



Department of Energy

Washington, DC 20585

MAR 03 1997

QA: L

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

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) YM-97-C-002 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-011 OF PACIFIC NORTHWEST LABORATORY

Enclosed is CAR YM-97-C-002 generated as a result of OQA Supplier Audit OQA-SA-97-011.

Please provide a response to this deficiency that meets the applicable requirements of Administrative Procedure 16.2Q, Corrective Action and Stop Work. Send the original of your response to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307. Response to the CAR is due 20 working days from the date of this letter. Any extension to due date must be requested in writing, with appropriate justification, prior to the due date.

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

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

OQA:JB-1078

Enclosure:
CAR YM-97-C-002

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PDR WASTE
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Recip: NMSS *[Signature]*



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L. D. Foust

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cc w/encl:

L. H. Barrett, DOE/HQ (RW-1) FORS
T. A. Wood, DOE/HQ (RW-55) FORS
J. O. Thoma, 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. A. Morgan, M&O, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV
W. E. Barnes, DOE/YMSCO, Las Vegas, NV
Records Processing Center

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

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

☒ Corrective Action
Request
☐ Stop Work Order
CAR NO. YM-97-C-002

CORRECTIVE ACTION REQUEST

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1 Controlling Document: Pacific Northwest Laboratory (PNL)
Quality Assurance (QA) Plan, Revision 8/ Lawrence
Livermore National Laboratory (LLNL), Quality Assurance
Requirements Specification (QARS)
LLNL QARS-001C 2/13/89

2 Related Report No.
OQA-SA-97-011

3 Responsible Organization:
Civilian Radioactive Waste Management System
Management and Operating Contractor
(CRWMS M&O) / PNL

4 Discussed With:
Steve Marshman/David Stahl/Orie Barnes

5 Requirement:
This Corrective Action Request (CAR) further supports the adverse conditions (CAR YM-97-001) identifying the lack of the CRWMS M&O procurement process in controlling supplier services..

LLNL QARS, Section 2.0, Subsection 2.1 states in part: "A Quality Assurance Program Plan shall be developed and shall provide the description of the organizations QA program and indicate the commitment of the applicable QA requirements..."

LLNL QARS, Section 1.0, Subsection 1.2 states in part: "The persons performing quality assurance functions shall have sufficient authority, access to work areas, and organization freedom to identify quality problems..."
(see page 3)

7 Initiator
Richard L. Maudlin *R. Maudlin*

Date 02/26/97

9 Does a Stop Work condition exist?
Yes ☐ No ☒ ; If Yes, Attach copy of SWO
If Yes, Check One: A ☐ B ☐ C ☐ D ☐

10 Recommended Action:

- A. Take immediate action to evaluate the impact of previous work since 1994 based on the above conditions.
- B. Develop measures which assure that QA has a budget independent of PNL project management.
- C. Evaluate the status of the PNL QA Program requirements to assure that all PNL work is being performed in compliance with the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description, Revision 5.
- D. Determine the cause of the above conditions and identify what actions the CRWMS M&O plans to take to prevent recurrence.

11 QA Review:

R. Maudlin

Date 02/26/97

12 Response Due Date:

20 Working Days From Issuance

13 Affected Organization QA Manager Issuance Approval:

Printed Name Donald G. Horton

Signature *R.W. Clap*

Date 3/3/97

22 Corrective Action Verified

QAR

Date

23 Closure Approved by:

AOQAM

Date

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

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☒ Corrective Action Request

☐ Stop Work Order

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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

15 Extent of Condition and Impact:

16 Root Cause Determination prepared in accordance with AP-16Q is attached.

17 Action to Preclude Recurrence:

18 Corrective Action Completion Date

19 Response Due

☐ Initial

☐ Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted

AOQAM

Date

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
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CAR CONTINUATION PAGE

5 Requirements (Continued)

LLNL QARS, Section 2.0, Subsection 2.6.4 states in part: "Prior to assigning personnel to perform quality affecting activities, they shall be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished."

LLNL QARS, Section 5.0, Subsection 5.2 states in part: "Reviews: An independent review of all instructions, procedures...shall be performed by the organization to assure the technical adequacy and inclusion of appropriate quality requirements."

LLNL QARS, Section 6.0, Subsection 6.1 states in part: "The document control system shall be documented, and the QA organization shall provide the appropriate review... Implementation of document control shall provide for... c. Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance."

LLNL QARS, Section 16.0, Subsection 16.1 states in part: "A corrective action system...shall insure that conditions adverse to quality or potentially adverse to quality are identified promptly and corrected as soon as practical."

LLNL QARS, Section 18.0, Subsection 18.3.1 states in part: "Internal Audits: Applicable elements of an organization's Quality Assurance Procedure shall be audited at least annually or at least once during the life of the activity, whichever is shorter.. Surveillances may be performed in lieu of an annual audit provided that the following conditions are satisfied... All applicable QA programmatic elements have been included within the scope of surveillances."

6 Description of Condition (Continued)

- B. The QA organization does not have the freedom of access for the purposes of evaluation and to identify quality problems. There has been minimal to no independent QA involvement in PNL activities since 1994 due to no funding provided for QA activities by PNL Project Management.
- C. There is no objective evidence to support that PNL project personnel have received training on the latest revision to the implementing quality procedures that were revised on July 30, 1996.
- D. Technical Instructions, which supplemented the analytical procedures, provided detailed steps for sample preparation prior to analysis. These technical instructions did not receive an independent technical review.
- E. PNL has implemented a new electronic procedure system which does not provide for documented evidence of review and approval of changes to quality implementing procedures.
- F. Documented evidence substantiated that PNL personnel were aware of a significant condition adverse to quality approximately 5 months prior (July 1996). Also, completion of corrective action to the significant Deficiency Report (DR) was to have been completed by December 31, 1996, but to date, there is no evidence to indicate any actions have been taken to follow up and/or close the deficiency.
- G. There was no objective evidence to support that an audit of PNL's activities has occurred since 1994. It should be noted that in 1995 two readiness review surveillances were performed, but they did not cover all aspects of the PNL quality programs. There have not been any PNL surveillances performed of PNL project activities since 1995.