



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608
SEP 13 1996

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for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
Bank of America Center, Suite P-110
101 Convention Center Drive
Las Vegas, NV 89109

**EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-96-D-070
RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT
OQA-SA-96-005 OF WESTINGHOUSE ENGINEERING SERVICES**

The Yucca Mountain Quality Assurance Division staff has evaluated the response to DR YM-96-D-070. 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, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

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-2599

Enclosure:
DR YM-96-D-070

cc w/encl:

T. A. Wood, DOE/HQ (RW-14) FORS
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. L. Strickler, M&O, Vienna, VA
B. R. Justice, M&O, Las Vegas, NV
R. P. Ruth, M&O, Las Vegas, NV
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
D.G. Horton, DOE/OQA, Las, Vegas, NV

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Recip: nmss/HLR

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

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☒ Deficiency Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

Westinghouse Eng. Services SAICT MSS Quality Control Manual, Revision 4

2 Related Report No.

OQA-SA-96-005

3 Responsible Organization:

CRWMS M&O / Westinghouse Eng. Services

4 Discussed With:

Greg Parker

5 Requirement/Measurement Criteria:

NOTE: This DR is issued to supersede PRs YMQAD-96-P004, YMQAD-96-P005, and YMQAD-96-P006 due to untimely implementation of corrective action.

SAICT MSS Quality Control Manual, Section 2, Subsection II, states in part: "Definitive guidelines are issued as QC procedures..."

Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description document, Section 12.0, Subsection 12.2.3, states in part: "Out of calibration Measuring and Test Equipment (M&TE) shall be controlled...when M&TE is found out of calibration during re-calibration, the validity of results obtained using the equipment since its last calibration shall be evaluated."

6 Description of Condition:

NOTE: This DR is issued to supersede PRs YMQAD-96-P004, YMQAD-96-P005, and YMQAD-96-P006.

- (A) Westinghouse Engineering Services has a computerized "reverse recall" system for notifying its customers when a standard is later found to be out of calibration. However, there are no procedures which describe this process.
- (B) Contrary to the above, there are no procedures which describe how Quality Assurance (QA) records are to be stored to prevent damage from fire, deterioration, etc.

7 Initiator

Richard L. Maudlin

Date 7/8/96

9 QA Review

QAR

Date 7/8/96

10 Response Due Date:

20 Working Days From Issuance

11 QA Issuance Approval

QAR (PR)/AOQAM (DR)

Date 7/11/96

12 Remedial Actions:

13 Remedial Actions Response By:

N/A

Date

14 Remedial Action Due Date

N/A

Date

15 Remedial Action Response Acceptance

QAR

N/A

Date

16 PR Verification /Closure

QAR

N/A

Date

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17 Recommended Actions:

Please provide a response to this DR which addresses the following and a new date of implementation of corrective action.

Develop and implement procedures which describe the "reverse recall" system presently in use.

Develop and implement procedures which describe how QA records are to be stored to prevent damage from fire, deterioration, etc.

Develop and implement procedures for the performance of supplier audits and the qualification and certification of Lead Auditors.

Provide evidence of completion of corrective action to Dick Munns' audit concern.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

SEE ATTACHED RESPONSE, BLOCKS # 14 + 17, DS 8/23/96

21 Response By: <i>SEE ATTACHED RESPONSE</i> Date <i>DS 8/23/96</i>	22 Corrective Action Completion Due Date <i>DS 8/23/96</i> <i>SEE ATTACHED RESPONSE</i>
23 Response Accepted QAR <i>[Signature]</i> Date <i>8/23/96</i>	24 Response Accepted AOQAM <i>[Signature]</i> Date <i>9/11/96</i>
25 Amended Response Accepted QAR _____ Date _____	26 Amended Response Accepted AOQAM _____ Date _____
27 Corrective Action Verified QAR _____ Date _____	28 Closure Approved by: AOQAM _____ Date _____

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Block 5, Requirements/Measurements Criteria, cont'd:

Section 18, Subsection V(B), states: "If records are required from the QC supervisor, they shall be copied and originals returned to the files."

SAICT MSS Quality Control Manual:

Section 8.2, Subsection V (A), states in part: "For calibration sources/services, the QC supervisor will perform triennial audits of calibrations sources/services..."

Section 8.2, Subsection V (A), states in part: "If discrepancies are found during the audit, the QC supervisor will confirm that all of the corrective actions were completed in full compliance..."

Block 6, Description of Condition, cont'd:

Contrary to the above:

- (C) There are no procedures in place which describe how supplier audits are performed and requirements for qualification and certification of Lead Auditors.
- (D) The supplier audit of Dick Munns, Audit 940316-1, resulted in one concern being generated. Since completion of the audit in March 1994, no evidence of completed corrective action could be provided.

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SEE CONTINUATION FORM

15 Extent of Condition: (Not required for PR)

THE QUALITY SYSTEM HAS BEEN REVIEWED AND NO SIMILAR
CONDITIONS HAVE BEEN FOUND

16 Root Cause Determination: (Not required for PR)

Required

☐ Yes☒ No

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

Required

☐ Yes☐ No

SEE # 14

18 Corrective Action Completion Due Date:

10/30/96

19 Response by:

☒ Initial☐ Amended

Date 8/12/96

Phone

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AQQAM

Date

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PR/DR CONTINUATION PAGE

Block 14:

The reverse recall system is documented in SOP 11.01, para. 9.1.10, rev.00

Quality records are preserved IAW SOP 16.01 para. 9.2.1 Rev. 00

Supplier audits are performed IAW a checklist supplied by our Quality Systems Operation located in Orlando, FL. Lead auditor certification is also controlled by Quality Systems Operation. No lead auditor certifications are issued by this office. The procedure governing supplier checklist preparation and lead auditor certification is QAP-13.0, R 03190.

Corrective action (Dick Munns) was verified; however, there is no signature block for verification. The "response accepted" block is generally used for acceptance and verification.