



Department of Energy

Washington, DC 20585

QA: L

OCT 05 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

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

The OQA staff has evaluated the amended response to CAR YM-97-C-002. The amended 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 that date. Please send a copy of extension request to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

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

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

OQA:JB-0062

Enclosure:
CAR YM-97-C-002

cc w/encl:

T. A. Wood, DOE/HQ (RW-55) FORS
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV
W. L. Clarke, M&O/LLNL, Livermore, CA
R. E. Monks, M&O/LLNL, Livermore, CA
J. M. Ziemba, OQA/LLNL, Livermore, CA

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
J. R. Dyer, DOE/YMSCO, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV

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

8
☒ Corrective Action Request
☐ Stop Work Order
CAR NO. YM-97-C-002

CORRECTIVE ACTION REQUEST

PAGE 1 OF 3
QA: L

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 *[Signature]*

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 Actions:

- 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:

[Signature]

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 *[Signature]*

Date 3/3/97

22 Corrective Action Verified

QAR

Date

23 Closure Approved by:

AOQAM

Date

Note: This signed form is missing
block "6." Please refer to page
1 A of 3, without the signature.
ENCLOSURE P. 1 of 22

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 <input checked="" type="checkbox"/> Corrective Action Request <input type="checkbox"/> Stop Work Order CAR NO. <u>YM-97-C-002</u>
CORRECTIVE ACTION REQUEST		PAGE 1A OF 3 -QA: L
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 Barns	
5 Requirement: This Corrective Action Request (CAR) further supports the adverse conditions (CAR YM-97-001) identifying the lack of the M&O procurement process in controlling similar 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)		
6 Description of Condition: Contrary to the above requirements, PNL has not implemented an effective quality program as follows: A. PNL's QA Plan has not been kept current. The organizational structure as noted in the current PNL QA Plan is not up to date with changes that have occurred in the organization. Also, the reference to the QA implementing procedures in the PNL QA Plan is significantly out of date in that references are made to procedures which have been deleted from the PNL QA Program and replaced by others. (see page 3)		
7 Initiator Richard L. Maudlin Date	9 Does a Stop Work condition exist? Yes _____ No _____ ; If Yes, Attach copy of SWO If Yes, Check One: A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>	
10 Recommended Actions: 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: Date	12 Response Due Date: 20 Working Days From Issuance	
13 Affected Organization QA Manager Issuance Approval: Printed Name Donald G. Horton Signature Date		
22 Corrective Action Verified QAR Date	23 Closure Approved by: AOQAM Date	

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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.

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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions

SEE RESPONSE ON PAGES 4 & 5
CAR/SWO CONTINUATION PAGE

15 Extent of Condition and Impact

SEE RESPONSE ON PAGE 6
CAR/SWO CONTINUATION PAGE

16 Root Cause Determination prepared in accordance with AP-15C is attached

SEE RESPONSE ON PAGE 5

17 Action to Preclude Recurrence

SEE RESPONSE ON PAGE 5
CAR/SWO CONTINUATION PAGE

18 Corrective Action Completion Date

WORK DEFINED HERE 7-31-97
ONGOING WORK T.B.D

19 Response Cue

☒ Initial

☐ Amended

Date 4-1-97

Phone

20 Response Accepted

QAR [Signature]

Date 04/04/97

21 Response Accepted

AOQAM [Signature]

Date 4/28/97

Exhibit AP-16.2Q.1-2

3/31/97 LV. MGDS.JJC.03/97.031

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CAR CONTINUATION PAGE

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113-28-97

5 Requirements (Continued)

LLNL QARS, Section 2.0, Subsection 2.5.4 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."

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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.

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RESPONSE TO RECOMMENDED ACTIONS FROM BLOCK 10 OF THE CAR

This introductory response is being provided in response to procedure items 5.3.2 a) and b) from procedure AP-16.2.Q, Rev. 01. ICN 00, Corrective Action and Stop Work:

A. The M&O performed a Post Audit visit to PNNL to evaluate the conditions covered by the Corrective Action Request (CAR) document received from OQA. The findings of this evaluation are in the document entitled "PRODUCT INTEGRITY Process Review of Quality affecting Activities Performed at Pacific Northwest National Laboratory" (PI-97-029). At the conclusion of this evaluation trip, the M&O manager issued a letter to the Project Manager at Pacific Northwest National Laboratory (PNNL) to "... to put an administrative hold on all technical Project activities." (See letter LV.WP.DS.03/97-059 dated March 14, 1997 from Stahl to Marschman).

B. Steps are being taken to provide separate funds so that the QA function for the PNNL work is clearly identified independent of the technical work management; this is expected to be in place by April 16, 1997. Funding is being provided up to the time of the QA transition which is presently set for June 2, 1997. This arrangement may have to be modified when the details of the QA transition are fully available, and Corrective Actions for YM-97-C001 are formalized.

C. In addition to the already performed Product Integrity review, a Readiness Review will assure that the required QA controls are in place so that the work can be restarted. See BLOCK 14 for further details.

D. The determination of the cause for this deficiency will be documented in Root Cause Determination performed in accordance with AP-16.4Q. See BLOCK 16 below for additional details.

RESPONSE TO BLOCK 14 REMEDIAL ACTIONS

A post-audit trip was taken to PNNL to broadly scope the quality of work performed since the 1994 audit and the 1995 Readiness Review of the TGA effort. The trip confirmed that the work was conducted according to the previous (and still current) technical procedures but that training and other procedural requirements were not updated. Once the contractual and quality assurance requirements have been agreed upon, a schedule will be developed to determine the impact of the prior work, likely by performing an independent technical assessment.

Per the attached letter from D. Stahl to S.C. Marschman dated March 14, 1997, an Administrative Hold has been placed on the technical project activities at PNNL. The letter allows the flow-through tests to continue to completion of the current tests. After completion, these tests will also be subject to the Administrative Hold, if applicable.

PNNL had written in a Deficiency Report (DR) in July 1996 to document a condition adverse to quality. This DR was closed and a new one written (PNNL DR-96-012). The status of this new DR will be followed to assure that the necessary remedial actions at PNNL have been performed.

The QA budget at PNNL will be uniquely identified separate from the budget for the technical work. For the short term PNNL will be provided with funds to cover independent QA functions until a final plan can be put into place. In the longer term, QA oversight will be accomplished by providing outside audits or surveillances conducted by OQA or by providing a separate budget specifically to cover the QA oversight provided by the PNNL Quality Engineers. The method chosen will depend on the result of actions taken to resolve CAR YM-97-C-001.

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BLOCK 14 REMEDIAL ACTION CONTINUED

The technical project activities will be re-started only after a Readiness Review is successfully completed following the M&O QAP-2-6 procedure. This review will confirm that the PNNL work will be performed to applicable requirements of the OCRWM QARD, Revision 6. The following actions will be taken: the PNNL QA Plan will be brought up to date, including the appropriate procedure references; Technical Instructions will be revised as necessary, reviewed and approved; and training to current procedures and instructions will be performed. Documentation of changes to procedures will be provided utilizing hard copy or electronic evidence that contains digitized signatures to assure that the proper reviews and approvals were obtained. It is the M&O's intent to conduct the readiness review so that work may be started in sequence once the essential elements of the QA program are in place for an individual item of technical work. For example, the initial effort will be spent getting the Thermal Gravimetric (TGA) work started first. Estimated completion date for the Readiness Review is June 2, 1997.

BLOCK 15 EXTENT OF CONDITION AND IMPACT

The conditions identified in the CAR affect the following PNNL quality affecting activities:

1. WBS: 1.2.2.4.1 (SA# TR241FB5): Measure Dissolution in Flow-Through Tests
2. WBS: 1.2.2.4.1 (SA# TR241FBB): Low Temperature Dry Bath Oxidation Tests
3. WBS: 1.2.2.4.1 (SA# TR241FB4): Measure Oxidation Using Thermogravimetric Apparatus Techniques

It should also be noted that the activities listed above involve supporting activities performed by the PNNL Analytical Chemistry Laboratory and the Hanford M&O Standards Laboratory. (It should be noted that as part of the investigative action performed thus far, the M&O has determined that the Hanford M&O Standards Laboratory is on the PNNL Qualified Suppliers List dated 2/18/97 but is identified as Westinghouse Standards Laboratory).

As noted in Item 6G of the Description of Condition, there is no objective evidence to support that audits or surveillances of PNNL activities have occurred since 1994. Thus, it is possible that the conditions identified in the Corrective Action Request have impacted testing activities as far back as 1994. However, the conditions should be bounded by the readiness reviews that were performed prior to the start of the testing activities in 1995. Further investigation is required to determine if this is the case.

In addition, the FY97 Statement of Work for Pacific Northwest Laboratories states that data from the Flow-Through Dissolution Tests, the Dry Bath Oxidation Tests, and the TGA test activities will be provided to model development and for inclusion in the GENESIS database and the Waste Form Characteristics Report (WFCR). Further investigation is required to determine the validity of the data generated thus far, and if problems exist with that data, determination of where that data has been used. Preliminary investigations by M&O Engineering and Integration Product Integrity staff suggest that there are no serious issues with the technical adequacy of the data, but a more thorough technical evaluation of the procedures and processes used to govern the testing activities is required to confirm this. The complete investigative actions regarding this is estimated to be July 31, 1997.

BLOCK 16 ROOT CAUSE DETERMINATION PREPARED IN ACCORDANCE WITH AP-16.4Q

A formal Root Cause Determination will be performed by July 3, 1997. It should be pointed out that the Root Cause Determination may have to be modified because of actions taken to resolve YM-97-C-001. For the present we plan to proceed. If the situation changes an AMENDED RESPONSE will be prepared in consultation with the QAR.

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BLOCK 17 ACTION TO PRECLUDE RECURRENCE

The Action to Preclude Recurrence will be developed during the performance of the Root Cause Determination. These results will be incorporated into an AMENDED RESPONSE that will detail the actions required to complete remediation. A date for completion will be established during the preparation of the AMENDED RESPONSE.

jjc
3-31-97
car002g.dbf

TRW Environmental
Safety Systems Inc.

1180 Town Center Drive
Las Vegas, NV 89134
702.295.5400

TRW
CAR YM-97-C-002 PAGE 7 OF

Contract #: DE-AC01-91RW00134
LV.WP.DS.03/97-059

QA: N/A

March 14, 1997

Dr. Steven C. Marschman, Project Manager
Geologic Disposal Support Project
Pacific Northwest National Laboratory
Battelle Boulevard
P.O. Box 999
Richmond, WA 99352

Dear Dr. Marschman:

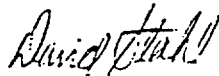
Subject: Technical Direction as a Result of the Recent Audit

As a result of the recent audit of your activities conducted for the Yucca Mountain Site Characterization Office under contract with the Civilian Radioactive Waste Management System Management and Operating Contractor, I am directing you to put an administrative hold on all technical Project activities. However, the ongoing flow-through dissolution tests will be allowed to continue through to their natural conclusion. No new tests will be started until the Administrative Hold is released.

Because of the potential loss of Brady Hansen (who is the graduate student working on this effort), ways are being explored to restart the Thermogravimetric Analysis (TGA) tests quickly.

I will keep you informed of our progress in moving this issue forward.

Sincerely,



David Stahl, Manager
Waste Package Materials Department

xc: J. N. Bailey
J. J. Clark
R. L. Fish, PMO
D. C. Haught, YMSCO
N. W. Hodgson
R. L. Howard

K. Kuhl-Klinger, PNNL
R. A. Morgan
A. M. Segrest
R. D. Snell
R. B. Stout, LLNL
RPC = 1 Page

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AMENDED
RESPONSE 8-01-97

CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

SEE AMENDED RESPONSE ON PAGE 10 OF THE CAR/SWO CONTINUATION PAGE

15 Extent of Condition and Impact:

SEE AMENDED RESPONSE ON PAGE 10 OF THE CAR/SWO CONTINUATION PAGE

BLOCK 16 ROOT CAUSE DETERMINATION--SEE AMENDED RESPONSE ON PAGE 10 OF THE CAR/SWO CONTINUATION PAGE

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached: SEE ABOVE

17 Action to Preclude Recurrence:

8/1/97

SEE AMENDED RESPONSE ON PAGE 10 OF THE CAR/SWO CONTINUATION PAGE

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18 Corrective Action Completion Due Date:

09/30/97

19 Response by:

ALDEN M SEQUEST

Date 8/4/97

Phon 702/295-4416

20 Response Accepted

21 Response Accepted

QAR

Date

DOQA

Date

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AMENDED RESPONSE

August 1, 1997

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PNNL QA PROGRAM

GENERAL STATUS

A meeting was held with the QAR on July 31, 1997 to discuss the status of the CAR. As a result of the meeting, the M&O agreed to provide objective evidence documentation on for the completed items from the original response. The accumulated objective evidence will be provided to the QAR by August 4, 1997. The QAR will review this information and provide the M&O with a response regarding the acceptance of the submitted documentation for the completed items. The documentation to be provided is:

1. Trip report, post OCRWM audit, by Rob Howard dated 3/x/97
2. Letter from Dave Stahl placing an administrative hold on work by PNNL dated 3/14/97
3. Subcontract Change Requests dated 4/2/97 and 5/30/97 regarding funding for QA activities at PNNL
4. Readiness Review report, approved 5/16/97
5. M&O Interim Requirements Document, an attachment to the letter dated 5/12/97 from Dave Stahl to PNNL regarding a partial lifting of the administrative hold
6. PNNL surveillance report GDSP-97-01 dated 5/30/97 concerning CAR YM-97-C-002 and PNNL internal deficiencies
7. PNNL QA Plan, WCT-018, Rev 9
8. Letter dated 7/25/97 from Dave Stahl to PNNL accepting the PNNL QA Plan and covering an additional partial lifting of the administrative hold
- (9. Complete controlled set of all PNNL QA procedures, available in Ron Berlien's office.)
10. Root Cause Determination for CAR YM-97-C-001

Remaining open items are covered in subsequent sections of this amended response. Estimated dates for completion are provided for each item.

RECOMMENDED ACTION FROM BLOCK 10 OF THE ORIGINAL CAR

The total release for PNNL to proceed will all aspects of the defined work related to the Yucca Mountain Project will be documented in a letter to PNNL. The expected completion date for this item is expected to be September 30, 1997. Partial releases are covered in the above referenced objective evidence.

A Root Cause Determination was initially scheduled to be completed by July 3, 1997. A specific root cause for this CAR has not been generated. However, a (An AP-16.4Q) Root Cause Determination was done for CAR YM-97-C-001 on June 2, 1997. The QAR has been requested to consider the RCD for CAR YM-97-C-001 as sufficient to address the key issues this CAR.

jjc
8-1-97
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AMENDED RESPONSE CONTINUED

August 1, 1997

RECOMMENDED ACTIONS FROM BLOCK 10 OF THE ORIGINAL CAR CONTINUED

All other items in this section are considered complete based on the above referenced objective evidence.

BLOCK 14 REMEDIAL ACTIONS

With the completion of the M&O requirements document, acceptance of the PNNL QA Plan, and completion of the Readiness Review, we now plan to perform a peer review to determine acceptability of prior work. An independent technical assessment will be conducted using M&O QA procedure QAP-3-3, Peer Review. This Peer Review will establish whether or not prior work is valid. The estimated completion date for the Peer Review is September 30, 1997.

All other items in this section are considered complete based on the above referenced objective evidence.

BLOCK 16 ROOT CAUSE DETERMINATION

Please refer to the second paragraph of the section entitled "RECOMMENDED ACTIONS FROM BLOCK 10" for a discussion of this item.

BLOCK 17 ACTION TO PRECLUDE RECURRENCE

The final resolution of this CAR cannot actually be made until CAR YM-97-C-001 is resolved. However, once the above items specific to this CAR are completed it is suggested that this CAR be closed. The resolution to CAR YM-97-C-001 will affect all of the organizations listed in the CAR, which specifically includes PNNL.

We will confirm that the commitments covered by this amended response have been completed by the scheduled dates for your verification and follow up.

car002i.dbf

Jjc

August 1, 1997

car002j.wpd

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8
☒ Corrective Action
Request
☐ Stop Work Order
CAR NO. YM-97-C-002

CORRECTIVE ACTION REQUEST

PAGE 1 OF 2
QA: L

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

096
3-26-97

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 Reason:
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)

6 Issued By:
Richard L. Maudlin *R. L. 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 Actions:

- 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. L. 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. Horton*

Date 3/3/97

22 Corrective Action Verified

QAR

Date

23 Closure Approved by:

AOQAM

Date

Enclosure

P. 13 of 21

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

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QA: L

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 2/13/88

2 Request Number: OQA-SA-97-011

186
3-16-97

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

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

This Corrective Action Request (CAR) further supports the adverse conditions (CAR YM-97-001) identifying the lack of the M&O procurement process in controlling similar 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)

5 Narrative of Condition: Conforms to the above requirements, PNL has not implemented an effective quality program as follows:

- A. PNL's QA Plan has not been kept current. The organizational structure as noted in the current PNL QA Plan is not up to date with changes that have occurred in the organization. Also, the reference to the QA implementing procedures in the PNL QA Plan is significantly out of date in that references are made to procedures which have been deleted from the PNL QA Program and replaced by others.
(see page 3)

6 Requester: Richard L. Mandlin

Date:

7 Does a Stop Work Order exist?

Yes ☐ No ☒ If Yes, Attach copy of SWO
If Yes, Check One: A ☐ B ☐ C ☐ D ☐

8 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.

9 QA Review:

Date:

10 Response Due Date:

20 Working Days From Issuance

11 Affected Organization QA Manager Issuance Approval:

Printed Name: Donald G. Horton

Signature:

Date:

12 Corrective Action Verified:

QAR

Date:

13 Closure Approved by:

AOQAM

Date:

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3-31-97
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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

SEE RESPONSE ON PAGES 4 & 5
CAR/SWD CONTINUATION PAGE

15 Extent of Condition and Impact:

SEE RESPONSE ON PAGE 6
CAR/SWD CONTINUATION PAGE

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

SEE RESPONSE ON PAGE 5

17 Action to Preclude Recurrence:

SEE RESPONSE ON PAGE 5
CAR/SWD CONTINUATION PAGE

18 Corrective Action Completion Date

WORK DEFINED HERE 7-31-97
ONGOING WORK T.B.D

19 Response Cue

☒ Initial
☐ Amended

Date 4-1-97

Phone

20 Response Accepted

QAR

Date

21 Response Accepted

AOQAM

Date

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113-28-97

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.

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RESPONSE TO RECOMMENDED ACTIONS FROM BLOCK 10 OF THE CAR

This introductory response is being provided in response to procedure items 5.3.2 a) and b) from procedure AP-16.2.Q, Rev. 01, ICN 00, Corrective Action and Stop Work:

- A. The M&O performed a Post Audit visit to PNNL to evaluate the conditions covered by the Corrective Action Request (CAR) document received from OQA. The findings of this evaluation are in the document entitled "PRODUCT INTEGRITY Process Review of Quality affecting Activities Performed at Pacific Northwest National Laboratory" (PI-97-029). At the conclusion of this evaluation trip, the M&O manager issued a letter to the Project Manager at Pacific Northwest National Laboratory (PNNL) to "... to put an administrative hold on all technical Project activities." (See letter LV.WP.DS.03/97-059 dated March 14, 1997 from Stahl to Marschman).
- B. Steps are being taken to provide separate funds so that the QA function for the PNNL work is clearly identified independent of the technical work management; this is expected to be in place by April 16, 1997. Funding is being provided up to the time of the QA transition which is presently set for June 2, 1997. This arrangement may have to be modified when the details of the QA transition are fully available, and Corrective Actions for YM-97-C001 are formalized.
- C. In addition to the already performed Product Integrity review, a Readiness Review will assure that the required QA controls are in place so that the work can be restarted. See BLOCK 14 for further details.
- D. The determination of the cause for this deficiency will be documented in Root Cause Determination performed in accordance with AP-16.4Q. See BLOCK 16 below for additional details.

RESPONSE TO BLOCK 14 REMEDIAL ACTIONS

A post-audit trip was taken to PNNL to broadly scope the quality of work performed since the 1994 audit and the 1995 Readiness Review of the TGA effort. The trip confirmed that the work was conducted according to the previous (and still current) technical procedures but that training and other procedural requirements were not updated. Once the contractual and quality assurance requirements have been agreed upon, a schedule will be developed to determine the impact of the prior work, likely by performing an independent technical assessment.

Per the attached letter from D. Stahl to S.C. Marschman dated March 14, 1997, an Administrative Hold has been placed on the technical project activities at PNNL. The letter allows the flow-through tests to continue to completion of the current tests. After completion, these tests will also be subject to the Administrative Hold, if applicable.

PNNL had written in a Deficiency Report (DR) in July 1996 to document a condition adverse to quality. This DR was closed and a new one written (PNNL DR-96-012). The status of this new DR will be followed to assure that the necessary remedial actions at PNNL have been performed.

The QA budget at PNNL will be uniquely identified separate from the budget for the technical work. For the short term PNNL will be provided with funds to cover independent QA functions until a final plan can be put into place. In the longer term, QA oversight will be accomplished by providing outside audits or surveillances conducted by OQA or by providing a separate budget specifically to cover the QA oversight provided by the PNNL Quality Engineers. The method chosen will depend on the result of actions taken to resolve CAR YM-97-C-001.

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BLOCK 14 REMEDIAL ACTION CONTINUED

The technical project activities will be re-started only after a Readiness Review is successfully completed following the M&O QAP-2-6 procedure. This review will confirm that the PNNL work will be performed to applicable requirements of the OCRWM QARD, Revision 6. The following actions will be taken: the PNNL QA Plan will be brought up to date, including the appropriate procedure references; Technical Instructions will be revised as necessary, reviewed and approved; and training to current procedures and instructions will be performed. Documentation of changes to procedures will be provided utilizing hard copy or electronic evidence that contains digitized signatures to assure that the proper reviews and approvals were obtained. It is the M&O's intent to conduct the readiness review so that work may be started in sequence once the essential elements of the QA program are in place for an individual item of technical work. For example, the initial effort will be spent getting the Thermal Gravimetric (TGA) work started first. Estimated completion date for the Readiness Review is June 2, 1997.

BLOCK 15 EXTENT OF CONDITION AND IMPACT

The conditions identified in the CAR affect the following PNNL quality affecting activities:

1. WBS: 1.2.2.4.1 (SA# TR241FB5) : Measure Dissolution in Flow-Through Tests
2. WBS: 1.2.2.4.1 (SA# TR241FBB): Low Temperature Dry Bath Oxidation Tests
3. WBS: 1.2.2.4.1 (SA# TR241FB4): Measure Oxidation Using Thermogravimetric Apparatus Techniques

It should also be noted that the activities listed above involve supporting activities performed by the PNNL Analytical Chemistry Laboratory and the Hanford M&O Standards Laboratory. (It should be noted that as part of the investigative action performed thus far, the M&O has determined that the Hanford M&O Standards Laboratory is on the PNNL Qualified Suppliers List dated 2/18/97 but is identified as Westinghouse Standards Laboratory).

As noted in Item 6G of the Description of Condition, there is no objective evidence to support that audits or surveillances of PNNL activities have occurred since 1994. Thus, it is possible that the conditions identified in the Corrective Action Request have impacted testing activities as far back as 1994. However, the conditions should be bounded by the readiness reviews that were performed prior to the start of the testing activities in 1995. Further investigation is required to determine if this is the case.

In addition, the FY97 Statement of Work for Pacific Northwest Laboratories states that data from the Flow-Through Dissolution Tests, the Dry Bath Oxidation Tests, and the TGA test activities will be provided to model development and for inclusion in the GENISIS database and the Waste Form Characteristics Report (WFCR). Further investigation is required to determine the validity of the data generated thus far, and if problems exist with that data, determination of where that data has been used. Preliminary investigations by M&O Engineering and Integration Product Integrity staff suggest that there are no serious issues with the technical adequacy of the data, but a more thorough technical evaluation of the procedures and processes used to govern the testing activities is required to confirm this. The complete investigative actions regarding this is estimated to be July 31, 1997.

BLOCK 16 ROOT CAUSE DETERMINATION PREPARED IN ACCORDANCE WITH AP-16.4Q

A formal Root Cause Determination will be performed by July 3, 1997. It should be pointed out that the Root Cause Determination may have to be modified because of actions taken to resolve YM-97-C-001. For the present we plan to proceed. If the situation changes an AMENDED RESPONSE will be prepared in consultation with the QAR.

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BLOCK 17 ACTION TO PRECLUDE RECURRENCE

The Action to Preclude Recurrence will be developed during the performance of the Root Cause Determination. This results will be incorporated into an AMENDED RESPONSE that will detail the actions required to complete remediation. A date for completion will be established during the preparation of the AMENDED RESPONSE.

jic
3-31-97
car002g.dbf

TRW Environmental
Safety Systems Inc.

1180 Town Center Drive
Las Vegas, NV 89134
702.295.5400

CAR YM-97-C-002 PAGE 7 OF

Contract #: DE-AC01-91RW00134
LV.WP.DS.03/97-059

QA: N/A

March 14, 1997

Dr. Steven C. Marschman, Project Manager
Geologic Disposal Support Project
Pacific Northwest National Laboratory
Battelle Boulevard
P.O. Box 999
Richmond, WA 99352

Dear Dr. Marschman:

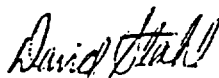
Subject: Technical Direction as a Result of the Recent Audit

As a result of the recent audit of your activities conducted for the Yucca Mountain Site Characterization Office under contract with the Civilian Radioactive Waste Management System Management and Operating Contractor, I am directing you to put an administrative hold on all technical Project activities. However, the ongoing flow-through dissolution tests will be allowed to continue through to their natural conclusion. No new tests will be started until the Administrative Hold is released.

Because of the potential loss of Brady Hansen (who is the graduate student working on this effort), ways are being explored to restart the Thermogravimetric Analysis (TGA) tests quickly.

I will keep you informed of our progress in moving this issue forward.

Sincerely,



David Stahl, Manager
Waste Package Materials Department

xc: J. N. Bailey
J. J. Clark
R. L. Fish, PMO
D. C. Haught, YMSCO
N. W. Hodgson
R. L. Howard

K. Kuhl-Klinger, PNNL
R. A. Morgan
A. M. Segrest
R. D. Snell
R. B. Stout, LLNL
RPC = 1 Page

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EVALUATION OF AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-97-C-002

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

As part of your amended response, you provided the status to actions which have been completed and the supporting documented evidence. In reviewing the supporting documented evidence, it was noted that a Subcontract Change Request (SCR no. 97-79-009) was initiated to provide a funding to PNNL QA for performing internal QA oversight of the work being performed. However, it was also noted that a non-contractually binding letter was the method used to identify the QA requirements which PNNL needs to implement on the work being performed. The rationale for using a letter instead of a SCR was given in TRW Letter LV.WP.DS.05/97-106 dated May 12, 1997, from David Stahl to Dr. Steven C. Marshmann. This letter states in part: "In lieu of further modification to your contract with TRW, which is dependent upon the resolution to OCRWM Corrective Action Request YM-97-C-001, please perform your work in accordance with the enclosed PNNL Interim QA Requirements for TGA work". In OQA's acceptance letter to your initial response to CAR YM-97-C-002, a statement was included that once the QA requirements were identified by the M&O that PNNL's contract be modified to include these requirements. It is requested that the M&O initiate the necessary QARD required procurement actions in order to have an effective procurement document in place for the start of GFY-98. Please note that CAR YM-97-C-001's resolution will include identification of PNNL as a supplier/contractor. Please take appropriate actions and provide an amended response to CAR YM-97-C-002 stating the actions taken with completion dates.

Your amended response also requested the QAR to consider the Root Cause Determination (RCD) for CAR YM-97-C-001 as sufficient to address the key issues of this CAR. When a response is provided for CAR YM-97-C-001 and accepted by the responsible QAR, the QAR of CAR YM-97-C-002 will perform an evaluation of the CAR YM-97-C-001 RCD for acceptability on CAR YM-97-C-002.

An amended response is required in order to complete my evaluation.



Richard L. Maudlin, QAR

09-02-97

Date

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

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AMENDED RESPONSE II

CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

The M&O will provide Pacific Northwest National Laboratory (PNNL) with a procurement modification that will contractually impose QA requirements for PNNL to implement a pertinent QA program for the work being conducted. The M&O is working with OQA to establish the exact way to accomplish this using existing procedures. The completion for the above action is expected to be December 1, 1997.

15 Extent of Condition and Impact:

There is no further work required in this category.

BLOCK 16 ROOT CAUSE DETERMINATION

A Root Cause Determination specific to CAR YM-97-C-002 will be completed by October 13, 1997.

9-12-97

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached *SEE ABOVE*

17 Action to Preclude Recurrence:

No further action is required in this category.

jic
9/22/97
car002n.dbf

18 Corrective Action Completion Due Date:

12/01/97

19 Response by:

[Signature]
Alden M. Segrest

Date *9/23/97* Phon (702) 295-4416

20 Response Accepted

QAR

[Signature]

Date *10/06/97*

21 Response Accepted

DOQA

[Signature]

Date

10/8/97