



**Department of Energy**  
Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office  
P.O. Box 98608  
Las Vegas, NV 89193-8608  
**FEB 07 1996**

L. Dale Foust  
Technical Project Officer  
for Yucca Mountain Site  
Characterization Project  
TRW Environmental Safety Systems, Inc.  
101 Convention Center Drive, Suite P-110  
Las Vegas, NV 89109

ISSUANCE AND EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT  
(DR) YMQAD-96-D004 RESULTING FROM YUCCA MOUNTAIN QUALITY  
ASSURANCE DIVISION'S (YMQAD) AUDIT OF SANDIA NATIONAL  
LABORATORIES (SCPB: N/A)

Enclosed is DR YMQAD-96-D004 generated as a result of a YMQAD  
Audit.

In accordance with the implementation of Administrative  
Procedures AP-16.1Q and AP-16.2Q, Corrective Action Request (CAR)  
YM-94-096 has been converted into a Deficiency Report (DR),  
specifically YMQAD-96-D004. CAR YM-94-096 is now closed. Under  
direction of the Office of Quality Assurance, this conversion to  
the new deficiency document was necessary for this nonsignificant  
condition CAR as its resolution date extends beyond the end of  
the calendar year.

The YMQAD staff has evaluated the amended response to this DR and  
determined it to be satisfactory. Verification of completion of  
corrective action will be performed after the effective date  
provided.

No additional action regarding resolution and closure of this DR  
is required on your part except that it will be necessary in  
future correspondence to refer to the new DR number in lieu of  
the original CAR number.

YMP-5

9602120314 960207  
PDR WASTE  
WM-11 PDR

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102.7  
WM-11

L. Dale Foust

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If you have any questions, please contact either Robert B. Constable at 794-7945 or Charles C. Warren at 794-7248.



Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1073

## Enclosures:

1. DR YMQAD-96-D004
2. PR/DR Continuation Page

## cc w/encls:

T. A. Wood, HQ (RW-14) FORS  
J. G. Spraul, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
R. L. Strickler, M&O, Vienna, VA  
R. P. Ruth, M&O, Las Vegas, NV

## cc w/o encls:

W. L. Belke, NRC, Las Vegas, NV  
A. W. Rabe, YMQAD/QATSS, Las Vegas, NV  
D. G. Sult, YMQAD/QATSS, Las Vegas, NV  
C. C. Warren, YMQAD/QATSS, Las Vegas, NV  
James Blaylock, YMQAD, NV

120073

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

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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: OCRWM QARD DOE/RW-0333P, Revision 0	2 Related Report No. YMP-94-09
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3 Responsible Organization: SNL	4 Discussed With: L. Shephard
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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:

- 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.
- 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 <i>James Blaylock</i> James Blaylock Date 1/30/96	9 QA Review <i>James Blaylock</i> QAR James Blaylock Date 1/30/96
10 Response Due Date N/A	11 QA Issuance Approval <i>James Blaylock</i> QAR (PRI/AOQAM (DR)) Date 2-1-96

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

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

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**DEFICIENCY REPORT**

**17 Recommended Actions:**

1. Correct the identified deficiency.
2. Evaluate all QAIPs to determine level of detail needed to adequately implement them.
3. Evaluate for impact to quality.

**18 Investigative Actions:**

See response to CAR YM-94-096

**19 Root Cause Determination:**

N/A

**20 Action to Preclude Recurrence:**

See response to CAR YM-94-096

**21 Response by:**

N/A Date

**22 Corrective Action Completion Due Date:**

**23 Response Accepted**

QAR N/A Date

**24 Response Accepted**

AOQAM N/A Date

**25 Amended Response Accepted**

QAR N/A Date

**26 Amended Response Accepted**

AOQAM N/A Date

**27 Corrective Actions Verified**

QAR Date

**28 Closure Approved by:**

AOQAM Date

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6 Description of Condition:

were found included: (1) use of looseleaf notebooks, (4) non-sequentially numbered pages.

3. The detail in QAIP 01-05, although incorporating the appropriate requirements from QARD 5.2.2 A through I, is not clearly delineated and confusing by providing several options for inclusion of requirements in work agreements. Consequently, work agreements are written that do not address, either by incorporation or reference as not applicable, all of the procedural/QARD requirements.
4. The level of detail in QAIPs 02-05 and 02-06, although addressing the appropriate QARD 2.2.1.1 requirements, is not sufficient for personnel to adequately implement the procedures. The procedures incorporate the QARD requirements, but do not include sufficient implementing details or process steps for people to adequately comply with the requirements. For example, SNL staff do not adequately assign training to achieve or maintain proficiency and do not adequately complete training and qualification requirements.
5. The detail in QAIP 19-01 (Software) is insufficient to provide that acquired or developed software would be suitable for use in licensing. The requirements in the QAIP are merely a restatement of the QARD Supplement I requirements. Unsatisfactory conditions were in verification and validation control of acquired and developed software, change control and use of software.

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17 Recommended Actions:

~~See Continuation page~~ N/A  
 PRP  
 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

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**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?

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