



Department of Energy

Washington, DC 20585

NOV 20 1996

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

**VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DR YM-96-D-086
RESULTING FROM OQA AUDIT YM-ARC-96-18 OF SANDIA NATIONAL
LABORATORIES**

The Office of Quality Assurance staff has verified the corrective action to Deficiency Report (DR) YM-96-D-086 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Stephen D. Harris at (702) 794-5522.

for Mario Diaz

Donald G. Horton, Director
Office of Quality Assurance

OQA:MRD-0376

Enclosure:
DR YM-96-D-086

cc w/encl:

- T. A. Wood, DOE/HQ (RW-55) FORS
- J. G. Spraul, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- B. R. Justice, M&O, Las Vegas, NV
- S. Y. Pickering, M&O/SNL, Albuquerque, NM, M/S 1395
Records Processing Center

cc w/o encl:

- W. L. Belke, NRC, Las Vegas, NV
- S. D. Harris, OQA/QATSS, Las Vegas, NV
- D. G. Sult, OQA/QATSS, Las Vegas, NV

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Deficiency Report

NO. YM-96-D086

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QARD, Revision 4	2 Related Report No. YM-ARC-96-18
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3 Responsible Organization: SNL	4 Discussed With: C. Jaramillo
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5 Requirement/Measurement Criteria:

QARD 17.2.2, D. states in part, "Records shall be considered QA records when stamped, initialed, or signed and dated as complete...."

QAIP 17-3, Revision 02, Appendix A, Page 10 & 11 identifies DRCs and mark-up procedures as QA records.

QAIP 6-3, Revision 03, Section 5.3 Step 6 - states (author/request), "Shall submit DRC form(s) and any markups to the local records center in accordance with Procedure 17-1."

(See individual document procedure to determine if the DRC is maintained as a QA record.)

6 Description of Condition:

DRC forms for review of QAIP 5-1, Revision 05 and QAIP 1-2, Revision 10 and mark-up procedures have not been submitted to the LRC.

Also, it appears the requirements of QAIP 17-3, Revision 02 and QAIP 6-3, Revision 03 are in conflict with one another. Specifically, Section 6.0, bullet, states, "See individual document procedure to determine if the DRC is maintained as a QA record," however, QAIP 17-3, Revision 02, Appendix A (see QAIP 6-3) lists DRC and other documents such as marked-up procedures as lifetime records.

A.L.W.
8/6/96

7 Initiator <i>Richard L. White</i> Stephen D. Harris Date 8/1/96	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
--	---

10 Recommended Action: (Not required for PR)

Obtain and submit missing records to the LRC.

Evaluate the issue described in the second paragraph of Block 6 above, and revise procedures as appropriate.

11 QA Review: <i>Richard L. White</i> QAR Stephen D. Harris Date <i>8/1/96</i>	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA manager Issuance Approval: (QAR for PR) Printed Name R.E. SPENCE Signature <i>Robert B. Constable</i> Date <i>8-7-96</i>
--

22 Corrective Action Verified QAR <i>Stephen Harris</i> Date <i>11-15-96</i>	23 Closure Approved by: (N/A for PR) <i>AOQAM</i> <i>Harris</i> Date <i>11-19-96</i>
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Continuation Page.

15 Extent of Condition: (Not required for PR)

See Continuation Page.

16 Root Cause Determination: (Not required for PR)

Required Yes No

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

Required Yes No

18 Corrective Action Completion Due Date:

October 1, 1996

19 Response by:

FOR R. RICHTER

OSF ELL

Initial

Amended

Date *9/4/96*

Phone *848-0641*

20 Response Accepted

QAR

N/A

Date

21 Response Accepted (N/A for PR):

AOQAM

N/A

Date

9/5/96 Brady to Spence

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Amended response CONTINUATION PAGE.

15 Extent of Condition: (Not required for PR)

SEE Amended response CONTINUATION PAGE.

16 Root Cause Determination: (Not required for PR)

Required Yes No

SEE Amended Response CONTINUATION PAGE.

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

Required Yes No

SEE Amended Response CONTINUATION PAGE.

18 Corrective Action Completion Due Date:

SEE A/R CONTINUATION PAGE

19 Response by:

Initial
 Amended

SEE AMENDED RESPONSE
CONTINUATION PAGE
Date _____ Phone _____

20 Response Accepted

OAR Stephen Harris

Date 10-15-96

21 Response Accepted (N/A for PR):

AQOAM Jane Blaylock & Ree Date 10/19/96

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BLOCK 14 - REMEDIAL ACTIONS:

The records have actually been processed correctly based upon the statement in QAIP 6-3, "See individual document procedures to determine if the DRC is maintained as a QA record." and the statement from QAIP 5-1 that states, "Non-processed records generated by this procedure may be retained by the Quality Assurance Department in a separate record package. The record package includes procedure review comment and resolution documentation including DRC forms." The Quality Assurance Department is maintaining the DRC forms and markup copies of QAIP 5-1, Revision 05 and QAIP 1-2, Revision 10 as non-processed records. However, QAIP 17-3, Appendix A is definitely in conflict with QAIP 6-3. Records and Quality Assurance personnel are developing a revision to QAIP 17-3 which removes Appendix A and places the LIFETIME - NONPERMANENT designation in the procedure that defines the record. This will both eliminate the current conflict and prevent the procedures from becoming out of sync with each other in the future. In the interim, the list of LIFETIME - NONPERMANENT records will be maintained as an appendix to the master file codes list. Also, the wording of QAIP 6-3 will be changed to clarify the fact that QAIP 6-3 generates no records; records are generated by the procedure which required the review (e.g. QAIP 5-1 for Quality Assurance Implementing Procedures). QAIP 5-1 will also be updated to require the LIFETIME - NONPERMANENT designation in the individual procedures.

BLOCK 15 - EXTENT OF CONDITION

QAIP 17-3, revision 02, Appendix A has been compared to the individual procedures which call for the generation of records. It conflicts in many areas. The deficiency, however, appears to be confined to that Appendix; authors of Quality Assurance Implementing Procedures have been keeping records information up to date. Therefore, there is no need for either root cause analysis nor action to preclude recurrence.

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YM-96-D086, Amended Response (the information below supercedes the content of blocks 14 through 19 on page 2 of this DR)

Block 14, Remedial Action:

The records have actually been processed correctly based upon the statement in QAIP 6-3, "See individual document procedures to determine if the DRC is maintained as a QA record." and the statement from QAIP 5-1 that states, "Non-processed records generated by this procedure may be retained by the Quality Assurance Department in a separate record package. The record package includes procedure review comment and resolution documentation including DRC forms." The Quality Assurance Department is maintaining the DRC forms and markup copies of QAIP 5-1, Revision 05 and QAIP 1-2, Revision 10 as non-processed records. However, QAIP 17-3, Appendix A is definitely in conflict with QAIP 6-3. Records and Quality Assurance personnel are developing a revision to QAIP 17-3 which removes Appendix A and places the LIFETIME - NONPERMANENT designation in the procedure that defines the record. This will both eliminate the current conflict and prevent the procedures from becoming out of sync with each other in the future. In the interim, the list of LIFETIME - NONPERMANENT records will be maintained as an appendix to the master file codes list. Also, the wording of QAIP 6-3 will be changed to clarify the fact that QAIP 6-3 generates no records; records are generated by the procedure which required the review (e.g. QAIP 5-1 for Quality Assurance Implementing Procedures). QAIP 5-1 will also be updated to require the LIFETIME - NONPERMANENT designation in the individual procedures.

Block 15, Extent of Condition:

QAIP 17-3, revision 02, Appendix A has been compared to the individual procedures which call for the generation of records. It conflicts in many areas. The records section of each active QAIP will be compared to the LIFETIME-NONPERMANENT records list, in order to establish an accurate list as the appendix to the master file codes list, referred to in block 14.

Block 16, Root Cause Determination Required No A root cause determination utilizing AP 16.4Q is not required, because the cause of the discrepant condition is sufficiently clear, as described below.

No mechanism was in place to assure that revisions of the records sections of QAIPs were also captured in changes to Appendix A of QAIP 17-3.

10/3/96 BRADY TO SPENCE

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Block 17, Action To Preclude Recurrence: Required Yes, based on the information in block 16.

The records section of each active QAIP will be compared to the Lifetime/Nonpermanent Record List to assure that generated records are properly identified and shown as Nonpermanent on the List. As new revisions of QAIPs are announced the Records Management staff will review the Lifetime/Nonpermanent Record List for necessary updates. The records management and Participant Data Archive staff members will be briefed on the changes to the list. The revised list will be placed into the Nuclear Waste Management Program icon on the SNL Nuclear Waste Management Local Area computer network for access by all personnel.

Block 18, Corrective Action Completion Due Date:

November 15, 1996

Block 19, Response by:

Amended For Peggy J. Warner



Date: October 3, 1996

Phone: 505 848 0130

DE Ym-96-D-086

**SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 17-3**

PROCESSING, STORING, AND PROTECTING CRWM QA RECORDS.

Revision 03

Effective Date: _____

Author: *Marlene R. Tucker*
Marlene Tucker

Date: 11/11/96

Concurrence: *Robert R. Richards*
Robert R. Richards, QA Reviewer

Date: 11/13/96

Approval: *Michael C. Brady*
Michael C. Brady, SML CRWM Lab Lead

Date: 11/13/96

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Verification of Corrective Action:

QAIP 6-3, revision 04, has been issued with clarifying words that this procedure generates no records. The QAIP 5-1, revision 06, has been issued with words requiring **LIFETIME-NONPERMANENT** designation of records be in individual procedures. Appendix A of QAIP 17-3 has been removed which had the conflicting matrix of record designations.

S. D. Harris 11/15/96