



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

FEB 24 1995

Larry R. Hayes
Technical Project Officer
for Yucca Mountain
Site Characterization Project
U.S. Geological Survey
101 Convention Center Drive
Suite 860
Las Vegas, NV 89109

EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR)
YM-95-022 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION'S (YMQAD) AUDIT YM-ARP-95-04 OF U.S. GEOLOGICAL
SURVEY (SCPB: N/A)

The YMQAD staff has evaluated the response to CAR YM-95-022.
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 date. Please send a copy of
extension requests to Deborah 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 James Blaylock at 794-7913.

Robert B. Constable

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2082

Enclosure:
CAR YM-95-022

cc w/encl:

- J. G. Spraul, NRC, Washington, DC
- S. W. Zimmerman, NWPO, Carson City, NV
- T. H. Chaney, USGS, Denver, CO
- R. W. Craig, USGS, Las Vegas, NV
- D. D. Porter, USGS/SAIC, Golden, CO
- D. G. Horton, OQA (RW-3) NV
- W. E. Barnes, YMSCO, NV

cc w/o encl:

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

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

8 CAR NO. YM-95-22
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CORRECTIVE ACTION REQUEST

1 Controlling Document QARD DOE/RW-0333P, Supplement III, 2.2, Revision 1		2 Related Report No. YM-ARP-95-04	
3 Responsible Organization USGS		4 Discussed With E. Kwickless	
5 Requirement: QARD DOE/RW-0333P, Supplement III, 2.2 requires that site characterization activities be governed by either technical procedures, a scientific notebook, or a combination of both.			
6 Adverse Condition: Contrary to the above, the Unsaturated Zone Modeling, SP 8.3.1.2.2.9, is not controlled by either a technical procedure or a scientific notebook. Acquired software that is being modified by UZ Modeling is not controlled by YMP-QMP-3.03, Software.			
9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No ___ If Yes, Check One: <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
13 Response Due Date: 20 Working Days from Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
12 Recommended Actions: 1) Initiate procedural controls for UZ Modeling. 2) Review ongoing activities to assure all site characterization activities are governed by scientific notebooks or technical procedures. 3) Establish criteria to determine when code should be placed under QA controls.			
7 Initiator <i>James Blaylock</i> James Blaylock		14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>12/23/94</u>	
15 Response Accepted QAR <i>James Blaylock</i> Date <u>2/16/95</u>		16 Response Accepted QADD <i>[Signature]</i> Date <u>2-23-95</u>	
17 Amended Response Accepted QAR _____ Date _____		18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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

CAR NO. YM-95022
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CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95022

A. REMEDIAL ACTION:

(1) Steps are underway at the USGS to redefine internal grading and exemptions from QA controls for scientific work. As a result of CAR-94043 grading reports that exempted QMP-5.05 (Scientific Notebooks) have been rescinded. Criteria to determine when code should be placed under QA control is described in QMP-3.03, R5 Section 5.0.

QMP-5.05 is now required for model development work for hydrologic studies (see guidance memo No. 95.01 dated 12/9/94 (copy attached)).

(2) A scientific notebook for model development work under Study 8.3.1.2.2.9 will be initiated by January 31, 1995.

B. EXTENT OF THE DEFICIENCY: N/A - See 1D.

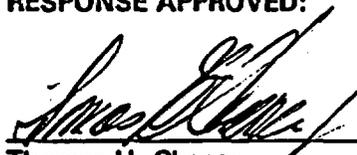
C. ROOT CAUSE DETERMINATION: As a normal course of conducting business, the YMP-USGS did not require the use of technical procedures or scientific procedures or scientific notebooks for interpretive work. This is reflected in both external and integral grading reports where model development work is described.

D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE: The remedial actions will prevent recurrence of this deficiency. Guidance Memo No. 95.01 directs all Principal Investigators to initiate a Scientific Notebook based on the criteria described in the Guidance Memo.

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

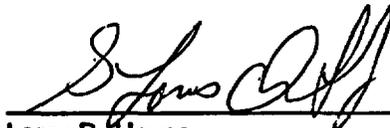
E. Kwicklis will initiate a notebook for 8.3.1.2.2.9 by January 31, 1995.

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

1/25/95
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

1/25/95
Date

YUCCA MOUNTAIN PROJECT - U.S. GEOLOGICAL SURVEY QUALITY ASSURANCE PROGRAM GUIDANCE NO. 95.01

TOPIC: Documenting Scientific Investigations

The DÔE QA Office has stated that all scientific investigations supporting site characterization shall be documented using either a technical procedure or a scientific notebook. Site-characterization activities are scientific investigations described in an approved Study Plan, and not exempted from the QA program requirements through the YMP-USGS QMP-3.15 grading process. This QA requirement is stated in Quality Assurance Requirement Description (QARD), Section III 2.2.A. Scientific investigation is defined in the QARD to include "analysis and explanation of natural phenomena." These statements have been interpreted to mean that, in addition to data collection activities, analysis and synthesis activities also should be documented by use of technical procedures or scientific notebooks. It is not the intent of this QARD requirement to exclude documentation of certain site-characterization "analysis" or "synthesis" activities by means of the publication process (QMP-3.04). Therefore, the use of scientific notebooks or technical procedures for USGS analysis and synthesis activities shall be governed by the following:

- o Technical procedures or scientific notebooks are not required to document syntheses of information derived solely from the published literature, statistical analysis of data, or straightforward, "once-through" analyses that involve the application of previously published analytical or other methods to transform sets of field measurements into properties or parameters (permeability, transmissivity, rock compressive strength, thermal conductivity). Such "analyses" may be documented through the publication review and approval process (QMP-3.04).

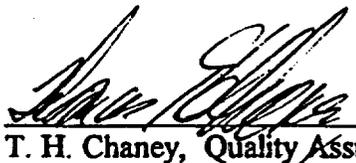
- o Technical procedures or scientific notebooks are required to document more complex analysis and synthesis activities that are iterative in nature and in which subsequent steps taken are dependent on results from previous steps. Such activities generally take place over a significant period of time (months, years). For such activities, the pathway taken to arrive at the end result may be technically significant and should be documented along with the end result. The scope of this requirement requires the documentation of the development of numerical models of natural phenomena.

YMP-USGS QMP-5.01 and 5.05 provide further guidance as to when a technical procedure or scientific notebook may be appropriate. The purpose of a technical procedure or scientific notebook is to provide a record of methods used, hypothesis tested, hypothesis accepted or rejected, and other information that might be pertinent to the decision making process for Yucca Mountain. A key requirement regarding the level of detail needed in a scientific notebook is stated by QARD, Supplement III. 2.2.C:

“Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to retrace the investigation and confirm the results, if feasible, or repeat the investigation and achieve comparable results, without recourse to the original investigator.”

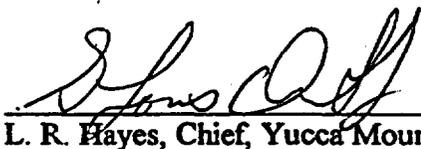
In reality the level of detail necessary is going to be dependent on the type of activity that is being documented. A data collection activity may require a precise and detailed description of the methods used while modeling work may require just a report of progress. The decision on the appropriate level of detail should be made by the principal investigator and concurred with by his or her manager.

An excellent source for guidance on the use of notebooks to document scientific investigations is the publication, Kanare, Howard, M., 1985, “Writing the Laboratory Notebook, The American Chemical Society, Washington, DC.” Copies are available from the YMP-USGS QA office.



T. H. Chaney, Quality Assurance Manager

2/15/95
Date



L. R. Hayes, Chief, Yucca Mountain Project Branch

2/14/95
Date