



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

OCT 16 1996

R. W. Craig
 Technical Project Officer
 for Yucca Mountain
 Site Characterization Project
 U.S. Geological Survey
 1261 Town Center Drive
 Building 4, Room 423, M/S 423
 Las Vegas, NV 89134

EVALUATION OF RESPONSE TO DR YM-96-D-093 RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT OQA-SA-96-027 OF DRI

The Yucca Mountain Quality Assurance staff has evaluated the response to Deficiency Report (DR) YM-96-D-093. The response has been determined to be unsatisfactory because Block 14, Remedial Action, needs to address item number 7, in Block 6 (of the DR), Description of Condition. The response given for the items covered in Block 14 is rather brief. More detail in the specific remedy needs to be expressed. It does not appear a detailed investigative action was performed. The remedial action block does not explain the extent of the condition. In addition, the extent of concern with this DR (i.e., the Quality Assurance [QA] Program at this facility for the most part had not been implemented) merits the performance of Root Cause Determination in accordance with procedure. The Action to Prevent Recurrence, Block 17, is to address the actions that will be taken based on the Root Cause Analysis. There needs to be discussion somewhere in the response about working with Desert Research Institute (DRI) to make these changes and assure the information contained in the changes will be clearly explained to the DRI representatives and the degree of effort required to perform the QA Program.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, YMQA/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Stephen D. Harris at (702) 794-5522.

Richard E. Spence
 Yucca Mountain Quality Assurance

YMQA:MRD-0094

Enclosure:
 DR YM-96-D-093

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 PDR WASTE PDR
 WM-11

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 WPH
 NH 33

Recip: NMSS/paHL

OCT 16 1996

R. W. Craig

-2-

cc w/encl:

J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
Records Processing Center

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
S. D. Harris, YMQA/QATSS, Las Vegas, NV
D. G. Sult, YMQA/QATSS, Las Vegas, NV
D. G. Horton, DOE/OQA, Las Vegas, NV

250037

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

8 Performance Report
 Deficiency Report
NO. YM-96-D-093
PAGE 1 OF 3
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
Quality Assurance Requirements and Description, DOE/RW-0333P, Revision 5

2 Related Report No.
OQA-SA-96-027

3 Responsible Organization:
U.S. Geological Survey/Desert Research Inst.

4 Discussed With:
Richard Powe, Tom Chaney, Herbert Haas

5 Requirement/Measurement Criteria:
Procurement Document Control, Section 4.0, paragraph 4.2.1C.1.: Procurement documents issued by each Affected Organization shall include the following provisions, as applicable to the item or service being procured: Quality Assurance Program Requirements including: A requirement for the supplier to have a documented Quality assurance (QA) program that implements applicable Quality Assurance Requirements and Description (QARD) requirements prior to the initiation of work.

Implementing Documents, Section 5.0, paragraph 5.2: Work shall be performed in accordance with controlled implementing documents.

6 Description of Condition:
Contrary to the above requirements, the complete QA program that applies to the Desert Research Institute scope of work, as described in their QA Manual, was not being implemented. The following discrepant conditions were observed during review of QA program implementation:

1. No objective evidence of QA Program training for Todd Enerson on form attachment 2.2. The forms, Attachment 2.1 and 2.2, were not used to indicate the QA Program Indoctrination and Training and Personnel Qualification for Dr. Haas. (QA Manual, 2.2.2)
2. Reports of data and tests run, submitted to U.S. Geological Survey, did not include dates of analysis. (P.O., Section III, Analytical Services)
3. There are no documented hand calculations for data manipulation by the spreadsheets used with signature and date traceable to the software. (QA Manual, 3.2.1, para. 2; Data Processing, 2.0, step 11)

7 Initiator
S.D. Harris *S. D. Harris* Date 08/26/96

9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)

Prior to further technical activities, resolve all issues not in compliance with the USGS Procurement Document and the Desert Research Institute QA Manual. Perform investigative action to determine the extent of the deficiencies. Perform root cause determination in accordance with AP-16.4Q, Root Cause Determination. Assure indoctrination and training to the QA program is performed and documented. Obtain verification of resolution of discrepant conditions by OQA.

11 QA Review
OAR S. D. Harris *S. D. Harris* Date 08/26/96

12 Response Due Date
20 days from issuance

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

Printed Name **RESSENCE** Signature *Robert R. Guastallo* Date **9.3.96**

22 Corrective Actions Verified
OAR Date

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

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

8 Performance Report
 Deficiency Report

NO. YM-96-D-093

PAGE 2 OF 3

QA: L

PR/DR CONTINUATION PAGE

6 Description of Condition (Continued from page 1):

4. There is no procurement agreement for calibration services for the balance used on YMP activities. [The balance is currently in calibration. A determination needs to be made based on the need for the precision and accuracy of the data, whether a procurement for calibration service is needed.] (QA Manual, 4.2.1, para. 3)
5. There is no documentation of receipt of Oxalic Acid from NIST on attachment 4.1. (QA Manual, 4.2.2)
6. There is no identification of QA records in the procedures. [The records are implied but not specified.] (QA Manual, 5.2.1)
7. There is no evidence of review by independent personnel of the technical procedures. (QA Manual, 6.2)
8. There is no evidence of a formal review of the QA Manual and procedures using the Document Review Form, attachment 6.1. (QA Manual, 6.2)
9. There is no calibration system in place for the balance used on YMP activities. (QA Manual, 8.2.1) The calibration sticker, attached to the balance, has no indication of the procedure used. No calibration stickers are on the counters used. (QA Manual, 8.2.7)
10. Records were not available for the following as required in the QA Manual, section 10.2.2:
 - o personnel indoctrination and training of the QA Program
 - o personnel qualification forms for Dr. Haas
 - o receipt inspection forms, Purchase Order forms
 - o review sheets (Document Review Records)
 - o sample tracking forms (attachment 7.1)

The following conditions should also be resolved to clarify the implementation process described in each procedure:

1. Data Processing procedure, section 4.0 states, "Current hard copy of data is held outside of room 229." This section should be rewritten in the procedure to indicate where all data is retained or be removed from the procedure.
2. Reference to procedure locations need to be clarified in RLD-02, Preparation of Benzene from Samples:
 - o section 2.1.6. The references made should be 2.1.4 and 2.1.5.
 - o Page 5, step 7. The references should be 2.1.5 through 2.1.11.
 - o Page 6, step 6. This reference should be 2.1.10.In addition, pages 23-25 are numbered incorrectly. The numbers should be changed to the correct sequence.
3. RLD-04, Scintillation Counting in Benzene Samples, section 2.2, paragraph 3 references section 7 of the procedure. The reference should be section 2.6.

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

PR/DR NO. YM-96-D-093
PAGE 3 OF 3
QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

16 Root Cause Determination: (Not required for PR) Required Yes No

17 Action to Preclude Recurrence: (Not required for PR) Required Yes No

18 Corrective Action Completion Due Date:

19 Response by:

Initial

Amended

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR):

QAR

Date

AQQAM

Date

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

PR/DR NO. YM-96-D-093
PAGE 3 OF 3
QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

Deficiency Item Numbers 3, 4, 5, 6, 8, 9 and 10 resulted from over commitments in the DRI QA Manual. The manual will be revised to correctly reflect DRI's standard procedures. The USGS has found that in cases where a manual is given to a vendor and it does not reflect their standard practices, that implementation of this requirement is poor. The practices being implemented in the two man laboratory operation were developed by Dr. Haas over many years. They are sound technical practices and the USGS has full confidence in DRI's capability and the analytical results provided to the USGS. Dr. Haas's internal record keeping practices support his analytical results. The manual revision will address these practices. The method of correcting the deficiencies identified in the finding Item 1 and 2 will be addressed after the manual revisions are complete. Editorial corrections identified in Block 6 (Items 1 - 3) will be corrected during the manual revision.

15 Extent of Condition: (Not required for PR)

See Block 6, Description of Condition.

16 Root Cause Determination: (Not required for PR)

Required Yes No

N/A

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

Required Yes No

The DRI QA Manual will be revised to reflect the current work practices being implemented.

18 Corrective Action Completion Due Date:

The QA Manual will be revised by
October 31, 1996.

19 Response by:

Initial
 Amended

Tom [Signature]
Date 10/01/96

Phone 236-0516/2299

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AQDAM

Date