



Department of Energy

Washington, DC 20585

QA: L

JUN 8 6 1997

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EVALUATION OF RESPONSE, VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORT (DR) YM-97-D-032 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SURVEILLANCE YM-SR-97-006

The OQA staff has evaluated the response and verified the corrective action to DR YM-97-D-032 and determined the results to be satisfactory. However, OQA takes exception and provides clarification to the following point of your response.

Your statement "... study plans were always intended to represent an initial planning basis for management-level exchanges between the DOE and the NRC on the scope and objectives for site characterization and do not represent detailed design requirements on the method for acquiring data." is misleading. Study Plans were, at their inception, a formalized methodology to ensure that Quality Assurance Requirements and Description planning requirements were satisfied and the objectives of the Yucca Mountain Site Characterization Plan were planned and implemented.

During meetings with Assistant Manager for Licensing staff and the OQA, it was demonstrated that the Yucca Mountain Site Characterization Office has adequate controls in place to effectively plan site characterization activities. To assure that these processes are effective, OQA will at a future date perform audits/surveillances of these activities.

Corrective action has been satisfactorily verified and this DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or John R. Doyle at (702) 794-1465.

OQA:JB-1820

Enclosure:
DR YM-97-D-032

R. W. Cent
for Donald G. Horton, Director
Office of Quality Assurance

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W. E. Barnes

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cc w/encl:

J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
J. A. Hall, M&O, Las Vegas, NV

cc w/o encl:

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

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

THIS IS A RED STAMP

8 ☐ Performance Report
☒ Deficiency Report

NO. YM-97-D-032

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
Quality Assurance Requirements & Description (QARD), DOE/RW-0333P, Rev. 6

2 Related Report No.
YM-SR-97-006

3 Responsible Organization:
Yucca Mountain Site Characterization Office

4 Discussed With:
Robert V. Barton

5 Requirement/Measurement Criteria:

QARD, Supplement III, Scientific Investigation, Paragraph III, 2.1 A, states: "Scientific Investigations shall be planned in accordance with Section 2.0, Quality Assurance Program."

QARD, Section 2.2.5, Planning Work, states in part, "Planning shall be documented to ensure work is accomplished under suitably controlled conditions ..."

In documenting and planning scientific investigations, the Department of Energy's (DOE) Office of Civilian Radioactive Waste Management (OCRWM) and Affected Organizations implement YAP-2.2Q, Revision 1, "Preparation, Review, Approval and Revision of Site Characterization Study Plans." (See Page 2)

6 Description of Condition:

Deficiency Report DR YM-97-D-023 was initiated on January 15, 1997, and identified that USGS had not maintained and/or revised their Study Plans when the methodology of scientific investigation detailed within the Study Plans had been changed.

In discussions with the Yucca Mountain Site Characterization Project Office Deputy Assistant Manager for Licensing and staff, the M&O and the United States Geological Survey (USGS) Technical Project Officer, it was found that in general Study Plans from all participants have not been revised or kept current. As such, it was agreed to close DR YM-97-D-023 and initiate a new DR addressed to the DOE Project Office for resolution of a generic deficiency within the project.

An example of the deficiencies found with USGS Study Plans and the flow down into implementing procedures are:

(See Page 2)

7 Initiator

John R. Doyle

Date 5/2/97

9 Is condition an isolated occurrence?

☐ Yes ☐ No ☒ Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)

1. Develop a plan of action to either: 1) revise study plans to reflect current scientific practices; or 2) provide an alternative method for the planning and documenting scientific investigations.
2. Determine impacts on commitments to the NRC and identify those actions necessary to resolve any conflicts.
3. Provide root cause determination.
4. Provide an evaluation as to the validity of results obtained from not following the Study Plans as committed on work that was performed.
5. Determine those actions necessary to preclude recurrent.

11 QA-Review

QAR

Date

12 Response Due Date

20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name D G HERTON

Signature

Date 5/12/97

22 Corrective Actions Verified

QAR

Date

23 Closure Approved by: (N/A for PR)

AOQAM

Date 6/30/97

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PR/DR CONTINUATION PAGE

Block 5 (Requirement/Measurement Criteria continued)

QARD, YAP-2.2Q, Revision 1, Section 1.0, "Purpose," states in part: "This procedure defines the responsibilities and process to prepare, review, approve, and revise Site Characterization Plan (SCP), DOE/RW-0199, Study Plans (SPs) in a consistent manner. This procedure implements the 1993 U.S. Department of Energy (DOE) Nuclear Regulatory Commission (NRC) Level of Detail Agreement and Review Process for SPs. ... This procedure also implements applicable requirements of the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD, DOE/RW-0333P)."

In addition, Attachment I to YAP -2.2Q states in part:

"The test program presented in Chapter 8 of the SCP will be subdivided into a hierarchy of increasing detail. The SCP test program will include (in increasing detail); generic program investigation study, activity and test procedures. Details for the studies listed will be presented in study plans. Study plans will be separate from the SCP proper and will be issued as required for site characterization. Individual test methods will be discussed in study plans. ..."

Block 6 (Description of Condition: continued)

1) In accordance with Study Plan 8.3.1.2.2.4, "Characterization of Yucca Mountain Unsaturated Zone in the Exploratory Studies Facility," Revision 1, Paragraph 3.8.3.1, the flow rate measurement during sample collection would be required to be taken to assure a flow rate of 500-ml/min. This would require that calibrated instrumentation be installed. However, Technical Procedure (HP) YMP-USGS-HP-56, "Gas and Water Vapor Sampling from Unsaturated-Zone Boreholes" Revision 4, Modification 1, Paragraph 2.2.2.2, stipulates that flow meters used for sample collection are not required to be calibrated. As a result, at the present time samples collected from Borehole ESF-NAD-GTB#1 located in North Ghost Dance Fault Alcove (Alcove #6) of the Exploratory Studies Facility cannot be verified to have been collected at the required flow rate of 500-ml/min.

2) Contrary to Study Plan 8.3.2.2.4, Paragraph 3.8.3.1, Section 2, CO₂ samples collected as a result of Item 1 sampling and CO₂ calibration standards utilized for the calibration of the Infrared Gas Analyzer (IRGA EGM-1. SN. 155) are collected and transported in rejected Mylar party balloons.

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

No remedial actions are planned because the site characterization data discussed in the DR are not compromised by the finding. This is because study plans were always intended to represent an initial planning basis for management-level exchanges between the DOE and NRC on the scope and objectives for site characterization and do not represent detailed design requirements on the methods for acquiring data. The requirements for data acquisition are specified in the applicable implementing procedures (e.g., YMP-USGS-HP-56) and, as long as data was acquired in accordance with the applicable procedures, no deficiency in the data exist. Current practices for planning and authorizing work do not utilize study plans. The planning process consists of the management-level determination of licensing strategy and data needs through the long-range and annual plans which are then used to prepare the planning document (PPS) IAW YAP2.6Q that specifies Statement of Work, Objective, Description of Work and Products, and Acceptance Criteria for specific activities. Work Products are accepted IAW YAP-5.1Q to close the requirements of the PPS.

15 Extent of Condition: (Not required for PR)

As noted in Section 5, study plans do not represent current plans. Discussions with the NRC have occurred and indicate that study plans do not need to remain in controlled distribution to continue the management-level review of program plans and progress. Commitments to the NRC will continue to be addressed by appropriate management processes and will not be affected by the removal of study plans from controlled distribution.

16 Root Cause Determination: (Not required for PR)

Required: ☐ Yes ☒ No

17 Action to Preclude Recurrence: (Not required for PR)

Required: ☒ Yes ☐ No

In order to remove any confusion that might occur because of differences between study plans, implementing procedures, and PPS, study plans will be removed from controlled distribution and YAP-2.2Q canceled. This will also clarify and simplify the planning process for site characterization and better account for the evolving nature of planning as data is received. Study plans will remain as file documents and may be referenced (along with the SCP) as the initial basis for site characterization planning.

18 Corrective Action Completion Due Date:

6/30/97

19 Response by:

Robert M. Denton

Date 6/9/97 Phone

20 Response Accepted

QAR

John R. Day, Jr.

Date

6/25/97

21 Response Accepted (N/A for PR)

DOQA

R.W. Chief

Date

6/30/97

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Verification of Corrective Action to DR YM-97-D-032

Block 14 Remedial Actions:

None Required

Block 15 Extent of Condition:

None Required

Block 16 Root Cause Determination:

None required

Block 17 Action to Preclude Recurrence:

Verified Document Action Request # 2037 dtd. 4/11/97, Document Development Form dtd. 5/27/97 and Cancellation Approvals dtd. 6/6/97 effective 6/26/97 that YAP 2.2Q has been withdrawn from use. In addition, CRWMS Quality Administrative Procedure (QAP) QAP-SIII-1 "Scientific Investigation Control" Rev. 1 para 5.1.2, effective 6/2/97, gives guidance on how work is planned when Study Plans are not utilized.

This DR is considered closed.

QAR John N. Day Jr. date 6/25/97.