



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

AUG 02 1996

Robert 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 U.S. GEOLOGICAL SURVEY'S (USGS) SUBMITTAL OF DRAFT QUALITY MANAGEMENT PROCEDURES QMP-4.01, REVISION 8 AND QMP-7.04, REVISION 3, DATED JULY 19, 1996 AND SUPPLEMENTAL RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-96-C-004

The Yucca Mountain Quality Assurance Division staff has evaluated the subject USGS procurement procedures and supplemental response that addresses interim completion dates to CAR YM-96-C-004, dated July 19, 1996. The procedures have been found to be acceptable pending resolution of the enclosed comments and the supplemental response regarding interim completion dates has been found acceptable provided the procedure comment resolution date does not exceed August 2, 1996. In other words, the corrective action due dates for steps C.3 and D.2 of the CAR Action Plan are considered to be on or before September 3, 1996.

If you have any questions, please contact either Robert B. Constable at (702) 794-5580 or John S. Martin at (702) 794-5591.

Robert B. Constable

Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-2324

Enclosure:
 Procedure Review Comments

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, OQA, NV
 W. E. Barnes, YMSCO, NV
 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

9608090059 960802
 PDR WASTE PDR
 WM-11

YMP-5

Recip: J. Spraul

*WM-11
 102.7*

*NH33
 1/1*

Robert W. Craig

-2-

AUG 02 1996

bcc w/encl:

J. R. Compton, YMSCO, NV

E. R. Cooper, YMSCO, NV

S. B. Jones, YMSCO, NV

D. R. Williams, YMSCO, NV

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

8 CAR NO. YMQAD-96-C004
PAGE 1 OF 4
QA: LOS
#3116

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 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 22 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. YMQAD-96-C-004
PAGE: 2 OF 4
QA:L

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:

[Signature]

Date 4/24/96

¹⁹ Corrective Action Completion Due Date

- See attached sheet

²⁰ Response Accepted
QAR

[Signature]

Date 5/18/96

²¹ Response Accepted
AQQAM

[Signature]

Date 5/18/96

²² Amended Response Accepted
QAR

Date

²³ Amended Response Accepted
AQQAM

Date

²⁴ Corrective Actions Verified
QAR

Date

²⁵ Closure approved by:

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

8 Corrective Action Request
 Stop Work Order

NO. YMQAD-96-C004

PAGE 23 OF 34

QA: L52
4/23/96

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".

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

8 Corrective Action Request
 Stop Work Order

NO. YMQAD-96-C004
PAGE 24 OF 24
QA: L

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.

**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.**

ORIGINAL

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

- Corrective Action Request
 Stop Work Order

NO. YMQAD-96-C-004
PAGE _____ OF _____
QA:L

CAR/SWO CONTINUATION PAGE

REMEDIAL ACTIONS: YMQAD-96-C004

1. QMP-4.01 will be revised as part of the attached YMQAD/USGS action plan.
2. The Huffman Labs PO 1434CR-96--SA-00036 will be evaluated as part of the YMQAD/USGS action plan. The final PO does contain what USGS believes to be appropriate QA requirements. The Kruger PO had all required QA reviews. See investigative actions.
3. No remedial actions are necessary at this time because the final PO contains requirements for Beta Analytic to work to their QA program which has been reviewed and accepted by USGS.
4. No remedial actions are appropriate at this time since this lab is moving under the M&O QA program.
5. Remedial actions for this deficiency will be determined as part of the YMQAD/USGS action plan.
6. The USGS will submit updated SER's to YMQAD as soon as agreement is reached on the appropriate criteria to be passed on to the vendors.
7. New SER's have been submitted to YMQAD restricting further procurements with these vendors until a satisfactory disposition to the identified deficiencies can be agreed upon.
8. Any revisions to this procedure will be as part of the YMQAD/USGS action plan.

INVESTIGATIVE ACTIONS:

The following investigative actions have already been completed and additional investigations will be undertaken as part of the attached YMQAD/USGS action plan.

1. USGS procedures were revised as part of the corrective actions for YMP-95-C41 and the CAR was closed as a result of those revisions. The three alternative methodologies were intended to be used as extensions of the USGS QA program to vendors that did not have programs that met all applicable QARD requirements. The USGS believed these to be acceptable practices in the nuclear industry. The USGS has the need to use a number of vendors that provide services necessary to support scientific investigations and that do not have QA programs that meet the QARD or NQA-1. Other affected organizations had implemented similar methods of accepting vendor services and these have not been

ORIGINAL

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

Corrective Action Request

Stop Work Order

NO. YMQAD-96-C-004

PAGE _____ OF _____

QA:L

CAR/SWO CONTINUATION PAGE

identified as a violation of QARD requirements. The USGS requires guidance from YMQAD to appropriately revise QMP-4.01..

2. The requisition request for the Huffman Lab PO had a QA review and the final PO contained all the QA requirements requested. The Kruger procurement documents received all required QA reviews. A 100% review of active QA procurements found one additional instance of no final review. It also received an initial review and contained the requested QA requirements.
3. The final PO for Beta Analytic contained a commitment for Beta to work to their QA program where reviewed by USGS and DOE. The requirement to add the attachments to all PO's is overly prescriptive and will be addressed as part of the procedure revisions undertaken as part of the YMQAD/USGS action plan.
4. USGS no longer had a procurement in effect with this lab and as a result had no means to enforce YMP program requirements. The conditions were PR conditions with no impact on work completed. The lab was notified of the conditions by letter and agreed to correct them. The DOE had stated that this lab along with all UNLV operations would be transitioned to the M&O QA program, so the USGS had every reason to believe that the lab's QA program would be completely revised.
5. The USGS has identified the procedures used for our calibrations through the documentation of our annual vendor evaluations and the triennial audit. The QARD does not specify where the procedure needs to be documented.
6. Therefore SERs are needed for USGS evaluations of all YMQAD audits of USGS vendors.
7. It was believed that acceptable resolution to the deficiencies would be obtained. The USGS had been in close contact with YMQAD personnel regarding the status of these deficiencies and their resolution. The deficiencies did not impact the technical quality of either vendors' work so there was no reason to delay further work. New SER's have been submitted identifying the deficiencies and restricting future procurements until agreement on the resolution of those deficiencies can be reached.
8. USGS will work with YMQAD to revise this procedure as appropriate. Other affected organizations are working directly to AP-7.4Q which provides no guidance on how to conduct a vendor evaluation and this has not been identified as a deficiency. The appropriate level of detail to include in a procedure is a subjective decision.

ORIGINAL

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

- Corrective Action Request
 Stop Work Order

NO. YMQAD-96-C-004

PAGE _____ OF _____
QA:L

CAR/SWO CONTINUATION PAGE

ROOT CAUSE DETERMINATION:

It is premature to try to identify a root cause at this time. This determination will be made once the YMQAD/USGS action plan is implemented.

ACTIONS TO PREVENT RECURRENCE:

If implementation of the YMQAD/USGS action plan does not cover actions to prevent recurrence a supplemental response will be submitted after root cause determination is completed.

COMPLETION DATE:

The USGS anticipates that it will take until September 30, 1996 to complete all required actions necessary to close this CAR. The USGS procurement QMPs will be revised and ready for review by June 15, 1996.

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

A. Revision of USGS Procurement Procedures

- 1) Initiate a review and revision of USGS-YMP procurement procedures in cooperation with the Director, YMQAD 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.

B. Corrective Actions For New or Amended 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) 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 prior to issuance of Purchase Orders or arrange for the supplier to work directly under the USGS quality program prior to initiation of final procurement actions.
- 2) Submit Suppliers Evaluation Reports to YMQAD for suppliers to be added to the Qualified Suppliers List (QSL) as appropriate.
- 3) 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 also will verify that sufficient technical details and appropriate quality requirements are contained in the PO to ensure the USGS receives an acceptable product.

- 4) After 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 the Director, YMQAD, is satisfied that USGS is effectively implementing a procurement process, at which time a documented release will be given to USGS to assume normal procurement actions.

C. Corrective Actions For 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 procurements for suppliers on the QSL "with YMQAD overview" to assure that necessary technical details and appropriate quality requirements are contained in the final PO to ensure the USGS receives an acceptable product. These reviews will be performed commensurate with the scope, nature, and complexity of the service provided and will address the need to incorporate requirements from those procedures revised under Section A above.
- 4) Coordinate with YMQAD to assure that those suppliers listed on the QSL that have not been previously audited by YMQAD are 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 implementing QA controls stated in the final PO, YMQAD will generate deficiency documents for USGS resolution with the supplier implementing actions deemed necessary.
 - C. An acceptable disposition or resolution will be agreed to prior to further work activities by the supplier or final acceptance of supplier services, depending upon the nature of the deficiency.
 - D. In addition, Supplier Evaluation Reports will be generated by USGS to reflect current status of the suppliers.
 - E. If any suppliers are removed from QSL the USGS will perform an impact analysis of the effects of the basis of removal on previous work.
- 5) For those current suppliers working directly under the USGS quality program who are not on the QSL, the USGS in cooperation with YMQAD, will assure that appropriate technical details 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 current 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 detail 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 the quality requirements implemented by the supplier.

- D. Where necessary, deficiency documentation will be generated against USGS accepted products.
- 7) After 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.

D. Actions for Completed Procurements

Invoke the following actions for completed procurements:

- 1. USGS will provide a listing of completed procurements initiated after September 1995 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.

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

8 Corrective Action Request
 Stop Work Order

NO. YMQAD-96-C004
PAGE OF
QA: L

CAR/SWO CONTINUATION PAGE

AMENDED RESPONSE - CAR YMQAD-96-C-004

<u>ACTION</u>	<u>COMPLETION DATE</u>
Remedial Action 6	June 15, 1996
Action Plan Item A.1	June 15, 1996
Action Plan Item C.3	May 17, 1996
Action Plan Item D.2	July 15, 1996

Submitted By: Martha A. Mustard
for T. H. Chaney, Quality Assurance Manager - YMP

Date 5-21-96



United States Department of the Interior

GEOLOGICAL SURVEY
BOX 25046 M.S. 425
DENVER FEDERAL CENTER
DENVER, COLORADO 80225



IN REPLY REFER TO:

QA: L

June 17, 1996

Richard E. Spence, Director,
Quality Assurance Division
Yucca Mountain Project Office
U.S. Department of Energy
P.O. Box 98608
Las Vegas, NV 89193-8608

RECEIVED
JUN 18 1996

SUBJECT: YMQAD- 96-C004 Revised USGS Procurement Procedures

As committed to in the response to the subject CAR, I have enclosed Preliminary Drafts of USGS QMP-4.01, R8 and QMP-4.01, R3. At this time they have not received any endorsement from USGS Yucca Mountain Project Management and are intended for the purpose of discussion only. In revising these procedures, I have tried to incorporate the results of the recent QSL Workshop as I understand them. Since you will have a liaison position established in Denver before the revision of these procedures is completed I wonder if you would like me to forward a copy to the person filling that position.

Sincerely,

T. H. Chaney, Quality Assurance Manager

THC/aa
Enclosure

Copies to: W. Hudson, QATSS, Las Vegas, NV
J. E. Therien, QATSS/SAIC, Las Vegas, NV
J. S. Martin, QATSS/SAIC, Las Vegas, NV
D. G. Sult, QATSS/SAIC, Las Vegas, NV
A. Anderson, USGS, Denver, CO

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).**

- **General**

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

MANAGEMENT PROCEDURES MANUAL

CHAPTER 4 - ADMINISTRATIVE OPERATIONS AND PROCUREMENT

**SECTION 1 - PROCUREMENT DOCUMENT CONTROL/RECEIPT
OF PROCUREMENTS**

1. **PURPOSE.** The purpose of this Quality Management Procedure (QMP) is to ensure that Yucca Mountain Project - U.S. Geological Survey (YMP-USGS) procurement documents contain the appropriate technical and quality assurance (QA) requirements, that procurements are adequately planned and executed, and that the requested services meet the specified technical and QA requirements.

2. **SCOPE OF COMPLIANCE.** This procedure applies only to the procurement of quality-affecting services. Guidelines for determining which services are quality-affecting are included in Attachment 1.

The steps contained in this procedure shall be used to process procurements and procurement modifications that involve changes to the scope of work, technical requirements, QA requirements, rights of access, documentation requirements, nonconformances, hold points, or lists of spare or replacement parts delineated in the initial procurement document.

This procedure applies to all YMP-USGS personnel, extended staff, and Suppliers working directly to the YMP-USGS QA Program.

This procedure, as noted in Para. 5.4, applies to YMP-USGS support participants initiating quality-affecting procurements and procurement modifications.

The acquisition of services from another Federal Government agency which involves a transfer of funds, or from Suppliers which receive funding directly from the Yucca Mountain Project Site Characterization

Office, shall be controlled through the use of a Management Agreement developed in accordance with QMP-4.02, Control of Agreements.

Services falling within the scope of this procedure shall not be purchased using third party drafts, imprest funds, bank cards, or blanket purchase agreements.

All procurements initiated after the effective date of this revision shall comply with all of the requirements of this procedure. Procurements initiated under previous revisions of this procedure need no re-work as a result of the revision. All new and open procurements shall be received in accordance with Section 5.2 of this procedure.

3. **DEFINITIONS.** Definitions of the first use of the terms written in *bold italics* in this procedure are listed in Attachment 2.
4. **RESPONSIBILITIES.** General responsibilities are included in Attachment 3. Specific responsibilities are identified throughout Section 5.0.
5. **PROCEDURE.**

5.1 **Initiating Procurements:**

NOTE: Modification to procurements shall be processed in accordance with the following steps with the following exception: The QA Office review is required only for modifications which involve changes in the technical or QA requirements. Modifications that involve only cost or schedule changes do not require the QA Office review.

5.1.1 **THE REQUESTOR:**

- a) Determines if the needed procurement is quality-affecting, using the guidance in Attachment 1.

NOTE: Non-quality-affecting procurements are to be processed using traditional USGS practices.

- b) Develops the information required for quality-affecting procurements using the requirements in Attachment 4, Part I.
- c) When appropriate, develops the Justification For Other Than Full and Open Competition (*JFOC*).
- d) Selects a proposed QA Procurement Option or Options using the guidance in Attachment 4, Part II. The Options are:
 - 1) A Supplier working to a documented QA program approved by the YMP-USGS Quality Assurance (QA) Office. These Suppliers are listed in the *Qualified Suppliers List (QSL)* maintained by the Yucca Mountain QA Division (YMQAD). Copies maybe obtained from the YMP-USGS-QA Office.
 - 2) A Supplier serving as extended staff to the YMP-USGS working directly to YMP-USGS Quality Management Procedures.
 - 3) A Supplier working to a graded QA program (see QMP-7.04).
- e) Requests the Administrative Management Section to initiate a U.S. Department of the Interior Requisition (Form *DI-1*, Attachment 5) by providing all of the applicable informa-

tion outlined in Attachment 4, Parts I and II. This information may be conveyed to the Administrative Management Section either in writing or verbally.

5.1.2 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Prepares a DI-1 form, using the information provided by the Requestor.
- b) ~~When the supplier is other than augmented staff, adds the following statement to the DI-1 form: "This procurement is Quality Affecting and all work shall be performed in accordance with the YMP-USGS Quality Assurance Requirements, attached."~~
- e)b) Forwards the completed DI-1 form to the YMP-USGS QA Office.

5.1.3 THE YMP-USGS QUALITY ASSURANCE (QA) OFFICE:

- a) Reviews the DI-1 form, and if ~~the procurement is for a new supplier initiates a supplier evaluation according to QMP-7.04 or if~~ for an approved supplier ensures the appropriate QA requirements identified in the initial supplier evaluation are included with the DI-1.
- b) ~~If the procurement is for a new supplier~~ concurs with the QA Procurement Option proposed by the Requestor ~~and if the supplier is not known attaches basic QA requirements appropriate for the required service (see QMP-7.04). If the supplier is known, initiates an evaluation of the suppliers QA program in compliance with QMP-7.04. It may be necessary for the Requestor and the YMP-USGS QA Office to resolve comments prior to concurrence.~~
- c) Applies the QA Review stamp, Attachment 9, to the front page of the DI-1 form, records the Procurement Option type selected by the requestor, signs and dates the stamp, and forwards ~~returns~~ the DI-1 form and attachment to the Administrative Management Section.

5.1.4 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Records the status and forwards the DI-1 form and attachment to the Requestor.

5.1.5 THE REQUESTOR:

- a) Reviews the DI-1 form and attachment to confirm the inclusion of appropriate technical and QA requirements. It may be necessary for the Requestor to resolve comments with the YMP-USGS QA Office or Administrative Management Section prior to approval. Signs the DI-1 form indicating approval, and forwards the DI-1 form and attachment to the Program Chief.

5.1.6 THE PROGRAM CHIEF (or delegate):

- a) Reviews the DI-1 form and attachment to ensure that the technical requirements are applicable, correct, technically adequate, complete, accurate, and in compliance with established requirements, if any. Approves the procurement by signing in the "Bureau Officer" box of the DI-1 form. This approval indicates technical review of the procurement document and expenditure authorization. Forwards the DI-1 form and attachment to the Administrative Management Section.

5.1.7 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Approves the DI-1 form and attachment and forwards the approved documentation to the USGS Central Region Procurement and Contracts Branch.

5.1.8 CENTRAL REGION PROCUREMENT AND CONTRACTS BRANCH: Upon receipt of the approved DI-1 form and attachment, the Central Region Procurement and Contracts Branch processes the requisition into a formal Purchase Order, *Contract*, or Modification as follows:

5.1.8.1 *Small Purchases* (both *Competitive* and *Sole-Source Purchase Orders* Under \$25,000):

- a) To complete a Competitive Purchase Order the Central Region Procurement and Contracts Branch:
 - 1) Prepares *Request For Quotations (RFQ)* utilizing the technical and QA requirements contained in the DI-1 form and attachment.
 - 2) Obtains quotations from prospective Suppliers.
 - 3) Determines the low offeror.
 - 4) When procurement Option 1 is selected, coordinates *Pre-award Supplier Qualification Evaluation* with the YMP-USGS QA Office if the Supplier has not been previously approved by the QA Office. See Para. 5.1.9.2.
 - 5) Obtains the YMP-USGS QA Office's review of the final Purchase Order. See Para. 5.1.9.1.
 - 6) *Awards* the Purchase Order.

- 7) Forwards a copy of the Purchase Order to the Administrative Management Section.

- b) To complete a Sole Source Purchase Order, the Central Region Procurement and Contracts Branch:
 - 1) Reviews and approves the JFOC.

 - 2) When procurement Option 1 is selected, coordinates Pre-award Supplier Qualification Evaluation with the YMP-USGS QA Office if the Supplier has not been previously approved by the QA Office. See Para. 5.1.9.2.

 - 3) Obtains the YMP-USGS QA Office's review of the final Purchase Order. See Para. 5.1.9.1.

 - 4) Awards the Purchase Order.

 - 5) Forwards a copy of the Purchase Order to the Administrative Management Section.

5.1.8.2 Contracts (Both Advertised and Negotiated):

- a) To initiate both advertised and negotiated contract actions, the Central Region Procurement and Contracts Branch:
 - 1) Prepares a *Solicitation Package* using the technical and QA requirements contained in the DI-1 form and attachment. When appropriate, develops

required *special responsibility factors*, such as financial, QA, and production issues, and incorporates them into the Solicitation Package.

- 2) Obtains reviews of the Solicitation Package from the Requestor and the YMP-USGS QA Office. Forwards a copy of these reviews to the Administrative Management Section. Approves JFOC if appropriate for sole-source action. ~~Coordinates any necessary QA Source Verification activities.~~
 - 3) Issues solicitation to all potential interested Suppliers.
 - 4) *Receives sealed Bids or Proposals.*
- b) Upon receipt of *Sealed Bids* (advertised) the Central Region Procurement and Contracts Branch:
- 1) Forwards the *Abstract* and low bid to the Requestor for review and award concurrence. Upon receipt, forwards a copy of the concurrence to the Administrative Management Section.
 - 2) When Option 1 ~~is~~ is selected, coordinates the Pre-award Supplier Qualification Evaluation with the YMP-USGS QA Office, if the Supplier has not been previously approved by the QA Office. See Para. 5.1.9.2.
 - 3) Assembles the final Contract package.
 - 4) Obtains the YMP-USGS QA Office review of the final Contract. See Para. 5.1.9.1.

- 5) Awards the Contract to the responsive/responsible contractor submitting the lowest bid.
 - 6) Forwards a copy of the contract to the Administrative Management Section.
- c) Upon receipt of proposals (negotiated), either competitive or sole-source, the Central Region Procurement and Contracts Branch:
- 1) Coordinates technical evaluation of ~~the~~ technical proposals to include QA requirements as specified in the *Request for Proposal (RFP) Technical Evaluation Criteria*. Required only for competitive proposals.
 - 2) Conducts negotiations with offerors, addressing both technical and QA requirements. Required for both competitive and sole-source proposals.
 - 3) When procurement Option 1 ~~is~~ is selected, coordinates Pre-award Supplier Qualification Evaluation with the YMP-USGS QA Office, if the Supplier has not been previously approved by the QA Office. See Para. 5.1.9.2. This is required for both competitive and sole-source proposals.
 - 4) Determines which contractor offers the best value based on cost, satisfactory QA evaluation, and technical merit, in accordance with the RFP requirements. Required only for competitive proposals.
 - 5) Obtains the YMP-USGS QA Office review of the final Contract. This is required for both competitive and sole-source proposals. See Para. 5.1.9.1.

- 6) Awards the Contract to the chosen contractor. Required for both competitive and sole-source proposals.

- 7) Forwards a copy of the contract to the Administrative Management Section. Required for both competitive and sole-source proposals.

5.1.9 THE YMP-USGS QUALITY ASSURANCE (QA) OFFICE:

5.1.9.1 QA Office Reviews:

- a) Reviews the **final** procurement documentation to ensure that the **appropriate** QA requirements are complete **included based on the QMP-7.04 review** and that they remain applicable to any changes incorporated during the bidding/supplier selection process.

- b) Applies, signs and dates the procurement documentation with the QA Review Stamp, Attachment 9.

- c) Forwards a copy of the stamped page to Central Region Procurement and Contracts Branch and to the Administrative Management Section.

5.1.9.2 Pre-Award Supplier Evaluations:

- a) When applicable, coordinates the performance of Pre-award Supplier Evaluations with the Central Region Procurement and Contracts Branch. Supplier Evaluations are performed in accordance with QMP-7.04, Supplier Evaluation.

5.1.10 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Retains copies of the DI-1 form, Purchase Order, Contract and Modification documentation, along with the evidence of the YMP-USGS QA Office and technical reviews, for subsequent transmittal to the Local Records Center ~~Records Management Facility~~.

5.2 Receipt of Services:

5.2.1 THE YMP-USGS QUALITY ASSURANCE (QA) OFFICE:

- a) When applicable, performs a Source Verification (reference ~~QMP 7.04 Para. 5.1.1, d.3~~) at the Supplier's facility to ensure that the procurement requirements have been met prior to ~~completion of the service~~ shipment.
- b) Obtains the QA Manager's approval of the completed Source Verification documentation.
- c) Forwards the original of the completed and approved Source Verification documentation to the Administrative Management Section and forwards a copy to the Requestor.

5.2.2 THE REQUESTOR:

- a) Upon receipt, compares the service ~~results~~ to the procurement document to ensure all requirements have been met.

NOTE: For Blanket Purchase Orders (BPOs) "upon receipt" is upon receipt of the last service for the BPO for a given fiscal year.

- b) Completes the back side of the Purchase Order form, (Attachment 10), documenting partial receipt, conditional acceptance, full receipt, etc.

- c) When applicable, completes the ~~Comprehensive Receiving Acceptance Plan~~ or Sample Analysis Quality Control Plan ~~documentation~~. See ~~OMP 7.04~~ Paras. 5.1.1, d.4 or d.5, respectively).

- d) Forwards the completed back side of the Purchase Order form and, when applicable, the ~~Comprehensive Receiving Acceptance Plan~~ or Sample Analysis Quality Control Plan ~~information~~ to the Administrative Management Section.

5.3 Closing Procurements:

5.3.1 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Uses the back side of the Purchase Order form to initiate payment via traditional USGS practices.

- b) Compiles and prepares the documentation associated with the procurement for transmittal to the Local Records Center. The package must contain, but is not limited to, the following items:
 - 1) DI-1 and attachments;

 - 2) Final *Purchase Order or Contract documentation*;

- 3) When applicable, the documentation from the ~~Comprehensive Receipt Acceptance Plan~~ the completed Sample Analysis Quality Control Plan, or the Source Verification Plan;
 - 4) The completed back side of the Purchase Order form; and
 - 5) Reference to any related YMP-USGS QDRs, DOE CARs, or DOE NCRs.
- c) Forwards the procurement documentation package to the ~~YMP-USGS Local Records Center~~ per ~~QMP-17.01, YMP-USGS Records Management Facility for Record Sources~~, upon receipt of the last received document. See Para. 6.2.

5.4 Procurements by Support Participants:

5.4.1 YMP-USGS SUPPORT PARTICIPANTS: ~~As if~~ authorized by management agreements or comparable documents, support participants may ~~shall~~ initiate quality-affecting procurements and procurement modifications as outlined below.

- a) Incorporate, as a minimum, the applicable technical and QA requirements identified herein.
- b) Perform technical reviews and approvals ~~by comparable staff~~.
- c) Obtain the approval of the YMP-USGS QA Manager for proposed suppliers and/or subcontractors.
- d) Submit final procurement documents, including modifications, to the YMP-USGS QA Manager for approval.

- e) Perform receipt acceptance of the purchased service.
- f) Submit the procurement and acceptance documentation to the ~~Records Management Facility~~
~~YMP-USGS Local Records Center in accordance with QMP-17.01.~~

6. RECORDS MANAGEMENT.

6.1 Controlled Documents: None.

6.2 Records Center Documents: QA Records identified in Para. 5.3.1.b shall be submitted to the YMP-USGS Local Records Center in accordance with QMP-17.01.

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes YMP-USGS-QMP-4.01, R6, Procurement Document Control; Modification QMP-4.01,R6-M1; QMP-7.01, R5, Receipt of Purchased Items and/or Services; and Modification QMP-7.01,R5-M1.

7.2 References Cited:

- YMP-USGS-QMP-3.03, Software
- YMP-USGS-QMP-4.02, Control of Agreements
- YMP-USGS-QMP-7.04, Supplier Evaluation
- YMP-USGS-QMP-17.01, YMP-USGS Records Management for Record Sources

8. ATTACHMENTS.

Attachment 1: Guidelines For Determining Quality-Affecting Procurements

Attachment 2: Definitions

Attachment 3: Responsibilities

Attachment 4: Procurement Requisition Requirements

Attachment 5: U.S. Department of the Interior Requisition (Form DI 1)

~~Attachment 6: YMP-USGS Quality Assurance Requirements for Suppliers of Analytical Services~~

~~Attachment 7: YMP-USGS Quality Assurance Requirements for Suppliers of Calibration Services~~

~~Attachment 8: YMP-USGS Quality Assurance Requirements for (NAME OF SERVICE)~~

Attachment 9: YMP-USGS QA Office Procurement Review Stamp

Attachment 10: USGS Purchase Order Form

9. APPROVALS AND EFFECTIVE DATE.

EFFECTIVE DATE:

YMP-USGS Quality Assurance Manager

Date

Chief, Yucca Mountain Project Branch

Date

Assistant Chief Hydrologist for Technical Support

Date

Science Advisor for Science Applications

Date

10. HISTORY OF CHANGES.

<u>Revision/ Modification No.</u>	<u>Effective Date</u>	<u>Description of Changes</u>
R0	08/24/85	Initial issue of QMP to describe procurement document control process.

R1	10/27/86	Provides guidance for "commercial grade" material and includes a procurement document checklist for QA review.
R2	-	Effective date was not assigned, document was not distributed.
R3	06/23/89	Provides list of exempted purchases; specifies YMP personnel procurement responsibilities; Blanket Purchase Agreements; REECo procurements; and contains Supplier Certificate of Conformance.
R3-M1	06/15/90	Changes procurement responsibilities for the contracting officers; QA and technical review requirements; and moves supplier Certificate of Conformance to QMP-7.01 (reference USGS-NCR-90-09 and USGS-AFR-9002-06).
R3-M2	08/01/91	Modifies distribution of procurement documents in response to USGS-NCR-90-31.

<u>Revision/ Modification No.</u>	<u>Effective Date</u>	<u>Description of Changes</u>
R3-M3	10/15/91	Provides for organization name changes to GSP and HIP.
R3-M4	11/13/91	Revision of Capital Equipment Request Form (Attachment 2) and corresponding text.
R4	04/09/93	Changes procedure scope and corresponding procurement process.
R4-M1	04/09/93	Modifies YMPB Administrative Management Section responsibilities and capital equipment (REECo, Attachment 2).
R5	12/13/93	Incorporates Modification QMP-4.01,R4-M1 and DOE/RW-0333P (QARD, R0) procurement requirements, CAR 93-053, and CAR-91-07,R1.
R6	05/10/94	Incorporates DOE/RW-0333P (QARD, R0) procurement language.
R6-M1	03/08/95	Changes made to reflect new organizational structure and corresponding responsibilities.
R7	07/21/95	Incorporated changes required as a result of DOE CAR YM-94-050.
R8		Incorporated changes required as a result of DOE CAR YM-96-C004

GUIDELINES FOR DETERMINING QUALITY-AFFECTING PROCUREMENTS

1. Procurements that are considered to be quality-affecting include the following:

- **Tasks and services used for YMP Site Characterization activities, including sample collection and data analysis.**
- **Examples typically include:**
 - calibration services or purchase of calibrated equipment
 - analytical services
 - software development
 - supporting research or data development
 - purchase of calibrated equipment

2. Procurements that are not considered to be quality-affecting include the following:

- **Activities that are not used for YMP Site Characterization.**
- **Examples typically include:**
 - Non-technical material and services such as office supplies, standard office equipment, clerical services, etc.
 - Equipment, tools and material, such as batteries, hammers, screw drivers, drills, generators, saws, nails, lumber; safety equipment, such as slings, tie-downs, hard hats; vehicles and related maintenance, supplies and repairs, such as oil and tires; and camping and personal equipment.
 - Standard computer and peripheral equipment, such as PCs, printers, interfaces, modems, monitors, keyboards, diskettes, supplies, etc.
 - Photographic film.
 - Commercial-grade mechanical and electronic replacement parts for equipment that is subject to calibration.
 - Periodicals, books, and publications, including maps.
 - Thin sections.
 - Mineral separations.

Procurements of made-to order items that are not quality-related should be considered for QA processing in order to ensure that procurement requirements are met.

DEFINITIONS

Abstract - A summary document prepared by the Contracting Officer (Central Region Procurements and Contracts Branch) containing line-item price details provided by respondents in sealed bids. Low bidder is identified from the abstract.

Qualified Suppliers List (QSL) - A list of suppliers that have worked to a Quality Assurance program that meets the applicable Yucca Mountain Project Quality Assurance requirements.

Award - The act of the Contracting Officer signing a Purchase Order, Contract, or modification.

Bids - Vendor's submissions in response to an Invitation For Bid (IFB) issued under the sealed bidding process. Bids must be submitted using the IFB package as issued, and must include any required additional documentation.

Contracts - Procurement actions which exceed the Small Purchase Threshold (currently \$25,000).

DI-1 and Attachments - The DI-1 form, including all required approvals and attachments.

JFOC - Justification For Other Than Full and Open Competition. This document is prepared by the Requestor to justify a sole-source acquisition.

Pre-award Supplier Qualification Evaluation - An evaluation performed by the QA Office to ensure that the Supplier's QA Program complies with the YMP-USGS QA requirements as incorporated into the RFP/RFO or solicitation.

Proposals - Vendor's submission in response to a Request For Proposals (RFP) issued under either the competitive or noncompetitive proposal process. Proposals generally consist of two types: cost and technical.

Purchase Order or Contract Documentation - The final Purchase Order or Contract, including all required reviews, approvals and attachments.

Request for Proposal (RFP) - A written solicitation used for a negotiated acquisition, either competitive or sole-source, to communicate the Government's requirements, and to solicit proposals from vendors. Proposals submitted under this method may be accepted unilaterally, without discussions, by the Government, resulting in a binding contract. Or, they may be used as a basis for technical evaluation and negotiations of both technical and cost factors. If negotiations are conducted under a competitive environment, a Best and Final Offer is required of all offerors who participated in negotiations.

Request For Quotations (RFQ) - A method used in small purchasing to obtain quotes for price, delivery, and other information from vendors. This method is used when the Contracting Office determines written quotes are necessary. The Standard Form 18 is generally used to obtain these written quotes unless Electronic Data Interchange (EDI) is used. Quotes received under either method are not legally binding on the vendor.

DEFINITIONS

Sealed Bids - Bids that are submitted under the Advertised method of procurement using the USGS prepared Invitation For Bid (IFB) as the bid package. Sealed bids are held by the Contracting Officer unopened until the date and time designated for bid opening. At this time, they are opened at a public bid opening.

Small Purchases - The procurement term for purchasing supplies or services up to the small purchase threshold, currently \$25,000, through the issuance of Purchase Orders, or Delivery Orders under Federal Supply Schedules Contracts up to the maximum order limitation (MOL) of the contract.

Sole Source Purchase Orders - Purchase Orders that are issued without competition to a single vendor based on rationale contained in a Sole-Source Justification prepared by the Requestor and approved by the Contracting Officer.

Solicitation Package - The documentation issued to vendors specifying a need of the Government for materials or services. Includes both Invitation for Bid (IFB) and Request For Proposals (RFP).

Special Responsibility Factors - Components of solicitation which must be addressed by the potential bidder to allow evaluation of responsiveness to requirements of the solicitation package. Such factors could include financial history of the company, QA issues, experience, and/or production issues relating to the bidder's ability to meet exact details of the DI-1 and attachments.

RESPONSIBILITIES

- The Quality Assurance Manager is responsible for: ensuring the QA requirements, incorporated into procurements, are appropriate; performing evaluations of proposed Suppliers; performing Source Verifications; and approving Sample Analysis Quality Control Plans.
- Program Chiefs are responsible for ensuring that appropriate technical requirements are incorporated into quality-affecting procurements in accordance with this procedure.
- Requestors are responsible for initiating, and for performing receipt acceptance of quality-affecting procurements, in accordance with this procedure and for providing any pertinent background information to reviewers as requested.
- The Administrative Management Section is responsible for: processing DI-1 form and attachments; verifying funding; tracking the status of procurements; coordinating procurement actions with the Central Region Procurement and Contract Branch; and submitting procurement QA records to the Local Records Center.
- The Central Region Procurement and Contracts Branch is responsible for: coordinating solicitation; preparing, awarding and distributing Purchase Orders and Contracts; coordinating supplier evaluation with the QA Office; and maintaining the principal interface with the Suppliers.

PROCUREMENT REQUISITION REQUIREMENTS

PART I DESCRIPTION

The following information, when applicable, shall be included in the Description Section of the DI-1 form, Attachment 5. The information is developed by the Requestor who conveys the information to the Administrative Management Section. The Administrative Management Section incorporates the information into the DI-1 form.

- The Yucca Mountain Project WBS Number.
- The Scope of Work to include, as applicable:
 - A description of the work;
 - Reference to design basis, if applicable;
 - Technical requirements, including specifications, tolerances and acceptance criteria;
 - Reference to specific governing documents, including current revision, such as:
 - * Technical procedures, scientific notebooks, study plans, or instructions;
 - * Drawings;
 - * Codes and or standards;
 - Spare or replacement parts or assemblies;
 - Hold and/or witness points beyond which work cannot proceed without YMP-USGS authorization; and
 - Required tests and or inspection and related acceptance criteria.
 - Documents necessary to provide evidence of the quality or acceptability of the service.
 - Rights of access to supplier's facilities.

PROCUREMENT REQUISITION REQUIREMENTS (Continued)

PART II QUALITY ASSURANCE PROCUREMENT OPTION CRITERIA

The following criteria shall be used in selecting a Quality Assurance Procurement Option:

Option 1) A Supplier working to a QA program approved by the YMP-USGS QA Office.

This is the preferred option to be used when the Supplier repeatedly performs a specific service for the YMP-USGS. With this option, the Supplier either has or develops a QA Program under which the work will be performed. These Suppliers are listed on the Qualified Suppliers List maintained by the Yucca Mountain QA Division.

Option 2) A Supplier serving as extended staff to the YMP-USGS working directly to YMP-USGS QMPs.

This option is normally used when the Supplier will work ~~directly to YMP-USGS QA Program~~ under the direct supervision of the YMP-USGS. With this option, the Supplier shall be placed on controlled distribution for QMPs and appropriate technical procedures. Determinations also will be made regarding QMP and technical procedure training requirements for the Supplier's personnel. Personnel qualification documentation shall also be prepared and submitted to the YMP-USGS in accordance with appropriate QMPs.

Option 3) Graded QA Supplier Requirements.

~~This option is used when a supplier needs its own QA program supplemented to ensure appropriate QA requirements are in place does not need to meet all applicable QA requirements for the service to be provided. The following criteria shall be addressed by the requestor to determine what QA requirements must be supplemented: Any justification for an exception to the requirements shall be submitted by the requestor that addresses the following criteria as applicable to the service:~~

1. Importance of the data being acquired to site characterization or licensing. Will the results be used directly to support those decisions.
2. Complexity of the activity or service or method.
3. Reliability of the process or methods used in performing the service.
4. Reproducibility of the results being procured.
5. Degree of standardization of the methods or processes used in performing the service.
6. History of service quality by the supplier.
7. Necessity for special controls or processes.
8. Degree to which functional compliance can be demonstrated through source verification or quality control samples.

All suppliers of quality affecting services must have qualified and trained personnel, and work to documented procedures. The degree to which these and other quality controls must be documented by the supplier shall be determined based on an evaluation by the QA Office

PROCUREMENT REQUISITION REQUIREMENTS (Continued)

of the ~~documentation justifications~~ supplied by the requestor. ~~The QA Office evaluation shall be documented in accordance with OMP 7.04~~

In cases where a ~~this~~ graded approach is applied, ~~the supplier's supplemented QA program may be enhanced by either a QC Sample Plan, a determination shall be made as to whether or not to supplement the vendor's QA program by either or a source verification.~~

MANAGEMENT PROCEDURES MANUAL

CHAPTER 7 - CONTROL OF PURCHASED SERVICES**SECTION 4 - SUPPLIER EVALUATION**

1. **PURPOSE.** The purpose of this Quality Management Procedure (QMP) is to establish methods to ensure that suppliers and support participants providing quality-affecting services, herein after referred to as suppliers, have the capability to meet the Yucca Mountain Project (YMP)-U.S. Geological Survey (USGS) Quality Assurance (QA) requirements, and that a Qualified Suppliers List (QSL) is maintained.

2. **SCOPE OF COMPLIANCE.** This procedure applies to the initial and annual evaluation of suppliers that provide quality-affecting services obtained in accordance with QMPs -4.01 or -4.02. The scope does not apply to suppliers who work to the YMP-USGS QA Program as augmented staff.

3. **DEFINITIONS.**
 - 3.1 **Qualified Supplier List (QSL):** A listing of suppliers currently qualified to supply services to the Office of Civilian Radioactive Waste Management (OCRWM) or other Affected Organizations. The QSL is maintained by the OCRWM, Yucca Mountain Quality Assurance Division.

 - 3.2 **Supplier:** Supplier or Vendor. One who provides quality- affecting services in support of USGS site characterization activities.

 - 3.2 **Supplier Evaluation:** A documented evaluation that determines if the supplier is qualified to provide quality-affecting services in accordance with the procurement document requirements.

3.3 Supplier Survey: An on-site evaluation of a potential supplier's facilities, personnel, performance history, current QA records, and QA program. The purpose of the evaluation is to determine the technical and quality capabilities of a potential supplier to satisfy the requirements of procurement documents and/or the applicable elements of the OCRWM QA program.

3.4 Support Participant: An organization providing a specific service under QMP-4.02 to the YMP-USGS.

4. RESPONSIBILITIES.

4.1 The YMP-USGS Quality Assurance (QA) Manager is responsible for determining appropriate QA requirements for a service and evaluating ~~suppliers' ability~~ ~~suppliers' ability~~ to meet those requirements. The YMP-USGS QA Manager also is responsible for submitting the QSL supplier evaluations to the OCRWM.

4.2 YMP-USGS Requestors are responsible for specifying the technical requirements, concurring with the QA requirements, and identifying the importance of the service to site characterization activities.

5. PROCEDURE.

5.1 Initial Evaluation: Upon determination of the need to evaluate a new supplier, the YMP-USGS QA Manager shall initiate an 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.

5.1.1 The evaluation of the supplier shall be by supplier evaluation or by surveillance (ref. QMP-18.02), and shall consider the requirements identified in the attachment to this QMP appropriate for

the service to be provided. The extent of the evaluation and the requirements applied to the supplier shall be a function of the supplier's quality performance and of the relative importance and complexity of the services being obtained.

5.1.2 The evaluation is documented by completing the attachment to this QMP appropriate for the service requested and the evaluation documentation prepared shall be performed as soon as practical after a vendor has been selected in accordance with DOE/YMP-AP-7.4Q QMP-4.01, Maintenance of the Office of Civilian Radioactive Waste Management Qualified Suppliers List QMP-4.02.

5.1.3 If a supplier does not have a documented QA program that meets all the applicable

QA requirements then by completing 1) Attachment I to this QMP as it applies to the YMP-USGS QA Manager, service requested and 2) the supplier evaluation documentation prepared in coordination accordance with the YMP-USGS

Requestor, shall modify DOE/YMP-AP-7.4Q, Maintenance of the requisition request to include the necessary QA controls Office of Civilian Radioactive Waste Management Qualified Suppliers List.

5.14 If a supplier does not have a documented QA program that meets all the applicable

QA requirements then the YMP-USGS QA Manager, in coordination with the YMP-USGS

Requestor, shall modify the requisition request other procurement documentation to include the

necessary QA controls. If it is determined that the supplier is unable or unwilling to implement the

YMP-USGS QA controls, the supplier will not be included in the QSL.

5.1.4.5 Upon determination that the supplier can meet YMP-USGS requirements, the YMP-USGS QA Manager shall add the supplier to the QSL, and the evaluation shall be distributed to the requestor and to the OCRWM in accordance with AP-7.4Q.

5.1.5 Any variation to the QA requirements stated in the attachments to this QMP shall be based on criteria identified in Attachment 4, to QMP-4.01 and evaluated by the QA Office to determine if they exceptions are appropriate. Consideration shall be given by the QA Office to the use of Sample Quality Control Plans or source verification described in Attachment 2 as a supplement to the supplier's QA program.

5.2 Annual Evaluations: Each supplier on the QSL shall receive an annual evaluation to determine retention on the QSL. These evaluations shall be conducted by the YMP-USGS QA Office prior to the date indicated on the QSL.

The evaluation shall be conducted as a desk-top evaluation or a surveillance (reference QMP-18.02); and shall consider the review criteria listed below:

- Supplier's performance in accordance with the requirements in current procurement or agreement documents.
- Review of documentation furnished by the supplier (such as calibration certificates, nonconformance reports, and corrective actions).
- Review of any changes by the supplier to QA procedures referenced in procurement document.
- Results of previous evaluations, source verifications, receiving acceptance, QC plans, or audits by other organizations.
- Experience with similar services furnished by the same supplier.

- A review of procurement documents or agreements to determine if the supplier has received additional work since the initial procurement or agreement.

5.2.1 The results of the evaluation shall be documented in accordance with Attachment XXX and AP-7.4Q and submitted by the YMP-USGS QA Manager to YMQAD.

5.2.2 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.

5.2.2.1 Delete the supplier from the QSL and evaluate the possible negative impact on the quality of services already furnished by the supplier. The evaluation results shall be documented in the annual evaluation. If the impact is negative, a deficiency document shall be initiated. The YMP-USGS QA Manager shall notify users of the QSL that the supplier has been removed from the QSL, and that purchased services in process at this time, from this specific supplier, shall be halted.

5.2.2.2 Retain the supplier on the QSL if the inadequacies to be corrected will not negatively impact future purchased services. Any impact on prior procurements shall be documented in the annual evaluation. If the impact is negative, a deficiency document shall be initiated. In this case, there will be no change to the QSL; and no change in the use of the supplier.

5.2.2.3 Retain the supplier on the QSL with restrictions. An evaluation of possible negative impact on the quality of services already obtained shall be performed and documented. Conditions requiring correction by the supplier shall be identified. The information in the QSL will be updated to include the restrictive conditions. The YMP-USGS QA Manager

shall notify the supplier of these conditions and request notification from the supplier when the conditions have been corrected. If deemed necessary, the YMP-USGS QA Manager shall schedule a verification to determine if the actions taken are adequate. Upon positive resolution, the restriction will be lifted and the information in the QSL will be updated. The documentation of the supplier evaluation shall include the justification for lifting the restriction and shall include the results of the evaluation of impact. If inadequacies still exist, they shall be handled in accordance with Para. 5.2.2.1.

6. RECORDS MANAGEMENT.

6.1 Controlled Documents: None.

6.2 Records Center Documents: QA Records associated with this procedure shall be submitted to the Records Management Facility by the YMP-USGS QA Manager as complete record packages, in accordance with AP-17.1Q, and may include the following:

Record Packages/Package Segments

- Documentation of initial or annual supplier evaluation (If surveillance, identify as per QMP-18.02.)
- Documentation of supplier deficiencies

Individual Records

- Documentation of initial or annual supplier evaluation (If other than surveillance, identify such as 92-E01.)

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes YMP-USGS-QMP-7.04, R2, Supplier Evaluation and QMP-7.04,R2-M1.

7.2 References Cited:

- DOE/YMP AP-7.4Q, Maintenance of the Office of Civilian Radioactive Waste Management Qualified Suppliers List
- DOE/YMP AP-16.1Q, Performance/Deficiency Reporting
- DOE/YMP AP-16.2Q, Corrective Action and Stop Work
- DOE/YMP AP-17.1Q, Records Management
- YMP-USGS-QMP-4.01, Procurement Document Control
- YMP-USGS-QMP-4.02, Control of Agreements
- YMP-USGS-QMP-12.01, Instrument Calibration
- YMP-USGS-QMP-18.02, Surveillances

8. ATTACHMENTS.

Attachment 1: YMP-USGS Supplier Checklist

9. APPROVALS AND EFFECTIVE DATE.

EFFECTIVE DATE:

YMP-USGS Quality Assurance Manager

Date

Chief, Yucca Mountain Project Branch

Date

Assistant Chief Hydrologist for Technical Support

Date

Science Advisor for Science Applications

Date

10. HISTORY OF CHANGES.

<u>Revision/ Modification No.</u>	<u>Effective Date</u>	<u>Description of Changes</u>
R0	04/09/93	Initial Issue.
R1	05/10/94	This revision incorporates Modification QMP-7.04,R0-M1 and meets DOE/RW-0333P (QARD, R0) requirements.
R1-M1	02/07/95	Added to coincide with changes to QMP-7.01,R5-M1 for the QC program.
R1-M2	03/08/95	Changes made to reflect new organizational structure and corresponding responsibilities.
R2		This revision incorporates Modifications QMP-7.04,R1-M1 and -M2, incorporates the necessary interface to DOE/YMP AP-7.4Q, and addresses appropriate issues identified in DOE CAR YM-94-050.
R3		This revision was made as part of the corrective actions for CAR-YMQAD-96-C004.



YMP-USGS SUPPLIER CHECKLIST

SUPPLIER NAME: _____

DOCUMENT TITLE: _____

REVIEWED BY: _____ DATE: _____

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
1.0 Organization				
The supplier shall include a description of the organizational structure and define responsibilities for verifying quality that are independent from those performing work.				
The supplier shall agree to allow YMP personnel, including the NRC, DOE, USGS, and other authorized personnel, upon reasonable notification, to perform audits and/or surveillances of the supplier's facilities, personnel, and QA implementation?				
2.0 Quality Assurance Program				
A program shall be established for indoctrination, training, and qualification of personnel performing quality-affecting activities to assure proficiency is achieved and maintained.				
The program shall include the documentation of personnel qualifications, indoctrination, and training prior to performing work.				
3.0 Software				
Methods shall address that: a) software programs perform as intended and b) provide evidence that data manipulation programs produce the intended results				
Data shall be traceable to the software version preceding it.				
4.0 Procurement Document Control				
The QA program shall describe the approach used to assure that technical and quality requirements are incorporated into procurement documents. The original procurement documents and modifications to them shall be reviewed for inclusion of technical and quality requirements				
The QA program shall include requirements to document the evaluation and selection of suppliers prior to the award of a contract.				

Supplier QA Plan Checklist

Supplier: _____

Date: _____

Page of 7

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
Methods shall be described to ensure that received services meet procurement requirements.				
5.0 Instructions, Procedures and Drawings				
Quality affecting activities shall be performed in accordance with approved procedures.				
The quality assurance program shall describe the process for preparation, review, approval, and control of QA implementing documents.				
12.0 Control of Measuring and Test Equipment (M&TE)				
The suppliers QA program shall describe the methods used to assure that measuring and test equipment, including equipment that contains software or programmable hardware, is adjusted and maintained as a unit at prescribed intervals, or prior to use, against reference standards having traceability to nationally recognized standards. Calibration standards shall have a greater accuracy than that required of the M&TE being calibrated.				
Calibration M&TE shall be uniquely identified to provide traceability to calibration data. The use of M&TE shall be documented. Measures shall be established to prevent the use of out-of-calibration M&TE. When M&TE is found to be out-of-calibration the validity of results using that equipment since its last calibration shall be evaluated.				

Supplier QA Plan Checklist

Supplier: _____

Date: _____

Page of 7

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
<p>Does the supplier's calibration documentation include the following:</p> <ul style="list-style-type: none"> a. YMP-USGS Purchase Order number. b. Name of the organization (company) performing the calibration. c. Name or identification of the person performing the calibration. d. A statement that accuracy of the Principal Reference Standard(s) used in the calibration is greater than (or equal to with documented justification) the required accuracy of the equipment being calibrated. e. The date the calibration was performed. f. Identification of equipment being calibrated (such as manufacturer, type, model, serial number, or other unique identifier). g. Identification of calibration standard (such as manufacturer, type, model, serial number, or other unique identifier) <u>and</u> NIST traceability or similar information when using other recognized standards, <u>and</u> calibration procedure or method used. Alternatively, it is acceptable for calibration documentation to provide a reference to documentation containing the standard's identity, range, accuracy, traceability, and the procedure or method used. h. Records of actual calibration data values, when applicable, both before and after any adjustments, enabling the determination of whether the equipment was, and is, within required tolerance or accuracy. If adjustments are not performed, a second set of data is not required. Clear indication of condition when instrument is found to be out of calibration, as submitted, and a statement or clear indication that the recalibrated equipment is within tolerance in all operating ranges. 				
<p>What are the supplier's calibration capabilities? What M&TE can be calibrated? Over what ranges? To what accuracies?</p>				
<p>Is the supplier willing to immediately notify the YMP-USGS technical contact when a calibration instrument used to calibrate and certify YMP-USGS equipment is found to be defective or out of calibration?</p>				
<p>Does the supplier have established methods for receiving, handling, storing, shipping and otherwise controlling YMP-USGS M&TE?</p>				
<p>Is the supplier willing to calibrate equipment in its as-received condition as well as after maintenance (before and after calibration)?</p>				

Supplier QA Plan Checklist
 Supplier: _____
 Date: _____
 Page of 7

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
Does the supplier maintain records of all actions affecting calibrations? For how long? Is the supplier willing to provide YMP-USGS with originals or copies of those records?				
16.0 Corrective Action				
The QA Program shall provide a control system for identifying and documenting deviations from technical and quality procedures.				
Adverse conditions shall be reported to appropriate management responsible for the condition who shall determine extent of the condition and take remedial actions.				
The QA organization or other independent group shall verify that corrective actions have been completed.				
17.0 QA Records				
The QA Program shall provide for specifying, preparing, and maintaining records that provide evidence of quality.				
The records shall be protected from damage, deterioration, or loss.				
The requirements and responsibilities for record transmittal, distribution, retention (3 years Minimum), maintenance, and disposition shall be established and documented				
18.0 Audits				
The QA Program shall provide for planned and scheduled audits to verify compliance with its requirements and determine its effectiveness.				
The audits shall be performed by independent personnel to perform the audits in accordance with prescribed procedures or checklists.				
Audit results shall be documented and reported to responsible management.				
Follow-up action to verify corrective action shall be taken where indicated.				

Supplier QA Plan Checklist

Supplier: _____

Date: _____

Page of 7

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
For Analytical Service Suppliers the following requirements shall also be met:				
The laboratory shall have a formal, logical way of receiving, handling, tracking samples submitted by the USGS. The disposition of samples that do not conform to requirements of the requested analysis shall be documented.				
Data (analyses) shall be properly records, received, stored, submitted to USGS requestor, and archived for an acceptable period of time.				
The laboratory shall have traceable procedures for creation of standards, conduct of analyses, calibration of instruments, and documentation of software.				
The laboratory already does satisfactory work of similar nature for other USGS offices or for other agencies such as the EPA, etc.; or has a national reputation based upon past work.				
The laboratory shall have an internal quality control program.				
Analytical results shall be traceable to the software version used to produce them. Software version changes shall be checked to verify that the software produces correct results.				
The laboratory participates in inter-laboratory comparisons such as round-robin studies or statistical comparisons.				
For suppliers of services other than calibration or sample analysis the following requirements shall be considered for inclusion:				
Scientific investigation activities shall be documented in a scientific notebook that provides a description of the work as performed and the results obtained.				
Data shall be identified in a manner that provides traceability to associated documentation and computer codes.				

USE OF SAMPLE ANALYSIS QUALITY CONTROL AND SOURCE VERIFICATION

A Sample Analysis Quality Control (SAQC) Plan developed by the Requestor to document the methods that will be used to confirm that analytical results are appropriate for the intended purpose.

This option is normally used for limited scope sample analysis of such a unique nature that the desired supplier does not work to a documented QA Program that meets QARD requirements.

When this option is selected the QA Office will assess the laboratory's capability to complete the requested analyses through a review of its analytical methods and quality control practices. If appropriate, an on-site review of the laboratory facilities will be conducted. The Requestor shall prepare the SAQC Plan (page 6 of this Attachment) identifying the verification method to be used, including acceptance criteria. Verification methods may include split samples, duplicate samples, known samples, etc. The SAQC Plan shall be prepared and approved prior to award of the procurement.

Upon receipt of the data analysis, the Requestor shall document the results of the QC analysis and submit the completed SAQC Plan to the QA Office. The QA Office shall review and approve the completed SAQC Plan, and forward the original to the Administrative Management Section and a copy to the Requestor.

A Source Verification (SV) performed by the QA Office, to a pre-approved plan, at the Supplier's facility prior to completion of service to ensure that the procurement meets the technical and QA requirements specified in the procurement documents.

This option is normally used when a supplier does not meet all applicable QA requirements and the procurement activity can be monitored, witnessed, or observed during the production process. (Examples include limited scope calibrations, and testing or assembly of made-to-order items.)

When this option is selected the supplier evaluation review will document what requirements are met, not applicable, and not met by the supplier. The QA Office shall prepare the Source Verification Plan (page 4 of this Attachment), incorporating witness points, as appropriate, assign a SV number and submit this Plan to the Requestor for approval. The QA Office will inform the Central Region Procurement and Contracts Branch who will advise the Supplier accordingly. The SV Plan is normally prepared after the procurement is awarded but sufficiently early to permit the Supplier to plan for the SV activities.

The QA Office shall perform the Source Verification according to the approved Plan. Following completion of the Source Verification and approval of the completed Plan by the QA Manager, the QA Office will forward copies to the Requestor and the Administrative Management Section.



YMP-USGS QUALITY ASSURANCE SOURCE VERIFICATION PLAN

SVN: _____

Date: _____

Page 1 of ____

COMPLETE ONLY APPLICABLE ITEMS:

SUPPLIER: _____

D.I. / _____ P.O. / _____
Number Date Number Date

DESCRIPTION: _____

Prepared by: _____ Date: _____

QA Manager Approval: _____ Date: _____

Technical Approval: _____ Date: _____

ELEMENTS TO BE VERIFIED:

ACCEPTABLE

UNACCEPTABLE

Verification has confirmed that the preceding activities are:

Acceptable Unacceptable Ref: QDR _____

Verified by: _____ Date: _____

QAO Approval: _____ Date: _____



YMP-USGS SAMPLE ANALYSIS QUALITY CONTROL PLAN

Page 1 of

COMPLETE ONLY APPLICABLE ITEMS:

SUPPLIER: _____ PURCHASE ORDER NO. _____ DATE: _____

DESCRIPTION OF PLAN: _____

PURPOSE OF PLAN: _____

SCOPE OF PLAN: _____

Prepared By: _____ / _____ Reviewed by (QAO): _____ / _____
Name Date Name Date

PLAN DESCRIPTION

Analytical Results of Samples Are: Acceptable Not acceptable. Comments: _____

Results Reviewed By: _____ Date: _____

Reviewed By (QAO): _____ Date: _____

YMQAD COMMENTS ON YMP-USGS-QMP-4.01, R8, DRAFT DATED 7/19/96

I T E M	P a g e	Para	Comment	Resolution
1	1	2	*Revise the second paragraph to reflect that the procedure applies to changes to technical requirements and QA requirements and then define the terms "technical requirements" and "QA requirements".	
2	2	5.1.1c	*Revise to read similar to: "If the procedure applies, uses Attachment 4 to develop the information required for the procurement and includes Attachment 5. Forwards this information to the Administrative Management Section."	
3	2	5.1.3a	*Revise to read: "Using Attachment 7, reviews ..."	
4	2	5.1.3b	*Change existing para. to 5.1.3c and change the attachment reference from Attachment 7 to Attachment 8, then create a new para. 5.1.3b that reads: "If not found acceptable, includes appropriate comments."	
5	2	5.1.6a	*Change to read: "Using Attachment 9, reviews..."	
6	3	5.1.8.1a) 1	Consider adding a step for Requestor and QA to review RFQ prior to issuance.	
7	3	5.1.8.1a) 3	Consider adding "(i.e. As appropriate, evaluates technical considerations; supplier personnel, capability, and past performance; alternatives and exceptions)."	
8	3	5.1.8.1a) 4	Consider adding a step for a final technical review.	
9	3	5.1.8.1b) 2	Consider adding a step for a final technical review.	
10	4	5.1.8.2b) 1	Consider clarifying evaluation by adding words similar to: "(i.e. As appropriate, evaluates technical considerations; supplier personnel, capability, and past performance; alternatives and exceptions)."	
11	4	5.1.8.2b) 3	Consider adding a step for a final technical review.	

I T E M	P a g e	Para	Comment	Resolution
12	4	5.1.8.2c) 4	Consider clarifying evaluation by adding words similar to "(i.e. As appropriate, evaluates technical considerations; supplier personnel, capability, and past performance; alternatives and exceptions)."	
13	5	5.1.9.1b)	*Change Attachment 7 to Attachment 8.	
14	5	5.2.1b)	*Change Attachment 8 to Attachment 10.	
15	Attac 1	NOTE	*add the following to the first sentence: "and if applicable, specify which USGS implementing documnets apply".	
16	Attac 2	N/A	*Add definition of QA Requirements and technical requirements that are similar to: QA requirements - An all inclusive term intended to address: QA program requirements; General Terms and Conditions (such as rights of access, hold points, and nonconformince reporting); source verification plan; and documentation requirements. Technical requirements - An all inclusive term intended to address: Scope of Work; Codes, specifications, drawings, procedures, instructions; Tests; Inspectionns; acceptance criteria (such as sample analysis QC plans).	
17	Attac 4	N/A	*In first paragraph change "Attachment 5" to "Attachment 6".	
18	Attac 4	N/A	*Change second bullet to read: "the technical requirements to include, as applicable:"	
19	Attac 4	N/A	*Under the second bullet add "- A Scope of Work" and "- Disposition of samples (refer to Attachment 5, Section II, Paragraph 10)"	
20	Attac 4	N/A	*Under the next to last line add: "Methods for accepting supplier services shall include one or more of the following, as appropriate to the services being procured: - Performing one or a combination of source verification, receiving inspection, or post-receipt testing - Technical verification of the service 0Surveillance or audit of the work - Review of objective evidence of conformance to purchase documwent requirements"	

I T E M	P a g e	Para	Comment	Resolution
21	Attac 4	N/A	*After the last line add: "When appropriate, include a submittal schedule that indicates if the document is to be submitted for information, review, or acceptance and when the documentation is expected to be submitted (Refer to Attachment 5, Section V."	
22	Attac 5	I	*Add the following to the NOTE: ",provided the supplier agrees to meet the terms and conditions described in III, IV and V."	
23	Attac 5	II 6.0	*Add a paragraph I that reads: "An authenticating dated signature of the person who is responsible for the service."	
24	Attac 5	II 8.0	*Change the first paragraph to read: Descibe methods used for specifying...." and add a second paragraph that reads: "Records are considered QA records when stamped, initialed, or signed and dated as complete. If the nature of the record (Such as magnetic or optical media) precludes stamping, initialing, or signing, then other means of authentication by authorized personnel are permitted."	
25	Attac 5	II 10.0	*Change the forth paragraph to read: "Describe the supplier's internal and external quality control methods used to verify the analytical results are correct."	
26	Attac 7	N/A	<p>Change to Attachment 8 and add a new Attachment 7 that reads:</p> <p>CRITERIA FOR REVIEW OF PURCHASE DOCUMENTS FOR APPROPRIATE QA REQUIREMNTS</p> <ol style="list-style-type: none"> 1. Is there a requirement for the supplier to have a documented QA program that implements applicable portions of the OCRWM QARD prior to initiation of work? 2. Is there a requirement for the supplier to incorporate appropriate QARD requirements into any sub-tier supplier issued procurement document? 3. Is the supplier expected to work to USGS implementing documents? If yes, are the USGS implementing documents that are applicable specified on the purchase document and have provisions been made to provide a copy of each applicable implementing document to the supplier? 4. Are there provisions written within the purchase document for rights of access to supplier facilities and records foe inspection, audit, surveillance by the USGS, OCRWM, or other designee authorized bt the USGS? 5. Is there a statement that either designates required hold points or indicating that there are no hold points? 	

I T E M	P a g e	Para	Comment	Resolution
26 cont	Attac 7		<p>6. Has documentation required to be submitted to the USGS for information, review, or acceptance been identified on the purchase document? Is there a submittal schedule identified?</p> <p>7. Does the purchase document have provisions for the supplier to maintain documentation that will become a QA record? If yes, have the specific types of documents to be maintained been identified and have retention times and disposition requirements been identified?</p> <p>8. Are there provisions for the supplier to report nonconformances to the USGS and obtain USGS approval for "use-as-is" and "repair" dispositions?</p> <p>9. If applicable, are there provisions for the supplier to identify any spare and replacement parts or assemblies and the appropriate technical and QA data required for ordering>"</p>	
27	Attac 8		<p>Change to Attachment 10 and add a new Attachment 9 that reads: CRITERIA FOR REVIEW OF PURCHASE DOCUMENTS FOR APPROPRIATE TECHNICAL REQUIREMENTS</p> <p>1. Is there an appropriate Statement of Work to be performed by the supplier?</p> <p>2. Have appropriate documents that describe the technical requirements of the services to be furnished been specified (e.g. codes, standards, regulations, drawings, procedures, or instructions)? Have the appropriate revision levels of the documents been specified?</p> <p>3. Have appropriate tests, inspections, and acceptance requirements been specified? Have the methods for USGS acceptance of the services been specified?</p>	

YMQAD COMMENTS ON YMP-USGS-QMP-7.04, R3, DRAFT DATED 7/19/96

I T E M	P a. g e	Para	Comment	Resolution
1	2	5.1.4	*Revise the last sentence to read: "The QA Manager ensures the appropriate QA requirements are included in the procurement documents."	
2	Attac 1	N/A	*Revise to be consistent with YMP-USGS-QMP-4.01, Attachment 5	