating the need to conduct spot checks of calculations to assure technical adequacy. this will be completed by 11/22/96.

18 Corrective Action Completion Due Date:

12/27/96

19 Response by:

F. Perry

Initial

Amended

Date 10/30/96 Phone 505/667-1033

20 Response Accepted

QAR

Mary H. McDaniel

Date 11-4-96

21 Response Accepted (N/A for PR):

SAOQAM

11/19/96

Date 31 Oct 96

MGM 11-6-96

Exhibit AP-16.1Q7

Rev. 07/15/96

10/31/96

EES-13-10-96-1317

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PR/DR CONTINUATION PAGE

Closure Verification For "Deficiency Report YM-96-D-106"

The Scientific Notebooks cited in Deficiency Report (DR.) YM-96-D-106 (Field Notebook TWS-EES-5-6-93-01 and Laboratory Notebook TWS-INC-03-93-06) were examined to determine if independent technical reviews were completed, including reviews of the data recorded and verification of calculations performed. The examination resulted in the following observations:

On August 18, 1997 an independent technical review was performed of Field Notebook TWS-EES-5-6-93-01. Results of the review were documented on pages 66 and 67 of the Notebook. As part of the review, examples of data recorded in the field notebook were identified and used to reperform the calculations necessary to determine if the information in the Volcanism Synthesis Report was properly derived from the data recorded. No problems were noted as a result of the independent technical review.

On August 21, 1997 an independent technical review was performed of Laboratory Notebook TWS-INC-03-93-06. The results of the review are documented on pages 253 and 254 of the Notebook and cross referenced to review comments on page 79 of Notebook TWS- EES-13-07-93-44. As part of the review, the acceptability of data reduction calculations was verified by reperforming some of the calculations. The reviewer noted that the information communicated by the Principle Investigator (PI) in 1997 differs from the information in the Notebook. The differences are attributed to changes in cosmogenic ³He production rates resulting in new lower results. The reviewer documented the new results provided by the PI in Notebooks TWS-INC-03-93-06 (Noble Gas # 3) and TWS-EES-13-07-93-44. The reviewer also classified the latest result "nonquality-related" because they were developed after the PI had left the Los Alamos National Laboratory (LANL) Yucca Mountain Project.

In addition to the two Scientific Notebooks cited above, fourteen Scientific Notebooks used in the development of the 1997 Volcanism Synthesis Report (identified in Table 1.1 of the volcanism report and page 85 of Notebook TWS-EES-13-07-93-44) were examined to determine if an independent technical review had been performed and if the data and calculations documented in the notebooks had also been verified. In most cases, field notebooks contained little to no data to be reviewed. Typically, field notebooks contained documentation of field observation of geological formations. The Scientific Notebooks examined and observations made are as follows:

Scientific Notebooks TWS-INC-7-2/88-2 (Noble Gas # 1) and TWS-INC-7-09-91-07 (Noble Gas # 2) were independently technically reviewed on August 21, 1997. These reviews are documented on page 253 of Notebook TWS-INC-03-93-06 (Noble Gas # 3) and were completed as part of the review of the Noble Gas # 3 notebook described earlier.

Scientific Notebook TWS-EES-13-07-93-44 was independently technically reviewed on August 28, 1997. The review is documented on page 86 and 87 of the notebook. As part of the review, calculations that could be readily checked were duplicated. In addition data in an associated binder were also reviewed. No problems were identified as result of the review.

Laboratory Notebooks TWS-INC-11-92-02 and TWS-INC-7-2/88-3 were both reviewed on August 26, 1997. The review is document on pages 20 and 21 of Notebook TWS-INC-11-92-02 and cross referenced on page 127 of Notebook TWS-INC-7-2/88-3. The review included data contained in the notebook and verification of a limited numbers of calculations available in the notebooks. The reviewer notes that the final isochrom calculations (bases for U-Th age) were done with software that was not qualified, as a result it can not be considered "Q".

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Closure Verification For "Deficiency Report YM-96-D-106"

Field Notebook TWS-EES-5-01-93-01 was independently technically reviewed on July 24, 1997. The review is documented on page 18 of the notebook. The notebook documented field observations and sample collection activities and was found to be acceptable. The notebook did not contain data that could be reviewed or calculations that could be checked.

Field Notebook EES-13-LV-02-93-08 was independently technically reviewed on August 1, 1997. The review is documented on page 35 of the notebook. The notebook documented field observations and was found to be acceptable. The notebook did not contain data that could be reviewed or calculations that could be checked.

Field Notebook EES-13-LV-02-93-09 was independently technically reviewed on August 18, 1997. The review is documented on page 36 of the notebook. The notebook documented field observations and was found to be acceptable. The notebook did not contain data that could be reviewed or calculations that could be checked.

Scientific Notebook EES-13-LV-04-92-29 was independently technically reviewed on August 21, 1997. The review is documented on page 48 of the notebook. The notebook documents research and development activities used to independently verify the results of United States Geological Survey studies. The reviewer indicates the data recorded in the notebook meets the highest scientific standards. The notebook is identified as "non Q" because it was outside the scope of the YMP Quality Assurance program.

Scientific Notebook EES-13-LV-08-94-07 was independently technically reviewed on August 20, 1997. The review is documented on page 234 of the notebook. The review notes the care taken in documenting the study and the use of commercially available statistical software for performing calculation. The review found that the data and calculations noted were acceptable.

Field Notebook TWS-EES-13-LV-05-91-16 was independently technically reviewed on August 26, 1997. The review is documented on the very last page of the notebook which does not have a page number. As a result of the review, it was determined that notebook adequately documented the field measurements taken during the course of Paleomagnetic studies.

Field Notebook EES-13-LV-02-93-07 was independently technically reviewed on August 29, 1997. The review is documented on page 71 of the notebook. The notebook documents field observations and sample descriptions. The notebook did not contain data that could be reviewed or calculations to check. No problems were identified as a result of the review.

Laboratory Notebook LA-EES-1-NBK-95-006 and an associated binder were independently technically reviewed on August 27, 1997. The review is documented on page 65 of the notebook. The review consisted of an evaluation of the data in the notebook and the associated binder. No problems were noted as a result of the review.

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WASHINGTON, D.C.

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Closure Verification For "Deficiency Report YM-96-D-106"

Scientific Notebook TWS-EES-13-LV-10-91-03 was independently technically reviewed on August 1, 1997. The review is documented on page 45 of the notebook. This notebook documents samples, including duplicates and splits sent to Intermountain Labs, Farmington New Mexico and LANL's EES-1 laboratory. The notebook provides interpretation of accuracy of results and acceptability of use of the samples. No problems were noted as a result of the review. During discussion with the Volcanism PI, it was discovered that the only information from the notebook used in the Volcanism Synthesis Report were some of the earth science principles discussed in the notebook. Because the scientific study and analytical activity being recorded in the notebook was never completed, none of the data contained in the notebook was used in the Volcanism Synthesis Report.

Examination of the notebooks identified above demonstrated that independent technical reviews, including evaluation of data acceptability and correctness of calculations, were performed of scientific notebooks associated with the Volcanism Syntheses Report. On November 4, 1996 LANL YMP also issued a memo reminding PIs the importance of adequate independent technical reviews, including checks of calculations and data acceptability. On November 26, 1996 a group meeting was held by LANL YMP which addressed the adequacy of notebook technical reviews and reinforced the November 4, 1996 memo.

Based on the information ^{7/10/97} cited above, it has been verified that LANL YMP has adequately resolved the deficiencies, Deficiency Report YM-96-D-106 is closed.



Verified By
Lawrence A. Souza, OQA/QATSS

9/25/97
Date



Concur
Mary G. McDaniel, OQA/QATSS/QAR

9/30/97
Date

Los Alamos

NATIONAL LABORATORY

memorandum

Earth and Environmental Sciences Division
 EES-13-Nuclear Waste Management R&D
 Mail Stop J521, Los Alamos, NM 87545
 Phone (505) 667-9768 Fax (505) 667-1934

To/MS: PI Distribution
 From/MS: J. Canepa, EES-13, MS J521 *jc*
 Phone/FAX: 7-4109/7-1934
 Symbol: EES-13-11-96-1318
 Date: November 4, 1996

Documentation and Review of Acquired (Generated) and Developed (Reduced) Data

During a recent DOE OCRWM audit I.AN1, YMP received two audit findings that dealt with the documentation and technical review of scientific data. The first finding identified that scientific notebooks had been reviewed but no check was ever performed to verify the accuracy of the calculations for the data generated and documented. The second finding identified that technical reports were issued to the project office that contained discrepancies with the data that had not been identified or corrected during technical reviews. Examples of the types of discrepancies identified are as follows:

- The same data was published differently in two sections of a report.
- Data published which had been previously superseded.
- Data that was supposedly the same was published with differences in two reports.
- Q and Non-Q data were combined and not individually or uniquely identified.

This memo is being issued to remind all PIs and supporting technical staff of the importance for data that is acquired or developed by LANL YMP to be correct, technically accurate, and complete (LANL-YMP-QP-03.5, subsection 6.4.3.4 and QP-03.23, Att. 4) prior to publication or submission as a QA record. Technical reviews must include spot checks of calculations to assure the adequacy of the data. Additionally, because of the regulatory environment in which LANL YMP data is to be used, it is most important that published documents be free from any inconsistencies or errors.

JC/JF/cv

Cy:
 A. Burningham, EES-13, MS J902
 M. Clevenger, ESH-14, MS J521
 J. Friend, LATA, MS J521
 A. Gallegos, LATA, MS J521
 J. Young, LATA, MS J521
 K. West, EES-13, MS J521
 EES-13 File, MS J521

**Los Alamos Yucca
Mountain Project's**

**All-Hands FY 97
Kick-Off Meeting!**

Welcome!

Los Alamos NATIONAL LABORATORY memorandum

Earth and Environmental Sciences Division
EES-13-Nuclear Waste Management R&D
Mail Stop J521, Los Alamos, NM 87545
Phone (505) 667-1934 Fax (505) 667-1934

To/AS: Distribution
From/MS: Michael J. Clevenger, EES-13, MS J521
Phone/FAX: 5-1454/7-1934
Symbol: EES-13-11-96-1319
Date: November 6, 1996

mc

Annual Yucca Mountain Project All Hands FY97 Kick-Off Meeting

We will hold the sixth annual Yucca Mountain Project All Hands FY-97 Kick-off Meeting on ~~Monday~~ ^{Tuesday}, November 25, 1996, from 1:30-4:00 p.m. at the ~~EST/DO~~ ^{EST/DO} conference room.
1677 mc 11/26/96

Tuesday 26
mc 11/26/96
mc 11/26/96

The following agenda will be presented. Attendance is strongly urged.

AGENDA

<u>Time</u>	<u>Subject</u>	<u>Speaker</u>
1:30 - 2:15	Changes in the Quality Assurance Program	Mike Clevenger, Karen West
2:16 - 2:45	Scientific Investigations: Changes; New Opportunities	Gilles Bussod
2:46 - 3:15	Data Management: Notebooks to Publications	Julie Canepa
3:16 - 4:00	YMP Update: Budget & Future The Latest Front Line News	Julie Canepa

MJC/cmv
Cy:
EES-13, MS J521

MARY:
I USED THIS MEMO AS A SLIDE

NOTICE

P. 8 of 13
SENT BY:

The Bad!

- **The Office Of Quality Assurance (OQA) taking over all QA Activities,**
 - **The 1 QA Program Approach,**
 - **Number of Deficiencies,**
 - **Analytical Services,**
 - **Technical Reviews,**
- **AP-17.1Q - Records Management,**
 - **Data/Milestone submissions.**

F. 9/8/13

YIM-92-5-104

Technical Reviews!

YH-96-D-106

P. Doyle

YM-96-D-106

Los Alamos NATIONAL LABORATORY memorandum

Earth and Environmental Sciences Division
EES-13-Nuclear Waste Management R&D
Mail Stop J521, Los Alamos, NM 87545
Phone (505) 647-8768 Fax (505) 647-1934

To: PI Distribution
From: J. Casco, EES-13, MS J521
Phone/FAX: 7-41097-1934
Subject: EES-13-11-96-1318
Date: November 4, 1996

Documentation and Review of Acquired (Generated) and Developed (Reduced) Data

During a recent DOE OCRWM audit LANL YMP received two audit findings that dealt with the documentation and technical review of scientific data. The first finding identified that scientific notebooks had been reviewed but no check was ever performed to verify the accuracy of the calculations for the data generated and documented. The second finding identified that technical reports were issued to the project office that contained discrepancies with the data that had not been identified or corrected during technical reviews. Examples of the types of discrepancies identified are as follows:

- The same data was published differently in two sections of a report.
- Data published which had been previously superseded.
- Data that was supposedly the same was published with differences in two reports.
- Q and Non-Q data were combined and not individually or uniquely identified.

This memo is being issued to remind all PIs and supporting technical staff of the importance for data that is acquired or developed by LANL YMP to be correct, technically accurate, and complete (LANL YMP-QP-88.5, subsection 6.4.3.4 and QP-81.21, Art. 4) prior to publication or submission as a QA record. Technical reviews must include spot checks of calculations to assure the adequacy of the data. Additionally, because of the regulatory environment in which LANL YMP data is to be used, it is most important that published documents be free from any inconsistencies or errors.

ICM/ev

Cy:
A. Bingham, EES-13, MS J521
M. Chivings, EES-14, MS J521
J. Fernald, LATA, MS J521
A. Galligo, LATA, MS J521
J. Young, LATA, MS J521
K. West, EES-13, MS J521
EES-13 File, MS J521

- 6.4.3** Has a technical review performed to assure that notebook entries meet the following criteria:
- 6.4.3.1** Sufficient detail is provided such that another similarly qualified individual could retrace the investigation and confirm the results, if feasible, or could repeat the investigation and achieve comparable results without recourse to the investigator.
 - 6.4.3.2** The software used is applicable to the investigation performed and the input parameters and assumptions are documented and valid.
 - 6.4.3.3** Information in the notebook is applicable to the notebook activity listed in the notebook according to subsection 6.1.3.
 - 6.4.3.4** Entries are correct, accurate, technically adequate, and complete.
- 6.4.4** Corrects each entry that does not meet the above requirements.
- 6.4.5** Ensures that the technical reviewer enters a statement, such as the following, on the notebook page after the last entry reviewed or in a section designated for review: "I have reviewed the entries on pages (*) through (*) and they meet the requirements described in subsection 6.4.3 and 6.4.4 of QP-08.5. All review comments noted have been corrected and/or accepted," followed by the reviewer's signature and date.

* Enter page numbers

6.5 Quality Assurance Review of Notebook

YMP personnel perform the following:

- 6.5.1** After the last technical review of a notebook is completed, a quality assurance review is performed on the notebook, including its attachments and/or data, if applicable, to ensure the following conditions are met:
- 6.5.1.1** The entries are legible and the configuration of the notebook meets the requirements of this procedure.
 - 6.5.1.2** Technical reviews were performed and documented according to subsection 6.4.5.

NOTE: YMP personnel may have the review performed by the group's Quality Assurance Liaison or may contact the Quality Assurance Project Leader (QAPL) for assignment of the review. It is recommended that a quality assurance review be performed after each technical review.

**1st compliment John
Friend has ever
received from a PI
while working on the
YMP!**

- **Thanx Steve - Mr. Chipera appreciated the QA review effort expended on several of the DPs he is revising and he let John know.**

Just 4 Humor

SENT BY:

12-18-86 9:32AM

EST. 10 1/2

441-96-2-106

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