



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

APR 10 1996

Robert W. Craig
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Site Characterization Project
U.S. Geological Survey
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ISSUANCE OF CORRECTIVE ACTION REQUEST (CAR) YMQAD-96-C004 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARC-96-10 OF U.S. GEOLOGICAL SURVEY (USGS) (SCPB: N/A)

Enclosed is CAR YMQAD-96-C004 generated as a result of YMQAD Audit YM-ARC-96-10. This CAR is issued under separate cover than the other deficiency documents.

CAR YMQAD-96-C004 documents deficiencies relative to USGS' procurement of analytical, calibration, and/or other supplier services. The subject CAR documents deficiencies which are repetitive in nature as delineated in previous audits and deficiency documents. Due to the seriousness of the deficiencies identified in this CAR, a Stop Work Order on USGS is being considered in the area of procurement and will remain an option during the implementation of the CAR corrective action process. It appears through the Office of Civilian Radioactive Waste Management Supplier Evaluation process that the technical adequacy of the deliverables performed by the suppliers is satisfactory. Should this prove to be incorrect during the corrective action process, a detailed data validation process will be implemented. An attachment to the CAR is a Corrective Action Plan that will reestablish procurement controls as required by the Quality Assurance Requirements and Description document. The Plan imposes specific restraints and additional processes for USGS to implement in evaluation of new, existing and completed procurements for technical and quality adequacy in resolution of the CAR. Revisions to this plan or alternate corrective actions proposed by USGS shall be approved by the Director, YMQAD, prior to implementation.

Please identify the corrective action to be taken and implemented to correct the deficiency as identified in the CAR and Corrective Action Plan. A CAR Continuation Page has been provided. Send the original of your response to Deborah G. Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

Response to the CAR is due 10 working days from the date of this letter.

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Robert W. Craig

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If you have any questions, please contact either Robert B. Constable at 794-7945 or John S. Martin at 794-7881.

A handwritten signature in black ink that reads "Robert B. Constable". The signature is written in a cursive style and is positioned above a horizontal line.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1530

Enclosures:

1. CAR YMQAD-96-C004
2. CAR/SWO Continuation Page

cc w/encls:

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

cc w/o encls:

- W. L. Belke, NRC, Las Vegas, NV
- J. S. Martin, YMQAD/QATSS, Las Vegas, NV
- D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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CORRECTIVE ACTION REQUEST

1 Controlling Document: See various documents listed below
2 Related Report No.: YM-ARC-96-10

3 Responsible Organization: U.S. Geological Survey (USGS)
4 Discussed With: T. Chaney / R. Craig

5 Requirement:
The following Quality Assurance program and procedural implementation deficiencies were found during the course of Audit YM-ARC-96-10. The requirements and the associated deficiencies correspond to the numbers given for each item.
1) QARD Section 4.0, paragraph 4.2.1, states: "Procurement documents issued by each Affected Organization shall include the following provisions, as applicable to the item or service being procured".
Paragraph 4.2.1.C (1), states: " A requirement for the supplier to have a documented QA Program that implements applicable QARD requirements prior to initiation of work. The extent of the QA Program shall depend on the scope, nature, or complexity of the item or service being procured".

6 Description of Condition:
1) In violation of the QARD USGS procedure YMP-USGS-QMP-4.01, Rev. 7, allows USGS to approve a supplier without having an approved QA Program. Approval of a supplier can be accomplished as delineated within YMP-USGS-QMP-4.01, via the following three methodologies 1) Source Verification, 2) Comprehensive Receipt Acceptance or 3) a Sample Analysis Quality Control Plan. Presently, the QARD does not recognize these three alternative methodologies for qualifying suppliers of items and services.
2) Contrary to the above, the final Purchase Order (P.O.) # 1434CR-96-SA-00036 for Huffman Labs, Inc. and P.O. 1434CR-95-SA-0610 Amendment dated 23 May, 1995 for Kruger Enterprises provides no documented evidence of having received a review by the QA Office.
3) No documented evidence exists to show that Quality Assurance Requirements stipulated on Attachments 6, 7, or 8 were attached to the DI-1 Form United States Department of Interior Requisition within P.O. 1434CR-96-SA-0517 as procedurally required. Subject P.O. was issued to Beta Analytic, Inc..
4) Supplier Evaluation/Surveillance performed 9 August, 1995 documented on USGS letter dated 17 November, 1995 from T. H. Chaney Quality Assurance Manager Yucca Mountain Project to MS. Amy Smiecinski, QA Office Harry Reid Center for Environmental Studies documents a programmatic discrepancy that was not documented in accordance with AP-16.1Q or AP-16.2 O.

7 Initiator: John S. Martin Date 03/29/96
9. Does a stop work condition exist?
Yes ___ No ; If Yes, Attach copy of SWO.
If Yes, Check One: A B C D

10. Recommended Actions:
Describe those action necessary to correct those deficiencies identified within the CAR.
Implement those actions imposed by Attachment 1, "Corrective Actions To Be Performed Prior to Issuing New or Amending Existing Quality-Affecting Procurements."
Determine the root cause of the deficient conditions identified.
Determine those actions necessary to preclude recurrence for the deficiencies identified.

11 QA Review: [Signature] Date 4-5-96
12 Response Due Date: 10 21 4-5-96
20 Working Days from Issuance

13 Affected Organization QA Manager Issuance Approval:
Printed Name RICHARD E. SPENCE Signature [Signature] Date 4.8.96

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Block 5, Requirement, cont'd.

2) USGS procedure YMP-USGS-QMP-4.01, Rev. 7, Procurement Document Control/Receipt of Procurement paragraph 5.1.9.1, states in part: "QA Office Reviews:

a) Reviews the procurement documentation to ensure that the QA requirements are complete and that they remain applicable to any changes incorporated during the bidding/supplier selection process".

3) USGS procedure YMP-USGS-QMP-4.01, Rev. 7, paragraph 5.1.3, states in part: "The YMP-USGS Quality Assurance (QA) Office:

a) Reviews the DI-1 Form, and completes and attaches the appropriate QA requirements Attachment to the DI-1 Form as follows:

- Attachment 6 YMP-USGS Quality Assurance Requirements for Suppliers of Analytical Services
- Attachment 7 YMP-USGS Quality Assurance Requirements for Suppliers of Calibration
- Attachment 8 YMP-USGS Quality Assurance Requirements for (Name of Services) to be used to develop tailored requirements based on the scope, nature, or complexity of the procurement".

4) USGS procedure YMP-USGS-QMP-7.04, Rev. 2, Supplier Evaluation paragraph 5.1, states: "Initial Evaluation: Upon determination of the need to evaluate a supplier, the YMP-USGS QA Manager shall initiate action to conduct a supplier evaluation to determine if the supplier is capable of meeting YMP-USGS QA and technical requirements as specified in the YMP-USGS procurement document or agreement".

Paragraph 5.1.3, further states in part that: "If inadequacies are identified, the YMP-USGS QA Manager, in coordination with the YMP-USGS Requestor, shall document the inadequacies and their resolution in accordance with DOE/YMP AP-16.1Q, Performance Deficiency Reporting, or DOE/YMP AP-16.2, Corrective Action and Stop Work: as appropriate".

5) QARD Section 12.0, paragraph 12.2.7, states in part: "Measuring and Test Equipment calibration documentation shall include the following information:

- B. Traceability to the calibration standard used for calibration.
- H. Identification of the implementing document (including revision level) used in performing the calibration.

6) Office Of Civilian Radioactive Waste Management (OCRWM) Administrative Procedure (AP) 7.4Q, Rev.1, Maintenance Of The Office Of Civilian Radioactive Waste Management Qualified Suppliers List paragraph 5.4.4, states in part that for initial audits of suppliers: "The Qualifier:

a) after receipt of the OQA initial audit report of the supplier and letter from the QADD, evaluates the audit report to assure the following: ...

- 3) determine if any further Affected Organization action is required.
- b) based on the above evaluation, completes SER pages 1 and 2 in accordance with Attachment 9.3 instructions; and
- c) forwards the SER (pages 1 and 2) to the QSL Coordinator for action as indicated in QAP 7.2, Supplier Evaluation".

Paragraph 5.6.3 reiterates these steps for the Qualifier when receiving a Triennial Audit from the OQA.

7) YMP-USGS-QMP-7.04, Rev. 2, paragraph 5.2.2, states: "If inadequacies are identified, the YMP-USGS QA Manager, in coordination with the YMP USGS Requestor, shall determine which of the following actions is the most appropriate.

Paragraph 5.2.2.1, states in part: "Delete the supplier from the QSL and evaluate the negative impact of services already furnished by the supplier. ...".

Paragraph 5.2.2.2, states in part: "Retain the supplier on the QSL if the inadequacies to be corrected will not negatively impact future purchased services. ...".

Paragraph 5.2.2.3, states in part: "Retain the supplier on the QSL with restrictions. ...".

8) QARD Section 5.0, paragraph 5.2.2, states in part: "Implementing documents shall include the following information as appropriate to the work to be performed: ...

C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations.

D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished".

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Block 6, Description of Condition, cont'd

5) Contrary to the above requirement, USGS procedures used for procurement and the qualification of suppliers YMP-USGS-QMP-4.01, Rev. 7, YMP-USGS-QMP-7.04, Rev. 2, and USGS procedure governing calibration YMP-USGS-QMP-12.01, Rev. 1; Instrument Calibration fails to require that the calibration standards identity and the procedure and revision level be included with the calibration documentation supplied by suppliers of calibration services.

As a result calibration documentation provided by Certified Balance Systems (CBS) does not identify the implementing document and revision level utilized to perform the calibration.

In addition, a calibration performed by the State of Colorado Department of Agriculture did not contain the standards identity utilized for calibration.

6) To date, USGS has not submitted SERs based on their evaluation of initial or triennial audits.

7) Contrary to the above requirements, inadequacies were identified to USGS for 1) Campbell Scientific, Inc. on Supplier Audit Report #OQA-SA-96-009, and 2) Beta Analytic, Inc. Supplier Audit Report #OQA-SA-95-002, without any action by the YMP-USGS QA Manager or YMP-USGS Requestor to update the QSL.

In addition, a new procurement was let to Beta Analytic, Inc. without the resolution of the deficiencies identified by Supplier Audit Report #OQA-SA-95-002.

Also, no action has been taken relative to Campbell Scientific, for the deficiencies identified through Supplier Audit Report #OQA-SA-96-009.

8) USGS procedure YMP-USGS-QMP-7.04, Rev. 2, fails to provide sufficient quantitative and qualitative acceptance criteria for determining that activities were satisfactorily accomplished. In performing evaluations it should be possible for an individual to repeat the evaluation and achieve comparable results, without recourse to the original evaluator. Presently, YMP-USGS-QMP-7.04, Rev. 2, Attachment 1, YMP-USGS Supplier Checklist does not contain sufficient detail or instruction to allow two competent individuals to consistently repeat the same evaluation.

An example of this is in the two evaluations of Beta Analytic, Inc.. One evaluation was performed on 17 February, 1995 and the other was performed on 23 May, 1995. Other than they were for the same vendor and service, the two evaluations and attributes identified on the checklist do not coincide.

**ACTION PLAN FOR U.S. GEOLOGICAL SURVEY (USGS) PROCUREMENT
ACTIVITIES RELATIVE TO CORRECTIVE ACTION REQUEST
YMQAD-96-C004**

**Corrective Actions To Be Performed Prior To Issuing New or Amending Existing
Quality-Affecting Procurements**

Invoke the following controls prior to initiating new or amending existing quality-affecting procurement actions relative to the procurement of analytical, calibration, and/or other services:

- 1) Revise procedures for the initiation of Purchase Requisitions and Purchase Orders (PO) to contain the necessary detail to ensure analytical, calibration, and/or other services are procured in accordance with the Quality Assurance Requirements and Description (QARD). This revision shall include the evaluation of suppliers and documentation of applicable quality requirements as outlined within the QARD for procurement of analytical, calibration, and/or other services.
- 2) Obtain concurrence from the Director, Yucca Mountain Quality Assurance Division (YMQAD), that these procedures reflect the requirements and the methodology for implementing those requirements as described in the QARD.
- 3) Assure that suppliers of analytical, calibration, and/or other services are qualified for the scope, nature, or complexity of the services to be procured by coordination with YMQAD, or arrange for the supplier to work directly under the USGS quality program prior to initiation of final procurement actions.
- 4) Submit Supplier Evaluation Reports to YMQAD for suppliers to be added to the Qualified Suppliers List (QSL) as appropriate.
- 5) Obtain concurrence from the Director, YMQAD, prior to issuance of any POs. This interim process step will assure that the supplier is qualified for the scope, nature, or complexity of the work to be performed, or is working directly to the USGS quality program. This concurrence will also verify that appropriate technical and quality requirements are contained within the PO.
- 6) Upon receipt of analytical, calibration, and/or other services and USGS acceptance, USGS will submit a copy of the PO and a copy of the documentation received from the supplier to the Director, YMQAD, for concurrence that the received documentation satisfactorily reflects the requirements of the purchase documents.

The above process shall remain in effect until a confidence level is obtained by the Director, YMQAD, that USGS is capable of effectively implementing a procurement process, at which time a documented release will be given to USGS to assume normal procurement actions.

Corrective Actions For Procurements Already In Existence

Invoke the following corrective actions for quality-affecting procurements already in existence:

- 1) USGS will identify all in-process quality-affecting procurements.
- 2) USGS will separate these quality-affecting suppliers into three groups:
 - A. Those suppliers who are listed on the QSL.
 - B. Those suppliers who are not on the QSL and are working directly to the USGS quality program.
 - C. Those suppliers who are not on the QSL nor working directly to the USGS program but whom USGS has found to be acceptable to perform work by other means.
- 3) USGS will review these procurements "with YMQAD overview" to assure that necessary technical and quality requirements were included in the PO and that final quality assurance review was obtained. These reviews will be performed commensurate with the scope, nature, and complexity of the service provided and will include the requirements from those procedures revised under "Corrective Actions To Be Performed Prior To Issuing New or Amending Existing Quality-Affecting Procurements."
- 4) Coordinate with YMQAD to assure that those suppliers listed on the QSL are or were audited for compliance to the purchase documents and acceptability for the scope, nature, and complexity of work being performed.
 - A. If the supplier is found to be acceptable, no further action is necessary.
 - B. If the supplier is found not to be acceptable, YMQAD will generate deficiency documents for USGS resolution with the supplier implementing actions deemed necessary, including evaluation of impact on work performed, based on the deficiencies identified.
 - C. Resolution will be accomplished prior to further work activities by the supplier or final acceptance of supplier services dependent upon the nature of the deficiency.
 - D. In addition, Supplier Evaluation Reports will be generated by USGS to reflect current status of the suppliers.

- 5) For those suppliers working directly under the USGS quality program who are not on the QSL, USGS will assure that appropriate technical and quality requirements have been passed on to those suppliers based on the scope, nature, and complexity of the work to be performed.
 - A. If the purchase documentation is found to be acceptable, no further action is required.
 - B. If the purchase documentation is found not to be acceptable, USGS will generate deficiency documentation as required.

- 6) For those suppliers who are not on the QSL, nor working directly to the USGS program, and who were deemed acceptable to perform work by other means, the following action will be taken:
 - A. USGS will perform an evaluation of the procurement documentation for technical and quality requirements based on the scope, nature, and complexity of work being performed.
 - B. Based on this evaluation, USGS, in conjunction with YMQAD, will determine a means of qualifying the supplier by either assisting in the development of a quality program or by extending the USGS quality program down into the supplier.
 - C. An evaluation will be performed and documented by USGS, in conjunction with YMQAD, to determine the acceptability and impact of work accomplished by these suppliers based upon technical and quality requirements implemented by the supplier.
 - D. Where necessary, deficiency documentation will be generated against USGS accepted products.

- 7) Upon receipt of analytical, calibration, and/or other services and USGS acceptance, USGS will submit a copy of the PO and a copy of the documentation received from the supplier to the Director, YMQAD, for concurrence that the received documentation satisfactorily reflects the requirements of the purchase documents.

This process shall remain in effect until a confidence level is obtained by the Director, YMQAD, that USGS is capable of effectively implementing a procurement process, at which time a documented release will be given to USGS to assume normal procurement actions.

Actions For Completed Procurements

Invoke the following actions for completed procurements:

- 1) **USGS will provide a listing of completed procurements for suppliers of analytical, calibration, and/or other services that fall into the following categories:**
 - A. **Those suppliers who are listed on the QSL or the USGS Approved Vendors List (AVL).**
 - B. **Those suppliers who are not on the QSL or the USGS AVL and who worked directly to the USGS quality program.**
 - C. **Those suppliers who are not on the QSL or the USGS AVL who did not work directly to the USGS quality program who have been found to be acceptable to perform work by other means.**

- 2) **Based on this listing, an evaluation will be made by the methods outlined in "Corrective Actions For Procurements Already In Existence" actions as applicable.**

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