



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608
JUL 09 1996

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Site Characterization Project
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EVALUATION OF DRAFT U.S. GEOLOGICAL SURVEY'S (USGS) QUALITY MANAGEMENT PROCEDURES QMP-4.01, REVISION 8 AND QMP-7.04, REVISION 3, REVISED IN RESPONSE TO CORRECTIVE ACTION REQUEST YM-96-C-004, RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARC-96-10 OF USGS (SCPb: N/A)

The YMQAD staff has evaluated the subject USGS procurement procedures. As stated within the USGS submittal letter, these procedures are preliminary drafts and as of the date of submittal have not been endorsed by USGS Yucca Mountain Project Management. However, the USGS Corrective Action Plan, which has been accepted by YMQAD, commits to initiating a revision and review of procurement procedures by June 15, 1996. It was expected that a final product would be transmitted for review and acceptance by YMQAD by the date provided. In either case, a YMQAD review was performed and comments are provided. Enclosed please find YMQAD comments relative to the preliminary draft procurement procedures QMP-4.01, Revision 8 and QMP-7.04, Revision 3.

It is requested that USGS coordinate the incorporation of YMQAD comments, with any comments from USGS management, and provide this office with a final product for YMQAD review within ten working days from the date of this letter. YMQAD will provide an on site representative at USGS to assist in the development and revision of the procedures during this time frame.

Should you have any concerns or questions regarding this matter, please contact Robert B. Constable at (702) 794-5580 or Woody W. Hudson at (702) 794-1490.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2090

Enclosure:

Major Comments
QMP-4.01, Rev 8
& QMP-7.04, Rev 3
(CAR YM-96-C-004)

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PDR WASTE
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JUL 09 1996

Robert W. Craig

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cc w/encl:

J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
R. E. Powe, YMQAD/QATSS, Denver, CO
Records Processing Center

cc w/o encl:

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

ENCLOSURE: EVALUATION OF DRAFT U. S. GEOLOGICAL SURVEY'S (USGS) QUALITY MANAGEMENT PROCEDURES QMP-4.01, REVISION 8 AND QMP-7.04, REVISION 3, REVISED IN RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-96-C-004, RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARC-96-10 OF USGS

MAJOR COMMENTS QMP-4.01, REVISION 8:

- **QARD 4.2.1 C** QARD does not recognize a supplier of items or services working to a graded QA program as used in this QMP. Delete this section and any references. As per previous discussions with USGS there are only two types of suppliers; those working directly under the purchaser's QA program (i.e.; staff augmentation) or those working directly under an approved QA program. QMP-7.04 will be impacted as a result of deleting this section.
- **General** The procurement document review and approval process does not comply with the QARD. For example there is no technical review for sole source purchase orders or solicitation packages for all steps after possible revision to the documents.
- **General** QARD requires that review criteria be established for each reviewing organization (i.e.; what are the reviewers reviewing for). Procedure refers the reader to QMP-7.04 for the review, however, no review criteria exists there.
- **General** Delete reference to section 5.4 procurement by support participants.
- **General** Provide RTN or equivalent to assist in the review to assure all applicable criteria are covered.

MAJOR COMMENTS QMP-7.04, REVISION 3:

- **General** Suggest that procedure be revised to identify the minimum QARD requirements for suppliers of calibration services and suppliers of scientific services (analytical and testing services).

Enclosure

- **General**

Provide RTN or equivalent to assist in the review to assure all applicable criteria are covered.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.8 CAR NO. YMQAD-96-C004
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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 Q.

7 Initiator:

John S. Martin

Date 03/29/96

9. Does a stop work condition exist?

Yes ___ No ☒ ; If Yes, Attach copy of SWOIf 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:

Date 4-5-96

12 Response Due Date:

10 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

ORIGINAL

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

CAR NO. YMOAD-96-C-004

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CORRECTIVE ACTION REQUEST

¹⁴ Remedial Actions:

SEE ATTACHED SHEET

¹⁵ Investigative Actions:

SEE ATTACHED SHEET

¹⁶ Root Cause Determination:

SEE ATTACHED SHEET

¹⁷ Action to Preclude Recurrence:

SEE ATTACHED SHEET

¹⁸ Response by:

Date 4/24/96

¹⁹ Corrective Action Completion Due Date

See attached sheet

²⁰ Response Accepted
QAR

Date 5/13/96

²¹ Response Accepted
AOQAM

Date 5/8/96

²² Amended Response Accepted
QAR

Date

²³ Amended Response Accepted
AOQAM

Date

²⁴ Corrective Actions Verified
QAR

Date

²⁵ Closure approved by:

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

8 ☒ Corrective Action Request
☐ Stop Work Order

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CAR/SWO CONTINUATION PAGE

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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8 ☒ Corrective Action Request
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CAR/SWO CONTINUATION PAGE

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.