Department of Energy
Washington, DC 20585

QA: L

FEB 2 1 1997

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 12, Room 1249, M/S 423
Las Vegas, NV 89134

EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT (DR) YM-96-D-093 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-96-027 OF DESERT RESEARCH INSTITUTE

The OQA staff has evaluated the amended response to DR YM-96-D-093. The response has been determined to be satisfactory with one clarification. Item 1 of the Root Cause Determination Questionnaire, page 3, appears to address the root cause of the deficiency, rather than that described on page 4, which is the identified deficiency. 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, OQA/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Stephen D. Harris at (702) 794-5522.

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0850

Enclosure:
DR YM-96-D-093

cc w/encl:
J. O. Thoma, 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, OQA/QATSS, Las Vegas, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV

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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:	2 Related Report No.
Quality Assurance Requirements and Description, DOE/RW-0333P, Revision 5	OQA-SA-96-027
3 Responsible Organization:	**4 Discussed With:**
U.S. Geological Survey/Desert Research Inst.	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	9 Is condition an isolated occurrence?
S.D. Harris S. D. Harris Date 08/26/96	☐ 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	12 Response Due Date
QAR S. D. Harris S. D. Harris Date 08/26/96	20 days from issuance

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

Printed Name R.E. SPENCE Signature Robert R Spence for Date 9.3.96

22 Corrective Actions Verified	23 Closure Approved by: (N/A for PR)
QAR Date	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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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 Chaney
Date 10/01/96 Phone 296-0516x29

20 Response Accepted
QAR N/A Date

21 Response Accepted (N/A for PR):
AOQAM N/A Date

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

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:
See December 18, 1996 amended response.

15 Extent of Condition: (Not required for PR)

16 Root Cause Determination: (Not required for PR) Required ☑ Yes ☐ No
See attached Root Cause Determination

17 Action to Preclude Recurrence: (Not required for PR) Required ☑ Yes ☐ No
See December 18, 1996 amended response.

18 Corrective Action Completion Due Date:	19 Response by: See December 18, 1996 amended response.
02/28/97	☐ Initial ☑ Amended Date Phone

20 Response Accepted	21 Response Accepted N/A for PR
QAR S. D. Harris Date 1-30-97	AQCAM Date 2/19/97

Exhibit AP-16.1Q.2 Rev. 07/15/96

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

☐ Performance Report
☒ Deficiency Report

NO. YM-96-D-093
PAGE _____ OF _____
QA:L

PR/DR CONTINUATION PAGE

12/17/96 AMENDED RESPONSE FOR DEFICIENCY REPORT (DR) YM-96-D-093

Block 14: Remedial Actions:

Deficiency Item 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)"

Response:

(a) Upon revision of the QA Manual, Dr. Haas and Todd Enerson will indoctrinate and train themselves to the requirements in their QA Manual. This information will be documented on a form prepared for this purpose and kept on file in the Radiocarbon Laboratory Director's office. The estimated completion date for the QA Manual revision and completion of indoctrination and training of Laboratory personnel is scheduled for February 28, 1997.

(b) Dr. Haas's résumé is available and on file for review in the Radiocarbon Laboratory.

Deficiency Item 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)"

Response:
All reports that are generated for USGS Yucca Mountain Project now include a date at the top of the report.

Deficiency Item 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)"

Response:
Dr. Haas has documented hand calculations in his Laboratory Notebook to verify spreadsheet calculations that he has performed.

Deficiency Item 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)"

Response:
Calibration of the balance is unnecessary; therefore, procurement of calibration services is not necessary. The process described in Dr. Haas's technical procedures includes obtaining the tare weight, how the containers are tracked, the cleaning of the containers, the accuracy of the container weights, and the other information pertinent to this analysis. Absolute weights are not critical and the process is not dependent upon the weight of the sample to calculate the apparent age of the sample. The weight of benzene synthesized from the standard (oxalic acid) should be the same as the weight of the benzene synthesized from the sample. The important feature for the balance is how it re-weighs the same thing. That can be satisfactorily demonstrated from the records involving the accuracy of the container's tare weights. Consistent weights are indicated in the records for these tare weights. The USGS has evaluated the scientific methods and found them to be technically sound. The QA Manual will be revised by February 28, 1997, to clarify that the calibration of the balance is not required for this method of analysis.

NOTE: As a good scientific practice and independent of the lab's work for USGS-YMP activities, the balance (Sartorius Balance 2404, serial number: 151743) is calibrated. The calibration service is not from an OCRWM-approved vendor. This service was last provided in July 1994 and is scheduled to be calibrated again in July 1997.

DR response continued on next page

12/15/96 CRAIG TO HORTON

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

☐ Performance Report
☒ Deficiency Report

NO. YM-96-D-093
PAGE _____ OF _____
QA:L

PR/DR CONTINUATION PAGE

Deficiency Item 5: "There is no documentation of receipt of Oxalic Acid from NIST on attachment 4.1. (QA Manual, 4.2.2)"

Response:
Oxalic Acid, which is used as a standard for scintillation counting in benzene sample, is procured directly from NIST. There is no need to impose QA requirements on a nationally recognized organization such as NIST, nor is there any need to qualify the organization. The NIST certificate that accompanied the Oxalic Acid is kept on file, and constitutes a receipt. The Oxalic Acid will continue to be obtained from NIST as a certified chemical. Attachment 4.1 will be deleted and Section 4.0 of the QA Manual will be revised by February 28, 1997.

Deficiency Item 6: "There is no identification of QA records in the procedures. [The records are implied but not specified.] (QA Manual, 5.2.1)"

Response:
QA Records will be identified in the QA Manual and Technical Procedures revisions, as applicable.

Deficiency Item 7: "There is no evidence of review by independent personnel of the technical procedures. (QA Manual, 6.2)"

Response:
The USGS will perform a technical review of the Radiocarbon Lab's technical procedures upon revision and document accordingly.

Deficiency Item 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)"

Response:
The USGS will perform a formal review of the Radiocarbon Lab's QA Manual upon revision and document the review. Evidence of document review will documented on a form prepared for this purpose.

Deficiency Item 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)"

Response:
See response to Deficiency Item 4.

Deficiency Item 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 system (attachment 7.1)"**

Response:
See response to previous items for specific records. QA Manual will be revised reflecting records requirements appropriate for DRI procedures. The QA Manual will also be revised to delete the Sample Tracking Form and address the current methodologies being implemented for the identification and control of samples.

DR response continued on next page

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

☐ Performance Report
☒ Deficiency Report

NO. YM-96-D-093
PAGE _____ OF _____

QA:L

PR/DR CONTINUATION PAGE

Responses for additional conditions listed in Block 6:

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."

Response:
1. A revision will be made to the QA manual to delete data retention requirements.

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 2.15.**
- **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."**

Response:
2. Reference to Procedure locations will be corrected upon revision of technical procedure RLD- 02 , Preparation of Benzene from Samples.

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."

Response:
3. RLD-04, Scintillation Counting in Benzene Samples will be revised to reference section 2.6.

Block 16: Root Cause Determination:
See attached Root Cause Determination

Block 17: Action to Preclude Recurrence:
The Purchase Order is now closed and requires no changes. At this time there is no funding to support additional work with DRI. Should funding become available, appropriate QA requirements will be incorporated into future Purchase Orders. The DRI QA Manual will be revised to reflect the positions described in Block 14. A new SER will be initiated. The QA Manual and the SER will be revised by February 28, 1997. The USGS will continue to work with DRI Radiocarbon Laboratory to resolve the deficiencies cited in this report and discuss the degree of effort that will be required.

Block 18: Corrective Action Completion Due Date: Actions noted in Blocks 14 & 17 to be completed by February 28, 1997.

Block 19: Response by: _____ Date: December 17, 1996
For R.W.Craig, Chief, Yucca Mountain Project Branch

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Refer to Subsections 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. **Identify the adverse condition.**

   - Vendor failed to fully implement QA manual dated 11-16-94 (reference DOE Deficiency Report YM-96-D093)

2. **Indicate *Where* the condition was found.**

   - In the vendor's facility at Desert Research Institute, Dr. Haas Radiocarbon Laboratory, Las Vegas, Nevada.

3. **Note *When* the condition was first found.**

   - During DOE OQA Supplier Audit at vendor's facility 8/22-23/96. USGS-95046-SE was performed but never issued on 8-10-95. USGS-96001-SE Limited scope was performed 8-15-96, and USGS-96-P020 was initiated as a result of the evaluation.

4. **Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)**

   - Repository: Site Investigation.

5. **Denote the specific area(s) or disciplines(s) of the major program element the condition occurred. (e.g., engineering, design, ES&M)**

   - Scientific investigation activities (Radiocarbon analyses of core samples) for Site Characterization work.

6. **Determine if the condition is isolated or recurring.**

   - Isolated to implementation of QA Manual put in place in 1994 at the Radiocarbon Laboratory specifically for the Yucca Mountain Project.

7. **Determine if the condition is hardware (item) or programmatic (procedures, personnel) related or both.**

   - Programmatic, due to non-implementation of Quality Assurance requirements.

8. **Denote what organizations are affected by this condition (M&O, USGS, Weston, OCRWM, etc.)**

   - USGS, Denver, CO

9. Document the changes that have taken place that could have caused the condition.

- Lack of understanding of QA documentation requirements by subcontractor personnel.

10. Determine the need for sketches or photographs.

- None.

11. Determine the need for laboratory tests.

- None.

12. Identify the physical evidence examined.

- None.

13. Note the relevant documents reviewed.

- QA Manual, dated 11-16-94, YMP-USGS Purchase Order 1434-CR-96-SA-00498, 3-1-96, USGS-95046-SE, 8-10-95(Draft Report), USGS-96001-SE, 8-15-96, USGS-96-P020, 8-20-96.

14. Document any other information that may be pertinent to supporting the selection of the correct root cause.

- See personnel interview record.

15. Interviews conducted: X☒ Yes ☐ No
If Yes, refer to page 3 of this attachment.

RI or designee: (Print)	Signature:	Date:
Emily S. Reiter	Emily S Reiter	November 11, 1996

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

TELEPHONE OR PERSONAL INTERVIEW RECORD

Person Interviewed: (Print)		Title:	
Dr. Herbert Haas		Director, DRI, Radiocarbon Laboratory	
Organization/Location	**Telephone No.:**	**Date/Time:**	**CAR No./DR No.**
Radiocarbon Lab Las Vegas, NV	(702)	10-28-96	YM-96-D093

1) **Determine Why QA Program requirements were not fully implemented:** The vendor stated that the QA Manual was "developed" for him by the USGS in the latter part of 1994, specifically for use on YMP sample analyses. The new QA Manual added requirements not familiar to DRI. He believed that his technical laboratory procedures were adequate for work that he was performing.

2) **Determine why attachments were not used:** The attachments that were developed for the vendor's use were not fully explained; therefore, implementation was not accomplished.

3) **Determine overcommitments in QA Manual:** The vendor feels that the current manual is too restrictive and contains overcommitments, specifically the attachments (excessive documentation requirements).

4) **Discuss QA Manual revision and willingness to implement QA program with USGS help.** The vendor stated willingness to revise QA manual and obtain USGS help in implementing key program elements.

Emily S Reiter

Interviewer (Emily Reiter)

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE Page 4 of 4

Root Cause Code:	**CAR No./DR No.**
3AC	DR YM-96-D093

Root Cause:
The deficiency resulted because of the failure to implement the existing QA Manual.

Justification or Rationale for Selected Root Cause:

Conditions described in Block 6 of DR YM-96-D093 state that the QA Program was not implemented by the Radiocarbon Laboratory. Reduced staff (USGS) made it impossible to provide appropriate follow-up support to the Radiocarbon Laboratory. Block 10 of the DR recommended actions listed performing Root Cause Determination.

Designee: (Print)	**Signature:**	**Date:**
NA	NA	NA
RI: (Print) Emily Reiter	**Signature:** Emily S Reiter	**Date:** 11/12/96