



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

MAR 21 1996

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for Yucca Mountain
Site Characterization Project
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Las Vegas, NV 89109

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YMQAD-96-D034
RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S
(YMQAD) AUDIT YM-ARP-96-05 OF SANDIA NATIONAL LABORATORIES
(SCPB: N/A)

The YMQAD staff has evaluated the response to DR YMQAD-96-D034. The 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 the due date. Please send a copy of extension requests to Deborah G. Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

If you have any questions, please contact either Robert B. Constable at 794-7945 or John R. Doyle at 794-7986.



Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1375

Enclosure:
YMQAD-96-D034

cc w/encl:

T. A. Wood, HQ (RW-14) FORS
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. R. Richards, SNL, Albuquerque, NM, M/S 1333
R. L. Strickler, M&O, Vienna, VA
R. P. Ruth, M&O, Las Vegas, NV

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
J. R. Doyle, YMQAD/QATSS, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.**

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Quality Assurance Implementing Procedure (QAIP) 1-5, Revision 09, QAIP 6-3	2 Related Report No. YM-ARP-96-05
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3 Responsible Organization: Sandia National Laboratories	4 Discussed With: David Hawkinson/Larry Costin
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5 Requirement/Measurement Criteria:
QAIP 1-5, Revision 09, "Establishing Work Agreements"

Paragraph 4.1.3, "Technical/QA Reviewer," states: "Review the draft W.A. in accordance with review criteria provided in procedure 6-3."
 Paragraph 4.1.4 states: "Resolve any comments with the customer."
 Paragraph 4.1.5 states: "Sign and date the WA to document their review and resolution."

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6 Description of Condition:
 Contrary to the above requirements, conversations with cognizant personnel and review of Work Agreement files for WA-205 and WA-185 reveal that there is no objective evidence that DRCs, for mandatory comments, have been completed as per QAIP 6-3 and the QARD.

7 Initiator John R. Doyle <i>John R. Doyle</i> Date 01/29/96	9 QA Review QAR <i>John R. Doyle</i> Date 1/29/96
10 Response Due Date 20 WORKING DAYS FROM ISSUANCE	11 QA Response Approval QAR (PRI/ADQAM ID#) <i>[Signature]</i> Date 2/6/96

12 Remedial Actions:
 QAIP 1-5 will be revised to clarify how WA review comments will be documented.

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

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17 Recommended Actions:

Recommend revising QAIP 1-5 to include the requirements of QAIP 6-3, and specifically, the requirements of Section 6.0, "Records."

18 Investigative Actions:

What the individual implementing documents (QAIPs) specify concerning documentation of reviews for all SNL product and implementing documents was evaluated. That investigation shows that the QAIPs concerning SNL implementing and product documents are somewhat inconsistent concerning how review comments are to be documented. For example, for product documents (technical reports), review are to be documented on DRCs which are kept as QA records; for QAIPs, DRCs are used but are maintained as non-processed records; for TPs QAIP 6-3 is invoked for review documentation, but the review comments are not treated as records; and for WAs, only the review criteria of QAIP 6-3 are invoked, with no mention of treating the review comments as records.

19 Root Cause Determination:

The condition cited in block 6 arose from the somewhat less-than-specific wording in step 4.1.3 of QAIP 1-5.

20 Action to Preclude Recurrence:

The following concept will be implemented: Reviews of product documents of all types will be documented by using QAIP 6-3, and the DRCs will be handled as QA records; reviews of QAIPs and TPs will be documented by using QAIP 6-3, and the DRCs will be handled as non-processed records; and reviews of Work Agreements will be documented by using QAIP 6-3 (for mandatory comments) with the DRCs handled as non-processed records, or by whatever means the reviewer prefers (for nonmandatory comments) - documentation of the occurrence of the review and resolution of comments will be via the reviewer's sign-offs on the WA. Implementing this concept will require revising QAIPs 1-5 (as stated in block 12) and 20-1.

21 Response by: <i>R.R. Richards</i> Date <i>3/8/96</i>	22 Corrective Action Completion Due Date: <i>April 1, 1997</i>
23 Response Accepted: <i>John N. Doyle</i> QAR Date <i>3/13/96</i>	24 Response Accepted: <i>[Signature]</i> AOQAM Date <i>3/20/96</i>
25 Amended Response Accepted QAR Date	26 Amended Response Accepted AOQAM Date
27 Corrective Actions Verified QAR Date	28 Closure Approved by: AOQAM Date

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PR/DR CONTINUATION PAGE

5 Requirement/Measurement Criteria: (Continued)

QAIP 6-3, "Conducting and Documenting Reviews of Documents," Revision 03, Appendix A (continuation page), "Instructions and Criteria for Document Review and Comment Form."

Section A states: "Review/Requester will complete top of form. Author/Requester will provide the Document Review and Comment (DRC) Form, along with the document to be reviewed, to the Reviewer."

Section B states, in part: "Reviewer will review the subject document, applying criteria as specified. Comments will be recorded in the "Reviewer" portion of the form, one comment per DRC form. Sign the DRCs and return them to the Author/Requester...."

In addition, QARD Subsection 2.2.10, "Document Review," Paragraph F, states: "Mandatory comments resulting from the review shall be documented and resolved before approving the document."