



Department of Energy

Washington, DC 20585

QA: L

APR 16 1997

R. W. Craig, Technical Project Officer  
for Yucca Mountain Site  
Characterization Project  
U.S. Geological Survey  
1261 Town Center Drive  
Building 12, Room 1249, M/S 423  
Las Vegas, NV 89134

EVALUATION OF AMENDED RESPONSE AND VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT (DR) YM-97-D-004 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-002 OF EPPLEY LABORATORY

The OQA staff has evaluated the amended response and verified the corrective action to DR YM-97-D-004 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Richard L. Maudlin at (702) 794-1302.

Donald G. Horton, Director  
Office of Quality Assurance

OQA:JB-1343

Enclosure:  
DR YM-97-D-004

cc w/encl:  
J. O. Thoma, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
T. H. Chaney, USGS, Denver, CO

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

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Recup: NMSS/HLUR

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

THIS IS A RED STAMP

Performance Report

Deficiency Report

NO. YM-97-D-004

PAGE 1 OF 2  
QA: L

**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document:  
Eppley Laboratory Quality Assurance Manual, May, 1995/ Quality Assurance Requirements and Description, (QARD), (DOE/RW-0333P), Revision 5

2 Related Report No.  
OQA-SA-97-002

3 Responsible Organization:  
U.S. Geological Survey (USGS) / Eppley Laboratory

4 Discussed With:  
George Kirk/Tom Kirk/Tom Chaney

5 Requirement/Measurement Criteria:

- (A) Eppley QA Manual, Section 6.0, Subsection 6.2.8 states in part: "Equipment calibration documentation shall include the following information: ... (d) date of calibration and the recalibration due date"
- (B) Office of Civilian Radioactive Waste Management QARD, Section 18.0, Subsection 18.2.1 states in part: "Scheduling internal audits: ... E. Internal audits of work to verify QA Program compliance shall be performed annually or at least once during the life of the work ..."

6 Description of Condition:

Contrary to these requirements:

- (A) Certificates of Calibration issued to the USGS for the calibrations of Pyrometers Serial Nos 11923, 10702, 10386, 9482, 8553, 8545, and 12015 did not reference a recalibration due date
- (B) The Eppley QA Manual, May 1995, does not require the performance of annual internal audit
- (C) There was no objective evidence to reflect the performance of annual internal audits of the Eppley Laboratory QA program.

Note: Documented evidence was provided indicating a USGS audit of Eppley Laboratory in 1991 and 1994.

7 Initiator *Richard L. Maudlin*  
Richard L. Maudlin

Date 10/14/96

9 Is condition an isolated occurrence?

Yes     No     Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

- (A) Evaluate the impact of no recalibration date referenced on the calibration certificates. Update calibration certification as appropriate with the recalibration due dates.
- (B) Identify actions taken to assure all future calibration certificates include a recalibration due date.
- (C) Revise the Eppley QA Manual to reference the performance of annual internal audits.

11 QA Review:

QAR *R. Maudlin*

Date 10/14/96

12 Response Due Date

20 working days from issuance

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

Printed Name *Richard E. Spence* Signature *Richard E. Spence*

Date 10/15/96

22 Corrective Action Verified

QAR *R. Maudlin*

Date 04/04/97

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

AQQAM *[Signature]*

Date 4/14/97

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WASHINGTON, D.C.

8  
PR/DR NO. YM-87-D-004  
PAGE 2 OF 7 QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See DR Continuation Page 3

15 Extent of Condition: (Not required for PR)

See DR Continuation Page 3

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

See DR Continuation Page 3

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

Required  Yes  No

See DR Continuation Page 3

18 Corrective Action Completion Due Date:

See DR Continuation Page 3

19 Response by:

Initial *T. W. Murray*  
 Amended Date 11/14/96 Phone

20 Response Accepted

QAR *D. J. Powell*

Date 11/21/96

21 Response Accepted (N/A for PR):

AQAM *David Son*

Date 12-12-96

*11/15/96 [Signature]*

*p. 2 of 9*

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

Performance Report

Deficiency Report

NO. YM-97-D004

PAGE 3 OF 4  
OAL

PR/DR CONTINUATION PAGE

**Block 14: Remedial Actions:**

1. The requirement for the recalibration due date to be included on the equipment calibration documentation is an overcommitment in the Eppley QA Manual. Each USGS Principal Investigator reports, tracks and submits all M&TE used for quality affecting activities for QA office review in accordance with USGS-QMP-12.01 (See attached Calibration Status Report dated 9/18/96 for specific Pyrometers in question for calibration due date). The Eppley QA Manual will be revised to delete this overcommitment.
2. The supplier does not have the capability to perform internal audits. The USGS will annotate the Supplier Evaluation Report (SER), to be submitted, that this element is not being implemented. The USGS will request that OQA perform an annual audit of the supplier to satisfy this element of the QA Program.

**Block 15: Extent of Condition:**

Investigative actions:

- a. A review of active calibration suppliers' quality assurance manuals will be performed to determine if similar overcommitments exist.
- b. A review of existing SERs will be performed to determine if annual internal audits have been appropriately addressed.

**Block 16: Root Cause Determination:**

Not applicable

**Block 17: Action to Preclude Recurrence:**

1. If upon review, additional overcommitments are identified, the USGS will contact each affected supplier and recommend the necessary change.
2. If required, SERs will be appropriately annotated and a request will be made that OQA perform annual internal audits of suppliers who do not have the capability to implement this element of the QA Program.

**Block 18: Corrective Action Completion Date:**

A supplemental response will be provided to your office after investigative actions have been completed. It is anticipated that investigative actions will be completed by February 15, 1997.

**CALIBRATION RECORD**  
**OR CALIBRATION STATUS = Active, Pending**

DK 101-91-U-004

September 18, 1997  
 Page 3

Page 4 of 4  
 12/16/97

PI or Delegate: A.L. Flint

\*\*\*\*\* ESIP, Nevada Test Site \*\*\*\*\*

<u>ACT.</u>	<u>ID NUMBER</u>	<u>INSTRUMENT NAME</u>	<u>LAST CAL</u>	<u>NEXT CAL</u>	<u>CALIBRATED BY</u>
A	FTLY11341	Pressure Gage	09/03/96	03/03/97	Bechtel Nevada
A	FTLY11342	Pressure Gage	09/03/96	03/03/97	Bechtel Nevada
A	FTLY11441/11078	Oven	10/17/95	04/17/97	ResCo
A	FY10378	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY10386	Pyranometer	03/26/96	03/26/98	Eppley Labs
A	FY10702	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY11923	Pyranometer	03/26/96	03/26/98	Eppley Labs
A	FY12017	Pyranometer	03/26/96	03/26/98	Eppley Labs
P	FY3137	Pyranometer (SR)	01/22/92	Pending	N/A
P	FY8538	Pyranometer (SR)	08/09/93	Pending	N/A
A	FY8545	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY8553	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY9482	Pyranometer (SR)	03/26/96	03/26/98	Eppley
P	FY9741	Pyranometer (SR)	08/09/93	Pending	N/A

\*\*\*\*\* ESIP, Unspecified Location \*\*\*\*\*

<u>ACT.</u>	<u>ID NUMBER</u>	<u>INSTRUMENT NAME</u>	<u>LAST CAL</u>	<u>NEXT CAL</u>	<u>CALIBRATED BY</u>
P	288-19-2	Wind Direction Sensor	06/14/90	Pending	N/A
P	B1372	Wind Direction Sensor	06/13/90	Pending	N/A

p. 4 of 9

# ORIGINAL

OFFICE OF CIVILIAN  
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WASHINGTON, D.C.

PR/DR NO. YM-87-D004.1  
PAGE 2 OF         
QA:L

### PERFORMANCE/DEFICIENCY REPORT RESPONSE

AMENDED RESPONSE to supersede response dated 11/14/96.  
(Letters correspond to Section 6 Description of Condition)

**<sup>14</sup>Remedial Actions:**

A. Section 6 of the Epley QA Manual pertains to Epley-owned equipment, not to equipment sent to them for calibration. While this distinction is not apparent in cited paragraph 6.2.8, it is apparent in other paragraphs such as 6.2.1 and 6.2.3. Purchase orders from USGS specify calibration documentation requirements and do not require the vendor to include a recalibration due date. Those dates are established by USGS and tracked by the USGS calibration record. No remedial actions necessary.

B. The SER has been annotated to indicate that OQA will perform annual internal audits.

C. Audits performed by DOE OQA will produce the objective evidence to reflect the performance of annual internal audits.

**<sup>15</sup>Extent of Condition (not required for PR):**

A. N/A

B. Internal to Epley.

C. Internal to Epley.

**<sup>16</sup>Root Cause Determination (not required for PR):**

Required

Yes  No

**<sup>17</sup>Action to Preclude Recurrence (not required for PR):**

Required

Yes  No

A. N/A

B. Notation on SER.

C. Same as B. above.

**<sup>18</sup>Corrective Action Completion Due Date:**

3/19/97

**<sup>19</sup> Response by:** *Wayne Radman*

Initial

Amended

Date

Phone

3/19/97

**<sup>20</sup>Response Accepted:**

QAR

*Orfanella*

Date

04/04/97

**<sup>21</sup> Response Accepted (N/A for PR):**

AOQAM

*Wayne Radman*

Date

4/14/97

3/19/97 Chaney to Boston

p. 5 of 9

PI or Delegate: A.L. Flint

\*\*\*\*\* ESIP, Nevada Test Site \*\*\*\*\*

<u>ACT.</u>	<u>ID NUMBER</u>	<u>INSTRUMENT NAME</u>	<u>LAST CAL</u>	<u>NEXT CAL</u>	<u>CALIBRATED BY</u>
A	PTLY11341	Pressure Gage	09/03/96	03/03/97	Bechtel Nevada
A	PTLY11342	Pressure Gage	09/03/96	03/03/97	Bechtel Nevada
A	PTLY11441/11078	Oven	10/17/95	04/17/97	ReeCo
A	FY10378	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY10386	Pyranometer	03/26/96	03/26/98	Eppley Labs
A	FY10702	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY11923	Pyranometer	03/26/96	03/26/98	Eppley Labs
A	FY12017	Pyranometer	03/26/96	03/26/98	Eppley Labs
P	FY1137	Pyranometer (SR)	01/22/92	Pending	N/A
P	FY8538	Pyranometer (SR)	08/09/93	Pending	N/A
A	FY8545	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY8553	Pyranometer (SR)	03/26/96	03/26/98	Eppley
A	FY9482	Pyranometer (SR)	03/26/96	03/26/98	Eppley
P	FY9741	Pyranometer (SR)	08/09/93	Pending	N/A

\*\*\*\*\* ESIP, Unspecified Location \*\*\*\*\*

<u>ACT.</u>	<u>ID NUMBER</u>	<u>INSTRUMENT NAME</u>	<u>LAST CAL</u>	<u>NEXT CAL</u>	<u>CALIBRATED BY</u>
P	288-19-2	Wind Direction Sensor	08/14/90	Pending	N/A
P	B1372	Wind Direction Sensor	08/13/90	Pending	N/A

p. 6 of 9

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
SUPPLIER EVALUATION REPORT**

1 PURPOSE:  INITIAL EVALUATION  TRIENNIAL AUDIT  Remove Supplier  
 INITIAL AUDIT  SCOPE CHANGE  
 ANNUAL EVALUATION  PROGRAM CHANGE

SUPPLIER INFORMATION	2 SUPPLIER NAME/ADDRESS <i>Espley Laboratories, Inc</i> <i>Newport RI 02840</i>	CONTACT NAME/TITLE <i>N/A</i>	
	TELEPHONE <i>401 847 1021</i>		
	ITEM(S) <i>N/A</i>	SERVICE(S) <i>CALIBRATION</i>	
	PROCUREMENT DOCUMENT NUMBER(S) <i>97 SA 00086</i>	QA MANUAL <i>CORPORATE</i>	REVISION LEVEL OR DATE
		CODES/STD COMMITTED TO IN QA MANUAL	
		<input type="checkbox"/> 10 CFR 50B	<input checked="" type="checkbox"/> ISO-9000
		<input type="checkbox"/> ANSI N 45.2	<input type="checkbox"/>
		<input type="checkbox"/> NQA-1	<input type="checkbox"/>

3 TYPE:  QUALITY RECORDS REVIEW  SURVEY  AUDIT  
 SUPPLIER HISTORY  MATRIX REVIEW

4 RESTRICTIONS & COMMITMENTS  
*NONE*

Continued

5 REMARKS  
*OQA WILL CONDUCT ANNUAL AUDIT TO SATISFY REQUIREMENTS FOR ANNUAL INTERNAL AUDIT.*

Continued

6 APPROVAL:  QUALIFIED  QUALIFIED WITH RESTRICTION(S)  NOT QUALIFIED

RE-EVALUATION DUE DATE *8/27/97* AUDIT DUE DATE *PENDING*

QA MANAGER: *Wayne Rodan* *for* Signature Date *3/19/97*

7 VERIFICATION: VERIFIED CORRECT INPUT OF DATA TO QSL

VERIFIER: \_\_\_\_\_ Signature Date *P. 7 of 9*



# OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT SUPPLIER EVALUATION REPORT

1 PURPOSE:  QA PROGRAM MATRIX REVIEW     QUALITY RECORDS EVALUATION  
 AUDIT     SURVEY

2 SUPPLIER NAME: EPPLEY

3	QA PROGRAM ELEMENT	SAT	UNSAT	N/A
1	ORGANIZATION	X		
2	QUALITY ASSURANCE PROGRAM	X		
3	DESIGN CONTROL			X
4	PROCUREMENT DOCUMENT CONTROL	X		
5	IMPLEMENTING DOCUMENTS	X		
6	DOCUMENT CONTROL	X		
7	CONTROL OF PURCHASED ITEMS AND SERVICES	X		
8	IDENTIFICATION AND CONTROL OF ITEMS			X
9	CONTROL OF SPECIAL PROCESSES			X
10	INSPECTION			X
11	TEST CONTROL			X
12	CONTROL OF MEASURING AND TEST EQUIPMENT	X		
13	HANDLING, STORAGE AND SHIPPING			X
14	INSPECTION, TEST AND OPERATING STATUS			X
15	NONCONFORMANCES			X
16	CORRECTIVE ACTION	X		
17	QUALITY ASSURANCE RECORDS	X		
18	AUDITS	X		
SUPPLEMENT I	SOFTWARE	X		
SUPPLEMENT II	SAMPLE CONTROL			X
SUPPLEMENT III	SCIENTIFIC INVESTIGATION			X
SUPPLEMENT IV	FIELD SURVEYING			X

MATRIX / RECORDS / AUDIT / SURVEY

DESCRIPTION OF QUALITY ASSURANCE PROGRAM PROCEDURES OR OTHER SIMILAR DOCUMENT(S) REVIEWED/EVALUATED

TITLE/REVISION: CORPORATE QA MANUAL, MAY 95

Continued

4 AUDIT/SURVEY: 97 0002    DATE: 10/8/96    PERFORMED BY: DOE

QUALIFIED

EVALUATION RESULTS

Continued

IF RESTRICTIONS OR DOCUMENTED COMMITMENTS ARE APPLICABLE, IDENTIFY ON SUPPLIER EVALUATION SHEET, PAGE 1.

EVALUATOR \_\_\_\_\_ SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_

P.8 of 9

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

8  Performance Report  
 Deficiency Report

NO. YM-97-D-004

PAGE \_\_\_\_\_ OF \_\_\_\_\_


QA: L

PR/DR CONTINUATION PAGE

EVALUATION AND CLOSURE OF DEFICIENCY REPORT (DR) YM-97-D-004

Based on the response provided, dated March 19, 1997, which identifies that USGS is responsible for the determination and documentation of due dates for the items being calibrated by Eppley Laboratory, this item is considered to be resolved. Also, USGS has identified that internal audits will be performed by OQA and the attached SER requesting OQA to perform the annual internal audits of Eppley supports this.

As a result of the above, no further action is required in the resolution to this DR. This DR is considered closed.

  
R.L. Maudlin, QAR

04/04/97  
Date

p. 9 of 9