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

SEP 20 1996

L. D. Foust
Technical Project Officer
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

VERIFICATION OF CORRECTIVE ACTION OF DEFICIENCY REPORT (DR) YM-96-D-004 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YMP-94-09 OF SANDIA NATIONAL LABORATORIES (SNL)

The YMQAD staff has verified the corrective action to DR YM-96-D-004 and determined the results to be unsatisfactory because of the following:

> YMQAD Audit YM-ARC-96-18 was a compliance based audit that, in part evaluated the adequacy and implementation of the SNL Quality Assurance Program procedures. During that audit, Criteria 5 and 17 implementing procedures were identified as inadequate.

Please provide a revised response on the actions SNL intends to pursue to resolve the inadequate procedure deficiency condition. Your response, indicating the appropriate corrective action completion date, is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response 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 James Blaylock at (702) 794-1420.

RE Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2680

Enclosure:
DR YM-96-D-004

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RECIP. NMSS/HLOR

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. R. Richards, M&O/SNL, Albuquerque, NM, M/S 1333
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
D. G. Sult, YMQAD/QATSS, Las Vegas, NV
D. G. Horton, DOE/OQA, Las Vegas, NV
James Blaylock, DOE/YMQAD, Las Vegas, NV

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

8 ☐ Performance Report
☑ Deficiency Report

NO. YMQAD-96-D004

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:	2 Related Report No.
OCRWM QARD DOE/RW-0333P, Revision 0	YMP-94-09

3 Responsible Organization:	4 Discussed With:
SNL	L. Shephard

5 Requirement/Measurement Criteria:
This DR is issued to supersede CAR YM-94-096 in order to implement the revised OCRWM Corrective Action Program.

Section 5.0, Paragraph 5.2.2, "Contents of Implementing Documents" states in part: "Implementing documents shall include the following information as appropriate to the work to be performed: (C) A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operation. The organization responsible for preparing the document shall determine the appropriate level of detail. (D) Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished....."

6 Description of Condition:
Contrary to the above, SNL's QAIPs do not meet all of the requirements of the OCRWM QARD as identified by those specific examples cited and referenced below:

1. The record packaging process implemented for procurement records is not addressed in QAIP 04-01 or QAIP 17-03. QAIP record sections do not clearly identify what records are processed individually and what records are processed as record packages.

   The record packaging process should be reflected in all applicable procedures.

2. The detail in QAIP 20-02 (Scientific Notebooks) is insufficient to provide a Scientific Notebook that would be suitable for use in licensing. The instructions in the QAIP are merely a restatement of the guidance provided in the QARD. Scientific Notebooks should be of a type and quality that would be suitable in a court of law. Unsatisfactory conditions that (continued)

7 Initiator	9 QA Review
James Blaylock Date 1/30/96	QAR James Blaylock Date 1/30/96
10 Response Due Date	**11 QA Issuance Approval**
N/A	QAR (PR)/AOQAM (DR) for Date 2.1.96

12 Remedial Actions:
See response to CAR YM-94-096

13 Remedial Action Response By:	14 Remedial Action Due Date
N/A Date	Date
15 Remedial Action Response Acceptance	**16 PR Verification/Closure**
QAR N/A Date	QAR N/A Date

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WASHINGTON, D.C.

8 DR NO. YMQAD-96-D-
PAGE 2 OF
QA: L

DEFICIENCY REPORT

17 Recommended Actions:

~~See Continuation page~~ N/A
PR
1/16/96

18 Investigative Actions:

See Continuation page

19 Root Cause Determination:

See Continuation page

20 Action to Preclude Recurrence:

See continuation page

21 Response by: [signature] Date Jan 16, 1996	22 Corrective Action Completion Due Date: APR. 30, 1996
23 Response Accepted QAR Date	24 Response Accepted AOQAM Date
25 Amended Response Accepted QAR [signature] Date 1/29/96	26 Amended Response Accepted AOQAM [signature] Date 2/1/96
27 Corrective Actions Verified QAR Date	28 Closure Approved by: AOQAM Date

Exhibit AP-16.1Q.2

Rev. 07/03/95

PR/DR CONTINUATION PAGE

Second Amended Response for Deficiency Report YMQAD-96-D-004 (previously CAR YM-94-096)

This response completely supersedes the previous response to this CAR.

12. Remedial Actions

SNL will conduct an evaluation of the following procedures cited in the examples provided in block 6 against the attached criteria, in order to identify weaknesses or shortcomings of those procedures: QAIPs 1-5, 2-5, 2-6, 4-1, and 17-3. Any such shortcomings will be corrected by revising the procedures. (Note: QAIP 19-1, cited in block 6, requires extensive revision as a result of QARD Revision 5; therefore evaluation of that procedure for the purposes of this CAR to determine if it needs revision is unnecessary. In the case of QAIP 20-2, also cited in block 6, that procedure has already been extensively revised to incorporate additional detail as a result of the earlier evaluation for this CAR and for other reasons. Therefore, for that procedure, the objectives of this CAR have been addressed, and no further evaluation is needed.)

Responsible party: R. R. Richards

Anticipated Completion Date: For evaluation of the procedures - Mar. 15, 1996. For revision of the procedures - Apr. 30, 1996.

18. Investigative Actions:

The results of the evaluation cited above will be analyzed for trends or commonalities. To the extent that such trends or commonalities exist, a plan for the evaluation of all remaining Quality Assurance Implementing Procedures and the correction/improvement of the QAIPs found lacking will be developed.

Responsible party: R. R. Richards

Anticipated Completion Date: Apr. 1, 1996.

20. Action to Preclude Recurrence:

Initiate implementation of the plan mentioned above.

Responsible Party: R. R. Richards

Anticipated Completion Date: Apr. 30, 1996.

Screening: Screen all QAIPs to determine if either of the following conditions exist.

- Is there evidence of inconsistencies in products generated by a procedure which have resulted in violation of requirements or a need for corrective action? Have investigative actions, root cause evaluations, or management assessments resulted in recommendations to modify and provide additional detail for specific procedural steps?

- Have personnel responsible for executing a procedure requested clarification or expressed confusion regarding implementation? Would additional training suffice to resolve this uncertainty?

Evaluation of Selected Procedures: For those procedures identified by screening, above, evaluate them against these criteria.

- Are the process steps following a decision point well-defined, e.g., if a process step requires someone's concurrence to proceed but that individual is unavailable, does the procedure provide alternatives or describe what actions are to be taken next?

- Are process steps clear and unambiguous to the average reader? Would rewording of certain steps, rather than incorporation of additional detail, improve clarity?

- Are expected actions and contextual terms adequately clear to the average reader; e.g., Are the meanings of "certify", "verify", "qualify", etc. understood in the context of the procedure? As another example, if a review is required, is it clear: (a) who may or may not be a reviewer; (b) if it is necessary to define and/or document review criteria; (c) if a formal, documented review and comment resolution process is to be conducted?

- Can products generated by a procedure (forms, documents, reports, etc.) be readily evaluated for whether they address the requirements stated in the procedure, i.e., do they satisfy qualitative or quantitative acceptance criteria?