

Department of Energy

Washington, DC 20585

QA: L

NOV 10 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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORT (DR) YM-96-D-093 RESULTING FROM OFFICE OF QUALITY
ASSURANCE (OQA) AUDIT OQA-SA-96-027 OF DESERT RESEARCH INSTITUTE

The OQA staff has verified the corrective action to DR YM-96-D-093 and determined the results to be satisfactory. As a result, the DR is considered closed.

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

R.W. Cel

For Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0293

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
D. J. Sinks, OQA/USGS, Denver, CO
A. M. Whiteside, OQA/USGS, Denver, CO

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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Recip: Nmss/PAHL

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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
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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 **R. SPENCE** Signature *Robert R. Spence* Date 9.3.96

22 Corrective Actions Verified
OAR *S. D. Harris* Date 10/31/97

23 Closure Approved by: (N/A for PR)
AOQAM *R. W. Clark* Date 11/7/97

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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 [Signature]
 Date 10/01/96

Phone 236-0516x229

20 Response Accepted

OAR

N/A

Date

21 Response Accepted (N/A for PR):

AOQAM

N/A

Date

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RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

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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)
See attached Root Cause Determination

Required Yes No

17 Action to Preclude Recurrence: (Not required for PR)
See December 18, 1996 amended response.

Required Yes No

18 Corrective Action Completion Due Date:

02/28/97

19 Response by: See December 18, 1996 amended response.

Initial

Amended

Date

Phone

20 Response Accepted

QAR

S. D. Harris

Date

1-30-97

21 Response Accepted N/A for PR

AQQAM

Date

[Signature]
2/19/97

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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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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 be 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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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: 

For R.W. Craig, Chief, Yucca Mountain Project Branch

Date: December 17, 1996

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE**

Page 1 of 4

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

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Page 2 of 4

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: Yes No
If Yes, refer to page 3 of this attachment.

RI or designee: (Print)
Emily S. Reiter

Signature:

Emily S. Reiter

Date:

November 11, 1996

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

Root Cause Code: 3AC	CAR No./DR No. DR YM-96-D093
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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) NA	Signature: NA	Date: NA
RI: (Print) Emily Reiter	Signature: <i>Emily Reiter</i>	Date: 11/12/96

HHactman A
(p. 1 of 1)



United States Department of the Interior

U. S. GEOLOGICAL SURVEY
Box 25046 M.S. 425
Denver Federal Center
Denver, Colorado 80225

February 18, 1997

IN REPLY REFER TO:

Dr. Herbert Haas
Director, Radiocarbon Laboratory
Desert Research Institute
P.O. Box 19040
Las Vegas, NV 89132

SUBJECT: Draft Quality Assurance Manual

We have enclosed the revised QA Manual for your review and approval. We performed the required independent quality assurance review using the Desert Research Institute Review/Comment Resolution Form. Your copy is in the enclosed binder. If you have any comments, let us know, otherwise, please sign and date. We need a signed copy for our files. The effective date is currently listed as March 1, 1997. There are still a couple of issues regarding your technical procedures and Emily will be giving you a call.

If you have any questions or require further information, please contact me at (303) 236-0516, extension 299, or Emily Reiter at extension 297.

Sincerely,

T. H. Chaney, Quality Assurance Manager
for Yucca Mountain Project

TCH/ESR
Enclosures

Copies to: E. S. Reiter, USGS/PWT, Denver, CO
Ardell Whiteside, USGS/SAIC, Denver, CO
Vendor file

4/16/97 CRAIG TO HORTON

D 11 2 70

Attachment B
(p. 1 of 2)



United States Department of the Interior

U. S. GEOLOGICAL SURVEY
Box 25046 M.S. 425
Denver Federal Center
Denver, Colorado 80225

IN REPLY REFER TO

QA: L
April 11, 1997

Dr. Herbert Haas
Director, Radiocarbon Laboratory
Desert Research Institute
755 E. Flamingo Road
Las Vegas, NV 89119

**SUBJECT: Desert Research Institute (DRI) Radiocarbon Laboratory Technical Procedures
Request for Review**

As part of the resolution of Yucca Mountain Project deficiency report YM-96-D093, it is requested that Todd Emerson of your laboratory perform a technical review of the following draft procedures:

- RLD-01, Rev. 1: Data Processing
- RLD-02, Rev. 1: Preparation of Benzene From Samples
- RLD-03, Rev. 1: Sample Identification and Control of Samples
- RLD-04, Rev. 1: Scintillation Counting in Benzene Samples

As you discussed with Donna Sinks, QATSS, on April 9, 1997, you indicated that the review would be completed by April 25, 1997. The draft procedures were sent to you in February. Document review forms for Todd to use to record his review are enclosed. Please record all comments on these forms. Also, please provide a list of quality assurance records generated as a result of each technical procedure by April 25. When the reviews have been completed, please return the review forms and the list to me.

We appreciate your attention to this request. If you have any questions or require further information, please contact me at (303) 236-0516, extension 299.

Sincerely,

T. H. Chaney
T. H. Chaney, Quality Assurance Manager
Yucca Mountain Project

THC/djs

Enclosure

P 12012

Dr. Herbert Haas
DRI/Radiocarbon Lab.
April 11, 1997
page 2 of 2

copies w/ encl. to: A. Anderson, USGS, Denver, CO
D.G. Sult, OQA/QATSS, Las Vegas, NV

copies w/out encl.: B. Parks, USGS, Denver, CO
G.L. Ducret, USGS, Denver, CO
S.D. Harris, QATSS/SAIC, Las Vegas, NV
Z. Peterman, USGS, Denver, CO
D.J. Sinks, QATSS/SAIC, Denver, CO
A.M. Whiteside, QATSS/SAIC, Denver, CO
I.C. Yang, USGS, Denver, CO
D.L. Zesiger, USGS/M&O/TRW, Las Vegas, NV



United States Department of the Interior

U. S. GEOLOGICAL SURVEY

Box 25046 M.S. 425

Denver Federal Center

Denver, Colorado 80225

February 18, 1997

IN REPLY REFER TO:

Dr. Herbert Haas
Director, Radiocarbon Laboratory
Desert Research Institute
P.O. Box 19040
Las Vegas, NV 89132

SUBJECT: Draft Quality Assurance Manual

We have enclosed the revised QA Manual for your review and approval. We performed the required independent quality assurance review using the Desert Research Institute Review/Comment Resolution Form. Your copy is in the enclosed binder. If you have any comments, let us know, otherwise, please sign and date. We need a signed copy for our files. The effective date is currently listed as March 1, 1997. There are still a couple of issues regarding your technical procedures and Emily will be giving you a call.

If you have any questions or require further information, please contact me at (303) 236-0516, extension 299, or Emily Reiter at extension 297.

Sincerely,

T. H. Chaney, Quality Assurance Manager
for Yucca Mountain Project

TCH/ESR
Enclosures

Copies to: E. S. Reiter, USGS/PWT, Denver, CO
Ardell Whiteside, USGS/SAIC, Denver, CO
Vendor file.

4/16/97 170 Chris to Horton

D. 14 & 29



IN REPLY REFER TO:

United States Department of the Interior

U. S. GEOLOGICAL SURVEY
Box 25046 M.S. 425
Denver Federal Center
Denver, Colorado 80225

Attachment B
(p. 1 of 2)
QA: L
April 11, 1997

Dr. Herbert Haas
Director, Radiocarbon Laboratory
Desert Research Institute
755 E. Flamingo Road
Las Vegas, NV 89119

**SUBJECT: Desert Research Institute (DRI) Radiocarbon Laboratory Technical Procedures
Request for Review**

As part of the resolution of Yucca Mountain Project deficiency report YM-96-D093, it is requested that Todd Emerson of your laboratory perform a technical review of the following draft procedures:

- RLD-01, Rev. 1: Data Processing
- RLD-02, Rev. 1: Preparation of Benzene From Samples
- RLD-03, Rev. 1: Sample Identification and Control of Samples
- RLD-04, Rev. 1: Scintillation Counting in Benzene Samples

As you discussed with Donna Sinks, QATSS, on April 9, 1997, you indicated that the review would be completed by April 25, 1997. The draft procedures were sent to you in February. Document review forms for Todd to use to record his review are enclosed. Please record all comments on these forms. Also, please provide a list of quality assurance records generated as a result of each technical procedure by April 25. When the reviews have been completed, please return the review forms and the list to me.

We appreciate your attention to this request. If you have any questions or require further information, please contact me at (303) 236-0516, extension 299.

Sincerely,

T. H. Chaney, Quality Assurance Manager
Yucca Mountain Project

THC/djs

Enclosure

Dr. Herbert Haas
DRI/Radiocarbon Lab.
April 11, 1997
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copies w/ encl. to: A. Anderson, USGS, Denver, CO
D.G. Sult, OQA/QATSS, Las Vegas, NV

copies w/out encl.: B. Parks, USGS, Denver, CO
G.L. Ducret, USGS, Denver, CO
S.D. Harris, QATSS/SAIC, Las Vegas, NV
Z. Peterman, USGS, Denver, CO
D.J. Sinks, QATSS/SAIC, Denver, CO
A.M. Whiteside, QATSS/SAIC, Denver, CO
I.C. Yang, USGS, Denver, CO
D.L. Zesiger, USGS/M&O/TRW, Las Vegas, NV

ORIGINAL

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WASHINGTON, D.C.

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5/30/97 NOTIFICATION OF COMPLETION OF ACTIONS (page 1 of 2)

Block 14: Remedial actions:

Deficiency Item #1 Response:

- a) Indoctrination and training on the DRI QA Manual and four technical procedures (RLD-01, R1; RLD-02, R1; RLD-03, R1; and RLD-04, R1) for Dr. Haas and Todd Enerson have been documented on the appropriate DRI forms.
- b) See response of 12/17/96.

Deficiency Item #2 Response:

See response of 12/17/96.

Deficiency Item #3 Response:

See response of 12/17/96.

Deficiency Item #4 Response:

See response of 12/17/96. Also, Section 4 of the DRI QA Manual was revised to remove the reference to procurements for calibration services.

Deficiency Item #5 Response:

See response of 12/17/96. Additionally, Section 4 of the QA Manual was revised to clearly state that oxalic acid is procured directly from NIST and that supplier qualification of NIST is not required. Attachment 4.1 to the QA Manual was deleted.

Deficiency Item #6 Response:

Section 17 of the QA Manual was revised to reference Attachment 1 (new) to the QA Manual which lists the QA records generated by implementing the four DRI technical procedures.

Deficiency Item #7 Response:

The four DRI procedures were reviewed by Todd Enerson on 4/29/97 (review forms attached). A USGS Reviewer Selection Form was completed for Mr. Enerson (form attached), according to requirements in YMP-USGS-QMP-3.07, R5, YMP-USGS Review Procedure.

Deficiency Item #8 Response:

The DRI QA Manual, draft dated March 1, 1997, was reviewed by T.H. Chaney, USGS, on 2/13/97 (attached). The four DRI technical procedures were reviewed by Wayne Rodman, USGS, on 5/16/97 (attached).

Deficiency Item #9 Response:

See 12/17/96 response to Deficiency Item #4 and this response to Deficiency Item #4.

(continued)

5/30/97 Craig G. Horner

217729

ORIGINAL

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

- Performance Report
- Deficiency Report

NO. YM-96-D093
 PAGE _____ OF _____
 QA:L

PR/DR CONTINUATION PAGE

5/30/97 NOTIFICATION OF COMPLETION OF ACTIONS (page 2 of 2)

Deficiency Item #10 Response:

See 12/17/96 response. Additionally, Section 17 of the DRI QA Manual was revised to include a list of QA records as Attachment 1. Section 7 (Supplement II in current revision) was revised, deleting reference to the Sample Tracking Form. Attachment 7.1 was removed from the QA Manual. Supplement II now refers to technical procedure RLD-03 for sample control.

Responses to additional conditions listed in Block 6:

Condition 1. Section 4 of technical procedure RLD-01 was revised to indicate that hard copies of all data are stored in the data office, room 229. Attachment 2 (new) of the QA Manual is a list of the location of data and files.

Condition 2. Technical procedure RLD-02 was revised as follows:

- The reference in section 2.1.6 was changed to 2.1.4 and 2.1.5
- In Section 2.1.12.1, step 7, references were changed to 2.1.5 and 2.1.11
- In Section 2.1.12.2, step 6, the reference was changed to 2.1.10. Pagination was also corrected.

Condition 3. Section 2.2, paragraph 3 now references Section 2.5 (the correct section).

Block 16 - Root Cause Determination:

See 12/17/96 response.

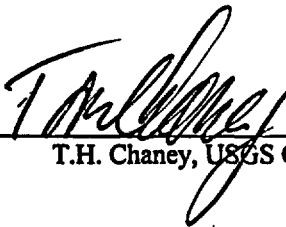
Block 17 - Action to Preclude Recurrence:

The QA Manual was revised as described in Block 14 above. An SER was prepared (attached).

Block 18 - Corrective Action Due Date:

See 12/17/96 response.

Block 19 - Amended Response by:



T.H. Chaney, USGS QA Manager

Date:

5/20/97

Phone: (303)236-0516, x299

ORIGINAL

DESERT RESEARCH INSTITUTE REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: Data Processing, RLD-01, Revision 1

Page 1 of 1

Date of Document (if applicable): March 1, 1997

Reviewer Name(s): Todd Enerson

Governing Procedure: QA Manual, Section 5

Reviewer's Signature(s): *Todd B Enerson*

Date: 4/29/97

Technical Review

Quality Assurance Review

Other:

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MANDATORY CO	
COMMENT NO.	PAGE NO	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
		<i>No Comments</i>					

Herbert Haas
Director

4/30/97
Date

1997 5

ORIGINAL

DESERT RESEARCH INSTITUTE REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: Preparation of Benzene From Samples, RLD-02, Revision 1 Page 1 of 1

Date of Document (if applicable): March 1, 1997

Reviewer Name(s): Todd Enerson Governing Procedure: QA Manual, Section 5

Reviewer's Signature(s): *Todd B Enerson* Date: 4/29/97

Technical Review Quality Assurance Review Other: _____

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MANDATORY CO	
COMMENT NO.	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
		<i>No Comment.</i>					

Herbert Hayes
Director

4/30/97
Date

0.20420

ORIGINAL

DESERT RESEARCH INSTITUTE REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: Sample Identification and Control of Samples, RLD-03, Revision 1 Page 1 of 1

Date of Document (if applicable): March 1, 1997

Reviewer Name(s): Todd Enerson Governing Procedure: QA Manual, Section 5

Reviewer's Signature(s): *Todd B Enerson* Date: 4/29/97

Technical Review Quality Assurance Review Other: _____

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION MANDATORY CC	
COMMENT NO.	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
		<i>No Comment.</i>					

Robert Hanco
Director

4/30/97
Date

021020

ORIGINAL

DESERT RESEARCH INSTITUTE REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: Scintillation Counting in Benzene Samples, RLD-04, Revision 1 Page 1 of 1

Date of Document (if applicable): March 1, 1997

Reviewer Name(s): Todd Enerson Governing Procedure: QA Manual, Section 5

Reviewer's Signature(s): *Todd B Enerson* Date: 4/29/97

Technical Review Quality Assurance Review Other: _____

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION MANDATORY CC	
COMMENT NO.	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
		No Comments					

Herbert Hulse

4/30/97

0 22 624

REVIEWER SELECTION FORM

[To be completed by the Chief, Geologic Studies Program/ Hydrologic Investigations Program, Chief, Yucca Mountain Project Branch or Quality Assurance Manager responsible for reviewer selection.]

Document(s) to be reviewed:

DEI-RLD-04, R1: Scintillation Counting of Benzene Samples
DEI-RLD-03, R1: Sample Identification and Control of Samples
DEI-RLD-02, R1: Preparation of Benzene from Samples
DEI-RLD-01, R1: Data Processing

Name of reviewer: Todd Emerson

Title of reviewer: Laboratory Technician

Selection of reviewer not documented under QMP-2.02 or QMP-2.08:

Employer of reviewer: Desert Research Inst, Las Vegas, NV

Basis of selection for reviewer: Extensive laboratory experience in a radiocarbon dating laboratory working with gas samples

Bruce Parks

Printed Name

Assoc. Chief, ESIP

Title

Bruce Parks

Signature

4/21/97

Date

ORIGINAL

DESERT RESEARCH INSTITUTE REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: Dr. Herbert Haas, Radiocarbon Laboratory, Desert Research Institute Quality Assurance Manual Page 1 of 1

Date of Document (if applicable): March 1, 1997

Reviewer Name(s): Tom Chaney, USGS YMP QA Manager Governing Procedure: YMP-11565 QMP 7.04, R3

Reviewer's Signature(s): *Tom Chaney* Date: 2/13/97

Technical Review Quality Assurance Review Other:

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION (MANDATORY CON)	
COMMENT NO.	PAGE NO.	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
		No comments					

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ORIGINAL

YMP-USGS REVIEW/COMMENT RESOLUTION FORM

Document No. and Title: DRI PROCEDURES RLD-01 R1, RLD-02 R2, RLD-03 R1, RLD-04 R1 Page 1 of 1

Date of Document (if applicable): N/A

Reviewer Name(s): WAYNE RODMAN Governing Procedure: DRI QA MAN R1

Reviewer's Signature(s): Wayne Rodman Date: 5/16/97

Technical Review QA Review Other: _____

REVIEWER'S COMMENTS			RESPONSE			REVIEWER DISPOSITION FOR MANDATORY COMMENTS	
COMMENT NO MANDATORY (M) NON-MANDATORY (NM)	PAGE NO	COMMENTS	ACCEPT	REJECT	JUSTIFICATION	ACCEPT	REJECT
1 NM	N/A	Contrary to DRI QA manual Section 5.0 (h) procedures do not list QA records generated. However, these records are listed as an attachment.					
2 NM	1	RLD-04 Incorrect reference in Section 2.1 should be "RLD-02 Section 2.5.4"					

* Justification(s) for rejection of reviewer's comment(s) is/are found to be justified:

ORIGINAL

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
SUPPLIER EVALUATION REPORT

- 1 PURPOSE:
- INITIAL EVALUATION
 - TRIENNIAL AUDIT
 - REMOVE SUPPLIER
 - INITIAL AUDIT
 - SCOPE CHANGE
 - ANNUAL EVALUATION
 - PROGRAM CHANGE

SUPPLIER INFORMATION	2 SUPPLIER NAME/ADDRESS	CONTACT NAME/TITLE
	<i>Orsco Research Inst</i>	<i>Dr. Herbert Haas</i>
	<i>RadioCarbon Lab</i>	
		TELEPHONE
	ITEM(S)	SERVICE(S)
		<i>C¹⁴ ANALYSIS of gas samples</i>
PROCUREMENT DOCUMENT NUMBER(S)	QA MANUAL	REVISION LEVEL OR DATE
	<i>RadioCarbon Lab QA Manual</i>	<i>Rev 2</i>
	CODES/STD COMMITTED TO IN QA MANUAL	
	<input type="checkbox"/> 10 CFR 50B	<input type="checkbox"/> ISO 9000
	<input type="checkbox"/> ANSI N 45.2	<input type="checkbox"/> <i>N/A</i>
	<input type="checkbox"/> NQA-1	<input type="checkbox"/>

- 3 TYPE
- QUALITY RECORDS REVIEW
 - SUPPLIER HISTORY
 - AUDIT
 - SURVEY
 - MATRIX REVIEW

4 RESTRICTIONS & COMMITMENTS

NONE

Continued

5 REMARKS

*NONE SER revised to reflect revision of QAM from documents
resulting from corrective actions for YM-96-0693*

Continued

6 APPROVAL

QUALIFIED

QUALIFIED WITH RESTRICTION(S)

NOT QUALIFIED

REEVALUATION DUE DATE *12/1/97* AUDIT DUE DATE _____

QA MANAGER: *TOM CHANDY* *5/23/97*
Signature Date

7 VERIFICATION

VERIFIED CORRECT INPUT OF DATA TO QSL

VERIFIER: _____
Signature Date

pc 5/23/97

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
SUPPLIER EVALUATION REPORT

1 PURPOSE: QA PROGRAM MATRIX REVIEW QUALITY RECORDS EVALUATION
 AUDIT SURVEY

ORIGINAL

2 SUPPLIER NAME: *Desert Research Institute*

3	QA PROGRAM ELEMENT	SAT	UNSAT	N/A
1	ORGANIZATION	✓		
2	QUALITY ASSURANCE PROGRAM	✓		
3	DESIGN CONTROL			✓
4	PROCUREMENT DOCUMENT CONTROL			✓
5	IMPLEMENTING DOCUMENTS	✓		
6	DOCUMENT CONTROL	✓		
7	CONTROL OF PURCHASED ITEMS AND SERVICES			✓
8	IDENTIFICATION AND CONTROL OF ITEMS	✓		
9	CONTROL OF SPECIAL PROCESSES			✓
10	INSPECTION			✓
11	TEST CONTROL			✓
12	CONTROL OF MEASURING AND TEST EQUIPMENT	✓		
13	HANDLING, STORAGE AND SHIPPING			✓
14	INSPECTION, TEST AND OPERATING STATUS			✓
15	NONCONFORMANCES			✓
16	CORRECTIVE ACTION	✓		
17	QUALITY ASSURANCE RECORDS	✓		
18	AUDITS			✓
SUPPLEMENT I	SOFTWARE	✓		
SUPPLEMENT II	SAMPLE CONTROL	✓		
SUPPLEMENT III	SCIENTIFIC INVESTIGATION			✓
SUPPLEMENT IV	FIELD SURVEYING			✓

MATRIX / RECORDS / AUDIT / SURVEY

DESCRIPTION OF QUALITY ASSURANCE PROGRAM PROCEDURES OR OTHER SIMILAR DOCUMENT(S) REVIEWED/EVALUATED

TITLE/REVISION: *DRP Radio Carbon Lab QA Manual Rev 1*

*RLD-01, R1 DATA PROCESSING; RLD-02, R2 PREPARATION OF BENZENE SAMPLES;
RLD-03, R1 SAMPLE ID AND CONTROL OF SAMPLES; RLD-04, R1 SCINTILLATION COUNTING
IN BENZENE SAMPLES*

Continued

4 AUDIT/SURVEY: _____ DATE: _____ PERFORMED BY: _____

EVALUATION RESULTS

Continued

IF RESTRICTIONS OR DOCUMENTED COMMITMENTS ARE APPLICABLE, IDENTIFY ON SUPPLIER EVALUATION SHEET, PAGE 1.

EVALUATOR _____ SIGNATURE _____ DATE _____

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

NO. YM-96-D-093

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PR/DR CONTINUATION PAGE

Verification Activities:

14 Remedial Actions:

Deficiency Item 1. Personnel Qualification documents for Todd Enerson and Dr. Haas were verified. They included :

- o a resume for Dr. Haas and a Biographical Sketch for Todd Enerson,
- o Record of Training forms for both Todd and Dr. Haas for:
 - o the QA Manual, Revision 1
 - o Technical Procedures: RLD-01, Data Processing, Rev. 1
RLD-02, Preparation of Benzene from Samples, Rev. 1
RLD-03, Sample Identification and Control of Samples, Rev. 1
RLD-04, Scintillation Counting in Benzene Samples, Rev. 1

This was satisfactory to close the concern.

Deficiency Item 2. Two recent reports submitted by Dr. Haas were verified to have the data at the top of the report:

Dr. Haas/ DRI to Dr. Patterson dated September 18, 1997 and Dr. Haas/DRI to Dr. Patterson dated April 22, 1997.

This was satisfactory to close the concern.

Deficiency Item 3. Data sheets that make up the lab notes for scintillation runs have a sample (at least 1 out of 5-12 samples depending on the number run) calculation performed by hand to assure accurate results. I verified two examples of data sheets with calculations indicated using a Sharp calculator and the resulting data performed by hand. These hand calculations had been compared to that reported by the spreadsheet application to make sure the results are within expected parameters. This was satisfactory to close the concern.

Deficiency Item 4. The QA Manual was verified to be changed to indicate that calibration of the balance is not required for the method of analysis used. USGS has taken the position that the absolute weights are not critical and the method of tare weight tracking, indicated in the technical procedures gives satisfactory accuracy for use. This was satisfactory to close the concern.

Deficiency Item 5. The NIST certificate was verified to be retained in the laboratory. It is actually an NBS (National Bureau of Standards) Certificate dated July, 1983: Oxalic Acid - SRM4990C. This number is indicated on all bottles of the standard material. This was satisfactory to close the concern.

Deficiency Item 6. Each technical procedure mentioned in Deficiency Item 1 above was verified to have a section added to indicate the QA records created by using the procedure. This was satisfactory to close the concern.

Deficiency Item 7. The response indicated the USGS would perform a technical review of the Radiocarbon Lab's technical procedures. At the time the response was submitted an USGS individual, qualified to perform this task, was prepared to do the review, but for various reasons could not do it. The QARD requires this type of review to be performed by one who was not the preparer. Todd Enerson, who works with Dr. Haas, but was not the preparer of the technical procedures performed the review. During verification of the revision 1 modification to the QA Manual, section 5.0, *Implementing Documents*, and Supplement I, *Software*, it was found a few requirements needed to be added to meet the QARD (Section 5.0: review criteria, unique individual to perform the review, documentation and resolution of mandatory comments prior to approval; Supplement I: clarification of control for acquired software). It was verified that the QA Manual, revision 2, was modified to include these requirements. The review comment forms for each procedure were verified and found to be satisfactory to close this concern. Also, the personnel training forms for reading QA Manual, revision 2, were verified as completed.

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

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QA: L

PR/DR CONTINUATION PAGE

Verification Activities (continued)

Deficiency Item 8. Documented review by USGS of the QA Manual was verified and found to be acceptable. This was satisfactory to close this concern.

Deficiency Item 9. As stated in Deficiency Item 4, the QA Manual was verified to be changed to not require calibration for the data obtained. This was satisfactory to close the concern.

Deficiency Item 10. The required record items below were verified:

- o personnel indoctrination and training to the QA Manual. (See Deficiency Item 1)
- o personnel qualification forms for Dr. Haas (See Deficiency Item 1)
- o Receipt inspection forms, Purchase Order forms. The only one needed was for Oxalic Acid, this was verified as retained in the laboratory. (See Deficiency Item 5).
- o Review sheets (Document Review Records). (See Deficiency Items 7 and 8)
- o Sample Tracking System. This was verified to be changed in the QA Manual. The process referenced in the QA Manual is now RLD-03, Sample Identification and Control of Samples (Section Supplement II, Page 6).

Verification of additional conditions to be resolved listed in block 6:

Item 1. The QA Manual was verified to be changed to indicate general records requirements in section 17.0. The individual technical procedures were verified to have a section for records generated.

Item 2. The references located in the technical procedure RLD-02, Preparation of Benzene from Samples, that had been incorrect were verified to have been changed to be the correct reference for the work to be performed.


Item 3. RLD-04, Scintillation Counting in Benzene Samples, was verified to be changed to indicate the correct referenced section for counter calibration..

16 Root Cause Determination. The Root Cause Determination forms were completed as required and were found to be satisfactory.

17 Action to Preclude Recurrence. The DRI QA Manual was verified to be changed as indicated by the agreed corrective action and the revision 2 as indicated by verification action described in Deficiency Item 7. A new SER was verified to have been prepared for DRI. It was verified that USGS had been working with Dr. Haas to resolve the deficiencies sited in this DR and to discuss the degree of effort required to perform the requirements. As of 10/8/97, it was verified that Dr. Haas has no current work being done for YMP.

Based on the above satisfactory verification activities, this DR is considered closed.


Stephen D. Harris


Date