



Department of Energy  
Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office  
P.O. Box 98608  
Las Vegas, NV 89193-8608

JUN 13 1996

Robert W. Craig  
Acting Technical Project Officer  
for Yucca Mountain  
Site Characterization Project  
U.S. Geological Survey  
1261 Town Center Drive  
Building 4, Room 423, M/S 423  
Las Vegas, NV 89134

EVALUATION OF RESPONSE TO PERFORMANCE REPORT (PR) YMQAD-96-P022  
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT  
OQA-SA-96-010 OF FLUKE MANUFACTURING COMPANY, INC. (SCPB: N/A)

The Yucca Mountain Quality Assurance Division (YMQAD) staff has  
evaluated the response to PR YMQAD-96-P022. The response has been  
determined to be unsatisfactory because of reasons stated in the  
enclosed PR.

An amended response is required to be submitted to this office within  
ten working days of the date of this letter. Send the original of  
your response to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop  
455, Las Vegas, Nevada 89193-8608. If an extension to the due date is  
necessary, it must be requested in writing, with appropriate  
justification, prior to that date.

If you have any questions, please contact either Robert B. Constable  
at (702) 794-5580 or Richard L. Maudlin at (702) 794-1302.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1906

Enclosure:  
PR YMQAD-96-P022

cc w/encl:  
J. G. Spraul, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
T. H. Chaney, USGS, Denver, CO  
Records Processing Center

cc w/o encl:  
W. L. Belke, NRC, Las Vegas, NV  
R. L. Maudlin, YMQAD/QATSS, Las Vegas, NV  
D. G. Sult, YMQAD/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. YMOAD-96-P022  
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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document:

OCRWM QARD, Rev. 5/ Fluke Corporate Quality Manual, QSD 111.0, Rev. 6/95

2 Related Report No.

OQA-SA-96-010

3 Responsible Organization:

Fluke Manufacturing Co., Inc./USGS

4 Discussed With:

Gwynn Blanchard / Tom Chaney

5 Requirement/Measurement Criteria:

QARD, Section 17.0, Subsection 17.2.11(A), states in part: "...QA records shall be temporarily stored in a container or facility with a fire rating of 1-hour, or dual storage shall be provided."

QSD 111.0, Section 16.0, states in part: "...All quality records...shall be stored and retained in such a way...that provide a suitable environment to prevent damage and deterioration and to prevent loss."

6 Description of Condition:

Contrary to the above, QA records such as audit reports, corrective action documents, and training records are not being stored to prevent damage by fire.

Note: QA records are considered completed documents with all required signatures.

7 Initiator

Richard L. Maudlin

Date 2/1/96

9 QA Review

QAR *[Signature]*

Date 2/1/96

10 Response Due Date:

20 Working Days From Issuance

11 QA Issuance Approval

QAR (PR)/AOQAM (R) *[Signature]*

Date 2/1/96

12 Remedial Actions

SEE ATTACHED SHEET

13 Remedial Action Response By

*[Signature]*

Date 3/6/96

14 Remedial Action Due Date

March 20, 1996

Date

15 Remedial Action Response Acceptance

16 PR Verification / Closure

Enclosure

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

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PR/DR CONTINUATION PAGE

**REMEDIAL ACTIONS:**

Fluke considers quality records (those which require fire-proof storage) to be the records pertinent to their type of business, e.g. records of design and service. Designs and service records are maintained on-line, down-loaded twice weekly, and stored in a fire-proof vault. They do not plan to change their records system to include audit reports and corrective action reports in their fire-proof storage. Their training information, however, has been transferred from "QA" category to "personnel" records.

On Fluke's behalf, we should point out that the QA requirements that are attached to purchases of calibration services do not specifically state that the supplier shall retain audit reports, etc., in fire-proof storage. In fact the documents that apply directly to the service they are performing for the YMP are the calibration certificates which are submitted to YMP and retained in dual storage by the YMP.

## EVALUATION OF RESPONSE OF PR YMQAD-96-P022

The response has been evaluated and found unacceptable in resolving the condition adverse to quality.

Your response states in part that their (Fluke Mfg) training information has been transferred from "QA" category to "personnel" records. I am not sure what this means. Documentation of training and qualification of personnel are "QA" records and any other status does not meet the QARD.

The USGS P.O. attachment for calibration services, which was attached to the Fluke P.O. states in part "Records - ...: Records of personnel qualification and training, procedures for performing work, equipment calibration documentation, and calibration results shall be retained for a period of three (3) years.... " What you state in your response appears to contradict with what you define as QA records in your procurement documents. You also instruct the supplier to maintain these records (i.e.; Personnel Qualifications and training, procedures for performing work, equipment calibration documentation, and calibration results) for 3 years.

The QARD, Section 17.0, Subsection 17.2.11 states in part: "The .... organization shall provide for temporary storage of QA records during processing, review, or use until turnover to .... for disposition, according to the following requirements: (A) QA records shall be stored in a container or facility with a fire rating of 1-hour, or dual storage shall be provided...."

The only other option that USGS may take to resolve this issue is to request all those documents described as records and request that they be sent to USGS for safe keeping. In taking this approach, USGS takes the responsibility for fulfilling the records storage requirements.

Please re-evaluate your response and indicate the method to be employed by Fluke Mfg in meeting the records storage requirements as specified by the QARD.

  
Richard L. Maudlin, QAR

6/3/96  
Date