

AUG 12 1996

Robert W. Craig

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cc w/encl:

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J. G. Spraul, NRC, Washington, DC

S. W. Zimmerman, NWPO, Carson City, NV

T. H. Chaney, USGS, Denver, CO

D. G. Horton, OQA, NV

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Records Processing Center

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV

S. D. Harris, YMQAD/QATSS, Las Vegas, NV

D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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

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CORRECTIVE ACTION REQUEST

1 Controlling Document: Quality Assurance Requirements and Description, DOE/RW-0333P (QARD), Rev. 5		2 Related Report No.: OQA-SA-96-022	
3 Responsible Organization: U.S. Geological Survey/University of Saskatchewan		4 Discussed With: 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: <ol style="list-style-type: none"> 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. <p style="text-align: right;">(see continuation page 2)</p>			
7 Initiator: <i>S. D. Harris</i> S. D. Harris Date 08/08/96		9. Does a stop work condition exist? Yes ___ No <input checked="" type="checkbox"/> ; If Yes, Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> 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: <i>S. D. Harris</i> QAR S. D. Harris Date 08/08/96		12 Response Due Date: 20 days from issuance	
13 Affected Organization QA Manager Issuance Approval: Printed Name R.E. SPENCE Signature <i>Robert B. Constable</i> Date 8.9.96			
22 Corrective Actions Verified QAR _____ Date _____		23 Closure Approved by: AQQAM _____ Date _____	

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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 system 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 determination 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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CORRECTIVE ACTION REQUEST RESPONSE

14 Remedial Actions:

15 Extent of Condition and Impact:

16 Root Cause Determination prepared in accordance with AP-16.4Q is attached.

17 Action to Preclude Recurrence:

18 Corrective Action Completion Due Date:

19 Response by:

Initial

Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted

AOQAM

Date