



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

QA: L

AUG 25 1994

Julie A. Canepa
Technical Project Officer
for Yucca Mountain
Site Characterization Project
Los Alamos National Laboratory
University of California
EES-13, Mail Stop J521
P.O. Box 1663
Los Alamos, NM 87545

ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) YM-94-078 THROUGH
YM-94-082 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT YMP-94-08 OF LOS ALAMOS NATIONAL
LABORATORY (SCPB: N/A)

Enclosed are CARs YM-94-078 through YM-94-082 generated as a
result of YMQAD Audit YMP-94-08.

Please identify the corrective actions to be taken and
implemented to correct the deficiencies. CAR Continuation Sheets
and instructions for completion have been provided. Send the
originals of your responses to Deborah G. Sult, YMQAD/QATSS,
101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.
Responses to the CARs are due 20 working days from the date of
this letter. Extensions to due dates must be requested in
writing, with appropriate justification, prior to the due dates.

If you have any questions, please contact either Robert B.
Constable at (702) 794-7945 or Stephen R. Maslar at (702)
794-7762.

Robert B. Constable for.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4813

Enclosures:
CARs YM-94-078
through YM-94-082

090050

YMP-5

9409120041 940825
PDR WASTE
WM-11 PDR

102.7
WM-11
NHD

Julie A. Canepa

-2-

AUG 25 1994

cc w/encls:

J. B. Tillman, LAAO

~~R. L. Johnson~~ NRC, Washington, DC

J. H. Hines, OGD, AL

S. W. Zimmerman, NWPO, Carson City, NV

S. L. Bolivar, LANL, Los Alamos, NM

N. Z. Elkins, LANL, Las Vegas, NV

T. L. Badredine, M&O/TRW, Las Vegas, NV

cc w/o encls:

W. L. Belke, NRC, Las Vegas, NV

D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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8 CAR NO.: YM-94-078
PAGE: 1 OF 2
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CORRECTIVE ACTION REQUEST

1 Controlling Document QARD DOE/RW-0333P, Revision 0	2 Related Report No. YMP-94-08
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3 Responsible Organization LANL-YMP	4 Discussed With M. Clevenger/S. Martinez
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5 Requirement:
QARD Subsection 17.2.2B requires that individuals creating QA records shall ensure that QA records are legible, accurate, and complete.

6 Adverse Condition:
Contrary to the above requirement, the following deficiency was noted:

- A. The record package for LANL-YMP-QP-06.1, Revision 7 contains errors in page number count, dates, identification of reviewing organization, and copies of the complete procedure.
- B. The record package for LANL-CST-DP-66, Revision 2 was missing DP Action Request Form, the even pages of the final approved procedure, and the review criteria sheet.
- C. Record package for LANL-LS2-DP-404, Revision 0 was missing the DP Action Request Form. Record package has been microfilmed.
- D. The microfilmed record package for LANL-EES13-DP-609, Revision 1 did not contain DP review sheets or DP review criteria.
- E. The record source's copy file for LANL-YMP-QP-06.1, Revision 7 was missing the Review Criteria form.
- F. The record source's copy file for LANL-CST-DP-63, Revision 4 was missing DP Review Criteria form.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
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11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:

- 1) The in-house copy of the record package was corrected on 8/15/94 for QP-06.1.
- 2) Obtain copy from records center and make appropriate corrections.

(Continued on next page)

7 Initiator Walter R. Coutier <i>W.R. Coutier</i> 8/18/94	14 Issuance Approved by: QADD <i>R. B. [Signature]</i> for Date <u>8-24-94</u>
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15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____
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17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____
--	---

19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____
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8 CAR NO.: YH-94-078
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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

13 Recommended Action(s) (continued)

- 3) Provide remedial actions to correct the specific deficiencies noted and conduct evaluation to determine extent of deficiencies in other record packages and provide corrective action to preclude recurrence.

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 - C. **Root Cause Determination - Identify the root cause of the condition as determined through investigative action. (Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA)**
 - D. **Corrective Action to Preclude Recurrence - Identify the actions required to address the root cause of the condition in order to preclude recurrence. (Required for all Significant Conditions Adverse to Quality or for any Condition Adverse to Quality if requested by OQA)**
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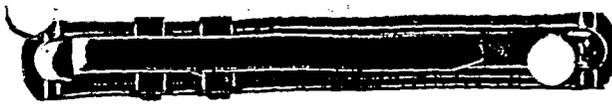
If it becomes apparent that any of the corrective action due dates cannot be met, a written request for extension must be provided to the identified CAR Coordinator. This request must include justification for the delay and must be provided to the CAR Coordinator prior to the due date.

3. **The response must include the dated signature of the Responsible Individual.**

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8 CAR NO.: YM-94-079
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CORRECTIVE ACTION REQUEST

1 Controlling Document
LANL-INC-DP-35, REVISION 2

2 Related Report No.
YMP-94-08

3 Responsible Organization
LANL-YMP

4 Discussed With
C. Drew/C. Tait

5 Requirement:

INC-DP-35, Revision 2, Paragraph 6.22, third sentence requires at least two buffers that have Ph values surrounding the expected Ph of the solution to be measured, be selected for calibration of the Ph meter.

6 Adverse Condition:

Contrary to the above requirement, buffers of Ph 7 and Ph 10 were always selected regardless of the expected Ph. Five examples of this condition were noted in scientific notebook TWS-INC-01-93-12, Pages 10, 13, 14, 21, and 88, where the actual Ph value was notably outside of the 7 to 10 Ph range.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Check One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Check One: A B C

13 Response Due Date:
20 Working Days
From Issuance

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:

1) Change procedure to more clearly specify buffers to be used.

7 Initiator
Paul L. Cloke *Paul L. Cloke 5/23/94*

14 Issuance Approved by:
QADD *[Signature]* Date 8.24.94

15 Response Accepted
QAR _____ Date _____

16 Response Accepted
QADD _____ Date _____

17 Amended Response Accepted
QAR _____ Date _____

18 Amended Response Accepted
QADD _____ Date _____

19 Corrective Actions Verified
QAR _____ Date _____

20 Closure Approved by:
QADD _____ Date _____

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8 CAR NO. _____
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YM-94-080</u> PAGE: <u>1</u> OF <u>2</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document QARD DOE/RW-0333P		2 Related Report No. YMP-94-08
3 Responsible Organization LANL YMP QA	4 Discussed With M. Clevenger/P. Gillespie	
5 Requirement: 1) Section 2.0, Quality Assurance Program Documents, Subsection 2.2.2, Step B . Affected organizations shall establish QA implementing documents applicable to their scope of work that translates QARD requirements into work processes. <p style="text-align: center;">(Continued on next page)</p>		
6 Adverse Condition: Contrary to the above requirements, LANL-YMP-QP-04.6, Revision 1, Procurement procedure, in some instances only reiterates the QARD requirements with no methodology on how to satisfy the requirements and no provisions or mechanism to demonstrate the requirements were satisfied, examples are: Paragraphs 6.1.6, 6.3, 6.4 and 6.5. NOTE: LANL-YMP-QP-04.6, Revision 1, Procurement, has not been implemented as of August 19, 1994.		
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
12 Recommended Actions:		
7 Initiator Donald J. Harris 8/17/94 <i>dharris</i>	14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>8-24-94</u>	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____	

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5 Requirements (continued)

- 2) Section 5.0, Implementing Documents, Subsection 5.2.2, Content of Implementing Documents, Step C requires in part, "...a sequential description of work to be performed."
- 3) Step D requires quantitative or qualitative acceptance criteria sufficient for determining the activities were satisfactorily accomplished.
- 4) Step G requires methods for demonstrating the work was performed as required, such as for provisions for recording inspection and test results, check off lists or sign off blocks.

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8 CAR NO.: YM-94-081
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CORRECTIVE ACTION REQUEST

1 Controlling Document LANL-YMP-QP-03.5, Revision 2		2 Related Report No. YMP-94-08	
3 Responsible Organization LANL-YMP		4 Discussed With C. Tait/M. Clank	
5 Requirement: Paragraph 6.6.1 of QP-03.5, Revision 2 requires that data be evaluated and a statement is entered into the notebook explaining the acceptance or rejection of the data.			
6 Adverse Condition: Contrary to the above requirement, data recorded in the following scientific notebooks had no evidence of any such evaluation. * TWS-INC-01-93-12 * TWS-CST-02-94-03 * LA-CSI-03-94-013 * TWS-INC-06-93-09 * TWS-INC-01-93-10			
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
13 Response Due Date: 20 Working Days from Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination			
12 Recommended Actions: * Comply with existing procedures.			
7 Initiator Thomas J. Higgins <i>[Signature]</i>		14 Issuance Approved by: QADD <i>[Signature]</i> for Date <u>8-23-94</u>	
15 Response Accepted QAR _____ Date _____		16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____		18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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8 CAR NO.: YH-94-082
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CORRECTIVE ACTION REQUEST

1 Controlling Document QP-03.26, Revision 1		2 Related Report No. YMP-94-08	
3 Responsible Organization LANL-YMP		4 Discussed With E. Gundlach	
5 Requirement: The third paragraph of QP-03.26, Revision 1, Section 6.1.2.1b. requires that during the design phase, traceability of software requirements into the software design be demonstrated as follows: Specify (in the requirements traceability section of each source-code documentation-prolog) the identifying number of each software requirement			
6 Adverse Condition: Contrary to the above requirement, the source code for TRACRM, requirements traceability section, indicates "None."			
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
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12 Recommended Actions:			
7 Initiator <i>S. D. Harris</i> Stephen D. Harris 8/16/94		14 Issuance Approved by: QADD <i>[Signature]</i> Date 8/24/94	
15 Response Accepted QAR _____ Date _____		16 Response Accepted QADD _____ Date _____	
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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

5 Requirements (continued)

satisfied by the module. Ensure that each requirement in the Software Requirements Specification is implemented within one or more modules of the software design (as embodied in the documentation prolog of each software module).

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