



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

**JUN 19 1996**

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VERIFICATION OF CORRECTIVE ACTION OF DEFICIENCY REPORT (DR)  
YMQAD-96-D044 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE  
DIVISION'S (YMQAD) AUDIT YM-ARP-96-07 OF SANDIA NATIONAL  
LABORATORIES (SCPB: N/A)

The YMQAD staff has verified the corrective action to DR YMQAD-96-D044 and determined the results to be unsatisfactory because the information placed into Work Agreement (WA)-0300 to address the deficiency is not quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished. To specifically resolve this deficiency, the following items must be addressed:

- Quality Assurance Implementing Procedure (QAIP) 2-4, Revision 3, needs to have specific steps indicated for the performance of model validation. (These steps must be in this procedure, or alternatively included in each individual WA.)
- QAIP 2-4, Revision 3, needs to be listed in the WA-0300 as being implemented for this activity.
- Training to the use of QAIP 2-4, Revision 3, needs to be required in the WA.
- Resolve the concerns identified during the investigation performed by Robert R. Richards, Quality Assurance (QA) Manager, dated May 30, 1996, for this DR.
- QA Advisory, dated May 3, 1996, needs to address the issue of process detail needed in implementing documents.
- The checklist used in review of WAs discusses quantitative or qualitative criteria to be expressed of a technical nature, in addition it needs to address the process detail needed in WAs.

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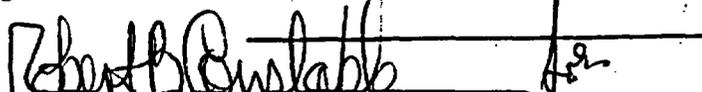
L. Dale Foust

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The issue of concern with this DR is the level of process detail contained in the implementing documents. This requirement comes from the Quality Assurance Requirements and Description document, Section 5.0. Missing from the implementing documents, both procedures and WAs, are the steps of the process that will be performed to accomplish model validation, i.e., "quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished," in this case model validation. The DR mentions the Principal Investigator described a process that appeared to be satisfactory for meeting the needs of model validation for the Geologic Framework Model. This process needs to be placed into the implementing documents for this task and similar ones in the other implementing documents covering those tasks investigated for this corrective action. The QAIP 2-4 appears to address only the technical criteria, not the documentation of procedural steps to be performed. This also seems to be the position of the QA Advisory and the checklist.

Your response, indicating the appropriate corrective action completion date, is required to be submitted to this office within 10 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 Stephen D. Harris at (702) 794-5522.



Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2000

Enclosure:  
DR YMQAD-96-D044

cc w/encl:

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. B. Justice, M&O, Las Vegas, NV  
R. P. Ruth, M&O, Las Vegas, NV  
R. R. Richards, M&O/SNL, Albuquerque, NM, M/S 1333  
Records Processing Center

cc w/o encl:

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

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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: Quality Assurance Requirements and Description, revision 4  
2 Related Report No. YM-ARP-96-07

3 Responsible Organization: Sandia National Laboratory  
4 Discussed With: Michael Brady

5 Requirement/Measurement Criteria:  
QARD section 5.2.2D. states in part, "Implementing documents shall include the following information as appropriate to the work to be performed: Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished." QARD section III.2.6A. and III.2.6B. are the specific requirements to be implemented for Model Validation.

6 Description of Condition:  
The Sandia National Laboratory procedure QAIP 2-4, revision 2, references QAIP 1-5, which is in revision 9, for development of a Work Agreement. The Work Agreement, however, does not contain quantitative or qualitative acceptance criteria for implementation of the above QARD requirements. The principal investigator described a process during the audit that appeared to be satisfactory for meeting the needs of model validation for the Geologic Framework Model. The appropriate implementing document needs to reflect the process intended to be used as well as meet the QARD requirements.

7 Initiator: Stephen D. Harris Date 03/01/96  
9 QA Review: Stephen D. Harris Date 3/5/96

10 Response Due Date: 20 working days from issuance  
11 QA Issuance Approval: [Signature] Date 3.12.96

12 Remedial Actions:  
see page 3

13 Remedial Action Response By: See pg 3 Date  
14 Remedial Action Due Date: See pg 3 Date

15 Remedial Action Response Acceptance: N/A Date  
16 PR Verification/Closure: N/A Date

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17 Recommended Actions:

Add quantitative or qualitative acceptance criteria to the Work Agreement to reflect the QARD requirements and the process for Model Validation.

18 Investigative Actions:

See page 3

19 Root Cause Determination:

See page 3

20 Action to Preclude Recurrence:

See page 3

21 Response by: <i>[Signature]</i> Date 4/4/96	22 Corrective Action Completion Due Date: May 15, 1996
23 Response Accepted QAR <i>Stephen D. Harris</i> Date 4/29/96	24 Response Accepted AOQAM <i>[Signature]</i> Date 5/15/96
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

**Response to Deficiency Report YMQAD-96-D044**

**12. Remedial Actions Work Agreement (WA) 300**, which is the lower-tier WA that directs the performance of the subject model development work, will be revised to address the approach used for model validation and to add qualitative or quantitative criteria (as appropriate) to be used in determining whether the model(s) developed are valid, i.e., model validation activities are successful. For this activity, the model validation approach will consist of verifying that the output is consistent with site data. (Resp. Individ. - L. S. Costin)

**18. Investigative Actions** All other Work Agreements that deal with model development will be reviewed to determine the extent that they meet the requirements for specifying the approach and criteria for the model validation portion of the activity. (Resp. Individ. - R. R. Richards)

**19. Root Cause Determination** In this case, the subject Work Agreement addressed acceptance criteria for the overall activity. However, the criteria for the embedded activity of model validation, as well as the desired approach to be used, were not specified. This indicates that the implementing procedure that guides the process of WA preparation, QAIP 1-5, is understood and was used in this case, but the implementing procedure applicable specifically to model development, QAIP 2-4, was not referred to as the WA was prepared or reviewed. Review of QAIP 2-4 also indicates that the need to specify acceptance criteria in the case of model validation analyses (a specific application of this QAIP) is not addressed.

**20. Action to Preclude Recurrence**

- QAIP 2-4, "Analysis Control and Verification", will be revised to specifically call out the need to establish acceptance criteria for the validation phase of model development in the Work Agreement for the model development activity. (Resp. Individ. - R. R. Richards)
- A QA Advisory will be issued to SNL staff and contractor personnel involved in model development activities in order to highlight the need to specify the approach to be utilized in model validation, as well as the criteria to be applied in determining "validity" of the model, in the governing Work Agreement. (Resp. Individ. - R. R. Richards)
- The checklist used in QA review of Work Agreements will be revised to include a check, for WAs for model development, that the approach to validation and the criteria for validation are included. (Resp. Individ. - R. R. Richards)

**22. (Proposed) Corrective Action Completion Due Date: May 15, 1996**