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

NOV 0 8 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 CAR YM-96-C-006 RESULTING FROM OQA SUPPLIER AUDIT OQA-SA-96-022 OF THE UNIVERSITY OF SASKATCHEWAN

The Office of Quality Assurance staff has evaluated the response to Corrective Action Request YM-96-C-006. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after February 1, 1997. If the analytical results are not submitted by the vendor in time to complete the corrective action by this date, an extension must be requested in writing. 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 Mario R. Diaz at (702) 794-1489 or Stephen D. Harris at (702) 794-5522.

R. E. Spence

Richard E. Spence
Office of Quality Assurance

OQA:MRD-0285

Enclosure:
CAR YM-96-C-006

cc w/encl:
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
D. G. Horton, DOE/OQA, Las Vegas, NV
W. E. Barnes, DOE/YMSCO, Las Vegas, NV
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

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Recip: NMSS/PAHL

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QA: L

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

CORRECTIVE ACTION REQUEST

1 Controlling Document:	2 Related Report No.:
Quality Assurance Requirements and Description, DOE/RW-0333P (QARD), Rev. 5	OQA-SA-96-022
3 Responsible Organization:	**4 Discussed With:**
U.S. Geological Survey/University of Saskatchewan	Tom Chaney / David Pezderic and Robert Kerrich

5 Requirement:

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: C. Quality Assurance Program Requirements including: 1. 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, although there was a documented QA program initiated in the form of a QA Manual and technical procedures, the complete QA program that applies to the University of Saskatchewan scope of work was not in place prior to initiation of work. Implementing documents for the performance of Quality Assurance activities were not available within the QA program and were not being used at the University. The following discrepant conditions were observed during review of the QA program:

1. The responsibilities for implementing the quality assurance program are defined in the QA Manual. As implementation has not been executed, it appears there may be misunderstanding as to responsibilities.
2. The documentation required to show evidence of the training to the QA Manual and procedures was not available for review although the requirements are described in the QA Manual. Attached forms described in the QA Manual are not being used.
3. Procurement documents packages as described in section 4.0 of the QA Manual are incomplete.
4. Calibration of balances, used for Yucca Mountain work did not show evidence of traceability to NIST standards. In addition, no documentation was available for traceability of the AGS standard to NIST 28.

(see continuation page 2)

7 Initiator:	9. Does a stop work condition exist?
S. D. Harris 8-8-96	Yes ___ No ✓ ; If Yes, Attach copy of SWO
S. D. Harris Date 08/08/96	If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

Prior to any further technical activities, resolve all issues not in compliance to the USGS Procurement document, the University of Saskatchewan QA Manual and SILAB.DOC2. Write appropriate implementing documents, such as QA procedures and more detailed technical procedures, perform indoctrination and training for all personnel, and request verification of these activities by OQA.

11. QA Review:	12 Response Due Date:
QAR S. D. Harris S. D. Harris 8-8-96 Date 08/08/96	20 days from issuance

13 Affected Organization QA Manager Issuance Approval:

Printed Name R.E.SPENCE Signature Robert B Cowtatte for Date 8.9.96

22 Corrective Actions Verified	23 Closure Approved by:
QAR Date	AOQAM Date

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

8 [Y] Corrective Action
[ ] Request

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CAR/SWO CONTINUATION PAGE

6 Description of Condition (continued from page 1):

5. Procurement documents do not exist for the requirements listed in the QA Manual, section 4.2.1, information for calibration or services.
6. Procurement planning, although possibly accomplished informally, does not show evidence of required activities listed in the QA Manual, section 4.2.2.
7. There is no evaluation of capabilities for Pulse Instrumentation LTD/SET Instrument Service: subcontracted service for calibration, as required in the QA Manual, section 4.2.3.
8. Receipt inspection is not being performed as required by the QA Manual, section 4.2.5.
9. There is no evidence that technical procedures SILAB.DOC2 are reviewed, approved and controlled in accordance with QA Manual, section 6.0 (reference section 5.2).
10. The QA Manual and technical procedures lack evidence of proper review, approval and distribution as required by section 6.0 of the QA Manual.
11. Two sets of the QA Manual, numbered and maintained, and a master set with current table of contents were not available for review as required in the QA Manual, section 6.2.
12. There is no evidence of data review by a qualified individual prior to submittal to the client as required by the QA Manual, section 3.2.2.
13. The Individual Tracking Form [attachment 7.1] is not used to track samples as required by the QA Manual, section 7.2.2.
14. There is no evidence of a calibration schedule or prescribed intervals identified for calibration as required by the QA Manual, section 8.0.
15. Calibration stickers are missing required information: calibration due date, individual performing calibration, serial number (identification) of instrument.
16. Reference standards are missing NIST standard certification.
17. Equipment calibration schedule [QA Manual, section 8.0, attachment 8.1] is not being used.
18. Calibration records are not maintained.
19. The deficiency reporting system is not being implemented as required by the QA Manual, section 9.0. Deficiency system logbooks are not being used as required.
20. A sysem to assure QA records are prevented from loss or deterioration has not been established and implemented as required by the QA Manual, section 10.
21. Those records identified in section 10.2.2 of the QA Manual, that includes audit assessment reports done internally, are not available as QA records.
22. The QA Manual, section 11, does not reflect the correct organization to perform internal audits. This is a requirement of the University.
23. There is no objective evidence of supervisory faculty determiantion of accuracy of data prior to release as required by SILAB.DOC2, Organizational structure, bullet 2.
23. There is no calibration of balances prior to each weighing procedure. Zeroing of the balance is performed. (See SILAB.DOC2, Extraction Procedures, bullet 3.
24. There is no evidence the first aliquot of BrF5 is discarded as stated in SILAB.DOC2, Extraction Procedures, bullet 7. There is also no evidence of monitoring and recording conversion of O2 to CO2 and residual gas pressures as required by bullet 9.
25. Optimization peaks are not always printed out as evidence of activity performed, see SILAB.DOC2, Mass Spectroscopy, iii, sentence 3.
26. The discrepancy in the use of a spreadsheet file in SILAB.DOC2, Sample Handling Protocol, viii, is in conflict with the QA Manual, section 7.2.2.

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WASHINGTON, D.C.

CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

SEE RESPONSE CONTINUATION PAGE.

15 Extent of Condition and Impact:

SEE RESPONSE CONTINUATION PAGE

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached. SEE RESPONSE CONT. PAGE.

17 Action to Preclude Recurrence:

SEE RESPONSE CONTINUATION PAGE.

18 Corrective Action Completion Due Date:	19 Response by:	
SEE RESPONSE CONT. PAGE	☒ Initial ☐ Amended	SEE RESPONSE CONT. PAGE Date Phone

20 Response Accepted	21 Response Accepted
QAR Stephen Harris Date 11-1-96	AOQAM [signature] Date 11/1/96

Exhibit AP-16.2Q.1-2

Rev. 07/15/96

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

☒ Corrective Action Request
☐ Stop Work Order

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CAR/SWO CONTINUATION PAGE

10/24/96 INITIAL RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-96-C-006

BLOCK 14 REMEDIAL ACTIONS: The YMP-USGS Earth Science Investigations Program (ESIP) Environmental Science Team Chief will coordinate with the vendor in order to obtain the analytical results. These results are expected on or before January 1, 1997. Within one (1) month of receipt of the vendor's results the Environmental Science Team Chief will assure that the analytical results are identified as "unqualified" and included within a procurement records package that references this Corrective Action Request.

For the deficiencies cited in Block 6 of this CAR, no specific remedial actions are warranted for each deficient condition because the YMP-USGS will not be relying upon the vendor's QA program or procedures to determine the acceptability of the analytical results. If, at a later date, the YMP-USGS determines that qualification of the data is needed, the guidance of YAP-SIII.1Q (or its successor) will be implemented.

BLOCK 15 EXTENT OF CONDITION AND IMPACT: This deficiency is limited to the vendor's 1995 QA program and implementation of that program at their Saskatoon, Saskatchewan, Canada facility. This deficiency only affects the analytical work (oxygen isotopic analysis of silicate rock samples) being performed by the vendor under one YMP-USGS purchase order (1434-CR-95-SA-01689).

BLOCK 16 ROOT CAUSE DETERMINATION PREPARED IN ACCORDANCE WITH AP-16.4Q IS ATTACHED.

BLOCK 17 ACTION TO PRECLUDE RECURRENCE: Through discussions between the Environmental Science Team Chief and the vendor, it has been determined that the vendor does not feel it is cost-effective at this time for them to update their written QA program and technical procedures solely for the Yucca Mountain Project. Therefore the YMP-USGS will not attempt to utilize their analytical services as a YMP-approved vendor, and the vendor's name should be deleted from the DOE OCRWM Qualified Suppliers List. The Environmental Science Team Chief has coordinated with the ESIP Implementation Team Chief and has requested the YMP-USGS Quality Assurance Office take the necessary actions to have the vendor's name removed from the Qualified Suppliers List (see attached 10/24/96 memorandum, Bruce Parks to Thomas H. Chaney).

BLOCK 18 CORRECTIVE ACTION COMPLETION DUE DATE:

Remedial Actions-----	**February 1, 1997 (provided analytical results are received from vendor on or before January 1, 1997)**
Preventive Actions---	**Completed October 24, 1996**

BLOCK 19 Initial Response by:

Robert W. Craig 10/24/96

Robert W. Craig, Chief, Yucca Mountain Project Branch **Date**

10/24/96 CRAIG TO SPENCE

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 did not fully implement QA manual RO/6-9-95 or Technical Procedure SILAB.DOC2 (reference DOE YMQA Corrective Action Request YM-96-C-006.)

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

   - In the vendor's facility at the University of Saskatchewan, Saskatoon, Saskatchewan, Canada.

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

   - During DOE OQA Supplier Audit at vendor's facility 8/1-2/96.

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)**

   - Part of scientific investigation activities (analyses) for Site Characterization work.

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

   - Isolated to implementation of recently developed requirements documents (QA Manual and Technical Procedure) put in place within 1995 specifically for the Yucca Mountain Project.

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

   - Programmatic, primarily, but lack of procedures/process impacts the status of the data (especially with calibration documentation problems).

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

   - USGS

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

- Change in vendor's personnel who had management responsibility for the development and implementation of QA and technical procedures.

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.

- None.

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

- YMP-USGS purchase order (referenced in CAR YM-96-C006) and associated Requisition.

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

RI or designee: (Print)	Signature:	Date:
Bruce Parks Ardell Whiteside	Bruce Parks Andrew M. Whiteside	October 24, 1996

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

TELEPHONE OR PERSONAL INTERVIEW RECORD

Person Interviewed: (Print)		Title:	
Zell E. Peterman		Chief, Environmental Science Team	
Organization/Location	**Telephone No.:**	**Date/Time:**	**CAR No./DR No.**
USGS-YMPB-ESIP	(303) 236-7883	See Below	CAR YM-96-C-006

Interview Details: Based upon discussions with Zell Peterman on 8/20, 8/27, 9/3, 9/24, 10/11 & 10/24/96 to:

1) **Determine status of vendor's analytical work and status of purchase order.** The purchase order was needed because YMP-USGS personnel could not accomplish all of the necessary analysis in time to meet project demands. The analytical work has not been completed yet and results are expected before the first of the year. The purchase order involves only one set of oxygen isotopic analysis of silicate rock samples. The purchase order remains open at this time pending completion of the analysis.

2) **Determine vendor's actions and interests with regard to revising their QA Manual and Technical Procedure given the small dollar amount ($1875.00) of the YMP-USGS order.** The vendor does not feel it is cost-effective to revise and maintain the quality assurance program/procedures written specifically for Yucca Mountain Project work. The vendor expressed concern about cost and necessity of "fixing" all problems that the QA auditors cited. Additionally, the vendor does not feel that all of the written requirements contribute positively to the quality of their analysis or analytical results.

3) **Discuss the vendor's personnel turnover and management changes that led to deficiency.** A proponent of the written QA program was Dr. T.K.Kyser who left the University in the Spring of 1995. The laboratory at the University is under new management who do not feel the written program contributes to their technical work.

4) **Discuss alternative approaches that would respond to CAR and reach acceptable closure. Also discuss alternate actions we could take to assess the technical soundness of the vendor's analysis if the vendor does not revise their program/procedures.** Discussed alternatives, such as 1) requesting vendor to revise manual and to correct all specific deficient conditions identified in CAR and resulting from additional investigative actions; 2) obtaining analytical results and conducting technical verification to accept results (QARD 7.2.6 C.3); 3) determining analytical results (data) are unqualified. The first alternative cannot be accomplished without the full cooperation of the vendor. The second alternative requires additional coordination and either development of a written implementation procedure requiring DOE QA acceptance or implementation of YAP-SIII.1Q. The third alternative is within the control of the YMP-USGS, requires identification of the affected data set as part of the project records system, and requires the least amount of time to put into place, thereby facilitating the quickest closure of the deficiency.

Splits of the samples that were sent to the vendor are on-hand with YMP-USGS and could be sent to another OCRWM QA-approved vendor or analyzed in-house by qualified YMP-USGS personnel using comparable methodology. This technical verification could include from approximately 10% up to 100% of samples as sent to University. Ten percent (10%) of samples would provide data adequate to establish whether or not vendor's data is sound and produced by acceptable technical methods. If unable to conduct a technical verification to assess soundness of vendor's analysis, then analytical results (data) are to be considered unqualified for use in YMP-USGS site characterization work.

Interviewers (Bruce Parks and Ardell Whiteside) 10-24-96

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

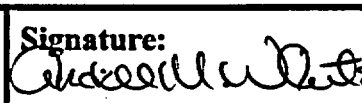
Root Cause Code:	**CAR No./DR No.**
3AC	CAR YM-96-C-006

Root Cause:

The deficiency resulted because of the failure to use the existing QA Manual and Technical Procedure.

Justification or Rationale for Selected Root Cause:

Conditions described in Block 6 of CAR YM-96-C-006 state that the QA Program and Technical Procedure were not being used by the University.

Designee: (Print)	**Signature:**	**Date:**
Ardell M. Whiteside		10/24/96
RI: (Print)	**Signature:**	**Date:**
Bruce Parks		10/24/96

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:

WBS #:1.2.3.1
INFORMATION COPY
October 24, 1996

MEMORANDUM

TO: Thomas H. Chaney, YMP-USGS Quality Assurance Manager

FROM: Bruce Parks, Chief, Implementation Team, Earth Science Investigations Program

SUBJECT: Yucca Mountain Project Qualified Suppliers List

REFERENCE: Corrective Action Request (CAR) YM-96-C-006 (QA Program and technical procedures not being implemented at University of Saskatchewan for Purchase Order 1434-CR-96-SA-01689)

As a result of investigative actions for the subject CAR, we have determined that the vendor, University of Saskatchewan, cannot meet the stipulated quality assurance requirements for the Yucca Mountain Project (i.e., update, maintain, or revise their written quality-assurance program developed for their Yucca Mountain work). Therefore, please initiate the necessary actions to assure that the vendor's name is deleted from the YMP Qualified Suppliers List.

If you have any questions or require additional information, please contact me at 236-5050 extension 236 or Ardell Whiteside at 236-5050 extension 233.

BP:aw

Copy to: Bob Craig
Lou Ducret
Joyce Golos
Mary Nelson
Alice Lykins
Ardell Whiteside