



Department of Energy

Washington, DC 20585

QA: L

JUN 05 1997

**R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 12, Room 1249, M/S 423
Las Vegas, NV 89134**

**VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE
ACTION REQUEST (CAR) YM-96-C-004 RESULTING FROM OFFICE OF QUALITY
ASSURANCE (OQA) AUDIT YM-ARC-96-10**

The OQA staff has verified the corrective action to CAR YM-96-C-004 and determined the results to be satisfactory. As a result, the CAR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or John S. Martin at (702) 794-5591.

**Donald G. Horton, Director
Office of Quality Assurance**

OQA:JB-1660

**Enclosure:
CAR YM-96-C-004**

**cc w/encl:
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV**

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R. W. Clark, DOE/OQA, Las Vegas, NV
W. E. Barnes, DOE/YMSCO, Las Vegas, NV**

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cc: ip: DWM/HLUR

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Nuclear Regulatory Commission

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Authors: HORTON, D.G. Energy, Dept. of

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WASHINGTON, D.C.

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 Smrecinski, QA Office Harry Reid Center for Environmental Studies documents a programmatic discrepancy that was not documented in accordance with AP-16.1Q or AP-16.2O.

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 actions necessary to correct those deficiencies identified within the CAR
Implement those actions imposed by Attachment I, "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 4-3-96
12 Response Due Date: 10 02 4-3-96
20 Working Days from Issuance

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

Rec'd with letter etc

THIS IS A RED STAMP

8 CAR NO. YMQAD-96-C004 DS
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6/5/97

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CORRECTIVE ACTION REQUEST

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

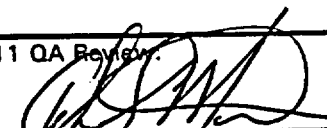
3 Responsible Organization: U.S. Geological Survey (USGS)
4 Discussed With: T. Chaney / R. Craig

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

6 Description of Condition:
1) In violation of the QARD USGS procedure YMP-USGS-QMP-4.01, Rev. 7, allows USGS to approve a supplier without having an approved QA Program. Approval of a supplier can be accomplished as delineated within YMP-USGS-QMP-4.01, via the following three methodologies 1) Source Verification, 2) Comprehensive Receipt Acceptance or 3) a Sample Analysis Quality Control Plan. Presently, the QARD does not recognize these three alternative methodologies for qualifying suppliers of items and services.
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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-16.2O.

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:  Date 4-5-96
12 Response Due Date: 102,7
10 ~~22~~ 4-5-96
20 Working Days from Issuance

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

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37-94-C-004⁰³
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CORRECTIVE ACTION REQUEST

¹⁴ Remedial Actions:

SEE ATTACHED SHEET

¹⁵ Investigative Actions:

SEE ATTACHED SHEET

¹⁶ Root Cause Determination:

SEE ATTACHED SHEET

¹⁷ Action to Preclude Recurrence:

SEE ATTACHED SHEET

¹⁸ Response by: *[Signature]* Date 4/24/96

¹⁹ Corrective Action Completion Due Date
 - See attached sheet

²⁰ Response Accepted QAR *[Signature]* Date 5/13/96

²¹ Response Accepted AOQAM *[Signature]* Date 5/8/96

²² Amended Response Accepted QAR *[Signature]* Date N/A

²³ Amended Response Accepted AOQAM *[Signature]* Date N/A

²⁴ Corrective Actions Verified QAR *[Signature]* Date 5/29/97

²⁵ Closure approved by *[Signature]* Date 6/3/97

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Block 5, Requirement, cont'd.

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

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

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

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

- Attachment 6 YMP-USGS Quality Assurance Requirements for Suppliers of Analytical Services
- Attachment 7 YMP-USGS Quality Assurance Requirements for Suppliers of Calibration
- Attachment 8 YMP-USGS Quality Assurance Requirements for (Name of Services) to be used to develop tailored

requirements based on the scope, nature, or complexity of the procurement".

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

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

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

B. Traceability to the calibration standard used for calibration.

H. Identification of the implementing document (including revision level) used in performing the calibration.

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

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

3) determine if any further Affected Organization action is required.

b) based on the above evaluation, completes SER pages 1 and 2 in accordance with Attachment 9.3 instructions; and

c) forwards the SER (pages 1 and 2) to the QSL Coordinator for action as indicated in QAP 7.2, Supplier Evaluation".

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

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

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

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

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

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

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

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

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Block 6, Description of Condition, cont'd

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

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

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

- Class S weight 2074, K. Futa 10/19/95

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

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

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

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

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

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

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

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

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

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

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

Corrective Actions For Procurements Already In Existence

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

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

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

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

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

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

Actions For Completed Procurements

Invoke the following actions for completed procurements:

- 1) USGS will provide a listing of completed procurements for suppliers of analytical, calibration, and/or other services that fall into the following categories:
 - A. Those suppliers who are listed on the QSL or the USGS Approved Vendors List (AVL).
 - B. Those suppliers who are not on the QSL or the USGS AVL and who worked directly to the USGS quality program.
 - C. Those suppliers who are not on the QSL or the USGS AVL who did not work directly to the USGS quality program who have been found to be acceptable to perform work by other means.
- 2) Based on this listing, an evaluation will be made by the methods outlined in "Corrective Actions For Procurements Already In Existence" actions as applicable.

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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

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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.

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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 H. 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

QA: L

IN REPLY REFER TO:

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 may be 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 ~~or 3~~ 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~~ 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 ~~or 3~~ 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~~ 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.

Revision/
Modification No.

Effective Date

Description of Changes

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/RFQ 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 first 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 a source verification.

MANAGEMENT PROCEDURES MANUALCHAPTER 7 - CONTROL OF PURCHASED SERVICESSECTION 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.

5.1.4 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.

5.1.5 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.

~~5.1.5.16~~ 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: _____

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REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
Methods shall be described to ensure that recieved 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 documments.				
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: _____

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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: _____

8/12/96
Craig D. Spence

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

ITEM	Page	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".	Agree
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."	Agree
3	2	5.1.3a	*Revise to read: "Using Attachment 7, reviews ..."	Agree
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."	Agree
5	2	5.1.6a	*Change to read: "Using Attachment 9, reviews...."	Agree
6	3	5.1.8.1a)1	Consider adding a step for Requestor and QA to review RFQ prior to issuance.	Change not needed because requestor and QA see DI-1 form prior to preparation of RFQ
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)."	Agree
8	3	5.1.8.1a)4	Consider adding a step for a final technical review.	Not needed. Previous reviews by requestor satisfy the need for this review.

I T E M	P a g e	Para	Comment	Resolution
9	3	5.1.8.1b)2	Consider adding a step for a final technical review.	Not needed. Previous reviews by requestor satisfy the need for this 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)."	Cannot give impression that exceptions to a sealed bid proposal can be taken.
11	4	5.1.8.2b)3	Consider adding a step for a final technical review.	Not needed. Previous reviews by requestor satisfy the need for this review.
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)."	Not needed
13	5	5.1.9.1b)	*Change Attachment 7 to Attachment 8.	Agree
14	5	5.2.1b)	*Change Attachment 8 to Attachment 10.	Agree
15	Attac 1	NOTE	*add the following to the first sentence: "and if applicable, specify which USGS implementing documnets apply".	Agree

I T E M	P a g e	Para	Comment	Resolution
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 nonconformance 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).	Agree
17	Attac 4	N/A	*In first paragraph change "Attachment 5" to "Attachment 6".	Agree
18	Attac 4	N/A	*Change second bullet to read: "the technical requirements to include, as applicable:"	Agree
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)"	Agree
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 - Surveillance or audit of the work - Review of objective evidence of conformance to purchase documwent requirements"	Agree
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."	Agree
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."	Agree

I T E M	P a g e	Para	Comment	Resolution
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."	Agree. Also clarified that "documentation" could mean more than just a Certificate of Calibration document.
24	Attac 5	II 8.0	*Change the first paragraph to read: Describe 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."	Agree
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."	Agree
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? 	Agree

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>	Agree
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>	Agree

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 services that must meet the QA program requirements delineated in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD) (DOE/RW-0333P). Guidelines for determining applicability 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 technical requirements and QA requirements.

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 and any modifications to open procurements 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.

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.**

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 Processing Procurements:

5.1.1 THE REQUESTOR:

- a) Using the guidance in Attachment 1 determines if the procurement must meet the requirements of this procedure. If this procedure does not apply then procurements are to be processed using traditional USGS practices.
- b) When appropriate, develops the Justification For Other Than Full and Open Competition (*JFOC*).
- c) 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.

5.1.2 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Prepares a DI-1 form (Attachment 6), using the information provided by the Requestor.
- b) Forwards the completed DI-1 form to the YMP-USGS QA Office.

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

- a) Using Attachment 7 reviews the DI-1 form, to determine that appropriate QA Requirements have been included.
- b) If not found acceptable, includes appropriate comments.
- c) Applies the QA Review stamp, Attachment 8, to the front page of the DI-1 form, signs and dates the stamp, and 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, if necessary, 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) Using Attachment 9 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:

Approves the DI-1 form and attachment and forwards the approved documentation to the USGS Branch of Acquisitions and Federal Assistance.

5.1.8 THE USGS BRANCH OF ACQUISITIONS AND FEDERAL ASSISTANCE:

Upon receipt of the approved DI-1 form and attachment, the USGS Branch of Acquisitions and Federal Assistance 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* \$100,000 or less).

- a) To complete a *Competitive Purchase Order* the USGS Branch of Acquisitions and Federal Assistance:
 - 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) Evaluates quotation in coordination with requestor (i.e. as appropriate, evaluates technical considerations; supplier personnel, capability, and past performance; alternatives; and exceptions) and determines responsive/responsible offerer.
 - 4) 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 Branch of Acquisitions and Federal Assistance:
 - 1) Reviews and approves the JFOC.
 - 2) 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 Branch of Acquisitions and Federal Assistance:
 - 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.
 - 3) Issues solicitation to all potential interested Suppliers.
 - 4) Receives sealed *Bids* or *Proposals*.
- b) Upon receipt of *Sealed Bids* (advertised) the Branch of Acquisitions and Federal Assistance:
 - 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) 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 Branch of Acquisitions and Federal Assistance:
 - 1) Coordinates technical evaluation of the 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) 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 For final procurement document the QA Office:

- a) Reviews the final procurement documentation to ensure that the appropriate QA requirements are 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 8.
- c) Forwards a copy of the stamped page to the Branch of Acquisitions and Federal Assistance 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 Branch of Acquisitions and Federal Assistance. 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 Records Coordinator.

5.2 Receipt of Services:

5.2.1 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 receiving report copy of the Purchase Order form, (Attachment 10), documenting partial receipt, conditional acceptance, full receipt, etc.
- c) When applicable, completes the Sample Analysis Quality Control Plan documentation.
- d) Forwards the completed receiving report copy of the Purchase Order form and, when applicable, the Sample Analysis Quality Control Plan information to the Administrative Management Section.

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

- a) When applicable, performs a Source Verification (reference QMP-7.04) at the Supplier's facility to ensure that the procurement requirements have been met prior to completion of the service.
- 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.

5.3 Closing Procurements:

5.3.1 THE ADMINISTRATIVE MANAGEMENT SECTION:

- a) Uses the receiving report copy 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 Records Coordinator. 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 completed Sample Analysis Quality Control Plan, or the Source Verification Plan;
 - 4) The completed receiving report copy of the Purchase Order form; and
 - 5) Reference to any related deficiency documents.

- c) Forwards the procurement documentation package to the Records Coordinator for Record Sources, upon receipt of the last received document.

6. RECORDS MANAGEMENT.

6.1 Controlled Documents: None.

6.2 Records Center Documents: QA Records identified in Para. 5.3.1.b are considered non-permanent and shall be submitted to the YMP-USGS Records Coordinator in accordance with QMP-17.01.

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes YMP-USGS-QMP-4.01, R7, Procurement Document Control/Receipt of Procurements.

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:	YMP-USGS Quality Assurance Requirements for Suppliers
Attachment 6:	U.S. Department of the Interior Requisition (Form DI 1)
Attachment 7:	Criteria for Review of Purchase Documents for Appropriate QA Requirements
Attachment 8:	YMP-USGS QA Office Procurement Review Stamp
Attachment 9:	Criteria for Reviews of Purchase Documents for Appropriate Technical Requirements
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
Senior 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 (REEC0, 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 APPLICABILITY OF REQUIREMENTS TO PROCUREMENTS

1. Procurements that must meet the YMP USGS QA program requirements include the following:

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

NOTE: If the supplier will be working in a direct support capacity, subject to the requirements of the YMP USGS QA program, the procurement document only needs a statement that commits the supplier to work to the requirements of the YMP USGS QA program (reference OQA Lesson Learned 92-001) and if applicable specify which USGS implementing documents apply. The procurement document is considered QA-NA.

2. Procurements that are not considered to be controlled by the YMP USGS QA program 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.

* When equipment is purchased as calibrated, the supplier must be qualified to provide calibration services in accordance with QMP-7.04.

DEFINITIONS

Abstract - A summary document prepared by the Contracting Officer (Branch of Acquisitions and Federal Assistance) containing line-item price details provided by respondents in sealed bids. Low bidder is identified from the abstract.

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 \$100,000).

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/RFQ 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.

QA Requirements - An all-inclusive term intended to address: QA program requirements; General Terms and Conditions (such as rights to access, hold points, non conformance reporting); source verification plan, and documentation requirements.

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 (Continued)

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 \$100,000, 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.

Technical requirements - An all-inclusive term intended to address: Scope of Work; codes, standards, specifications, drawings, procedures, instructions; tests; inspections; acceptance criteria (such as sample analysis QC plans).

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 Branch of Acquisitions and Federal Assistance; and submitting procurement QA records to the Records Coordinator.
- The Branch of Acquisitions and Federal Assistance 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

The following information, when applicable, shall be included in the Description Section of the DI-1 form, Attachment 6. 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 technical requirements to include, as applicable:
 - A Scope of work;
 - A description of the work;
 - Reference to design basis, if applicable;
 - Reference to 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;
 - Disposition of samples (refer to Attachment 5, Section II, Paragraph 10)
 - Required tests and or inspection and related acceptance criteria.
 - 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 test.
 - * Technical verification of the service
 - * Surveillance or audit of the work
 - * Review of objective evidence of conformance to purchase document requirements
 - Documents to be provided to USGS that provide evidence of the quality or acceptability of the service. 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).

YMP-USGS QUALITY ASSURANCE REQUIREMENTS FOR SUPPLIERS OF QUALITY SERVICES

I INTRODUCTION

The services quoted upon or furnished for this procurement are for the use by the U.S. Geological Survey, Yucca Mountain Project Branch (YMPB-USGS) in connection with the Civilian Radioactive Waste Management Program sponsored by the U.S. Department of Energy.

The services shall be provided in accordance with the Supplier's documented QA program, accepted by the YMP-USGS prior to the award. The YMP-USGS acceptance of the supplier's QA program is predicated on the degree of compliance with the YMP-USGS QA Requirements described in Section II and the Supplier's agreement to meet the terms described in III, IV and V.

NOTE: If a calibration supplier's QA program meets the requirements of ANSI/NCLC Z540-1-1994 *Calibration Laboratories and Measuring and Test Equipment-General Requirements* it is considered acceptable, provided the supplier agrees to meet the terms and conditions described in III, IV, and V.

COMPLIANCE WITH THE QUALITY ASSURANCE REQUIREMENTS IMPOSED HEREIN IS MANDATORY TO THE DEGREE APPROPRIATE.

II. SUPPLIER'S QA PROGRAM.

The Supplier's documented QA Program shall address the following topics to the degree appropriate for the nature, scope and complexity of the activity:

NOTE: The QA program could take the form of a QA manual that contains a QA program description and implementing documents or a series of implementing documents with a matrix that reflects how the following topics are addressed.

1.0 Organization

Provide a description of the supplier's organizational structure and define responsibilities for the personnel verifying quality achievement. Personnel who perform verification of quality achievement must be independent from those performing the work.

2.0 QA Program

Provide for indoctrination, training, and qualification of personnel performing the activities to assure suitable proficiency is achieved and maintained prior to performing the work.

3.0 Software

Provide evidence that data manipulation programs produce intended results.

Software to be developed or modified for YMPB site characterization activities shall meet the requirements of the YMP-USGS-QMP-3.03, Software.

4.0 Procurement Control

Describe the approach used to assure that scope of work, technical and quality requirements are incorporated into procurement documents and changes to the documents.

**YMP-USGS QUALITY ASSURANCE REQUIREMENTS FOR
SUPPLIERS OF QUALITY SERVICES**
(Continued)

Include requirements to document the evaluation and selection of suppliers prior to the award of a contract/purchase order. Methods used to ensure that received services meet requirements shall be described.

The procurement documents for services directly supporting this procurement work shall incorporate appropriate YMP USGS QA program requirements

5.0 Instructions, Procedures and Document Control

Provide for conducting activities in accordance with documented approved implementing documents (e.g. procedures). These implementing documents shall consider the appropriateness of the following:

- A. Responsibilities and organizations affected by the document.
- B. Technical requirements.
- C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and operations. The organization responsible for preparing the document shall determine the appropriate level of detail.
- D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished.
- E. Prerequisites, limits, precautions, process parameters, and environmental conditions.
- F. Quality verification points and hold points
- G. Methods of demonstrating that the work was performed as required (such as provisions for recording inspection and test results, check-off lists, or sign-off blocks).
- H. Identification of QA records generated by the implementing document.
- I. Identification of associated items and activities.

Describe the process used for preparation, review, approval and control of implementing documents. This process must include: methods used for ensuring that only the latest revision is used; and, methods used to ensure that documents are reviewed for adequacy, correctness, and completeness.

6.0 Control of Measuring and Test Equipment (M&TE)

Describe the methods used to assure that M&TE, 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

**YMP-USGS QUALITY ASSURANCE REQUIREMENTS FOR
SUPPLIERS OF QUALITY SERVICES**
(Continued)

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.

NOTE: The following is applicable only to calibration suppliers.

The supplier's calibration documentation (e.g. Certificate of Calibration) shall include the following:

- 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 the accuracy of the Principal Reference Standard(s) used in calibration is greater than (or equal to with 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) and NIST traceability or similar information when using other recognized standards, and calibration procedure or method used. Alternatively, it is acceptable for calibration documentation to provide a reference to documentation containing the standard's identity, 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 out-of-calibration, as submitted, and a statement or clear indication that the recalibrated equipment is within tolerance in all operating ranges.
- I. An authenticating dated signature of the person who is responsible for the service.

7.0 Corrective Action

Provide a control system for identifying and documenting deviations from technical and quality implementing documents. Adverse conditions shall be reported to appropriate management responsible for the condition who shall determine the extent of the condition and take remedial actions. The QA organization or other independent organization shall verify that corrective actions have been completed.

**YMP-USGS QUALITY ASSURANCE REQUIREMENTS FOR
SUPPLIERS OF QUALITY SERVICES**
(Continued)

8.0 QA Records

Describe methods used 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, maintenance, and disposition shall be established and documented.

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.

QA records shall be reviewed to ensure that they are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.

Corrections to previously transmitted QA records, including documents that will become QA records, shall include the initials or signature of the individual authorized to make the correction and the date the correction was made.

9.0 Audits

Planned and scheduled audits to verify compliance with the QA program requirements and determine its effectiveness shall be performed at least annually or once during the life of the contract. The audits shall be performed in accordance with prescribed procedures or checklists by qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to responsible management. Responsible management shall take action to correct identified deficiencies in accordance with Section 7 and follow-up action to verify corrective action shall be taken in accordance with Section 7.

If the supplier does not have a means of providing for an annual audit, USGS may elect to request that DOE conduct the audit.

10.0 Documentation of Analytical Services

Describe the process for receiving, handling, tracking samples submitted by USGS. The disposition of samples that do not conform to conditions required for the requested analysis shall be documented, and provided to the USGS.

Data (analyses) shall be properly recorded, received, stored, submitted to USGS requestor, and stored in accordance with Section 8.0.

Describe the methods for creation of standards, conduct of analyses, calibration of instruments, and documentation of software.

Describe the supplier's internal and external quality control methods used to verify the analytical results are correct.

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.

**YMP-USGS QUALITY ASSURANCE REQUIREMENTS FOR
SUPPLIERS OF QUALITY SERVICES
(Continued)**

Unless otherwise stated in the purchase document, it is not a requirement that the samples be returned to YMP-USGS.

11.0 Scientific Investigation

When technical or other implementing procedure are not utilized, 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.

III. GENERAL TERMS AND CONDITIONS

1. Where possible sub-tier procurements should be with suppliers that are approved by the YMP-USGS/YMP USGS .
2. The supplier shall 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.
3. The supplier shall notify the YMP-USGS technical contact when the supplier identifies any nonconformances (deviations) from the procurement document. Nonconformances where the proposed disposition is "repair" or "use-as-is" require YMP-USGS approval.
4. The supplier will identify any spare part or replacement parts or assemblies and the appropriate technical and QA requirements/information required for ordering.

IV. ACCESS FOR VERIFICATION

The supplier shall agree to allow YMP-USGS personnel, the NRC , the DOE or their representatives, upon reasonable notification, access to supplier facilities and records to perform inspections, audits, or surveillances to verify QA program compliance.

YMP-USGS verification activities shall not relieve the supplier of the responsibility for verification of quality achievement.

**YMP-USGS QUALITY ASSURANCE REQUIREMENTS FOR
SUPPLIERS OF QUALITY SERVICES**
(Continued)

V. REQUIRED DOCUMENTATION

The following documentation is required.

DOCUMENT DESCRIPTION	SUBMITTAL REQUIREMENT
Supplier QA Program document	Submit to the USGS for acceptance prior to start of work
Calibration Certificate and calibration reports (Supplier of calibration services)	Submit for acceptance with the calibrated equipment or after calibration
QA Records such as: implementing documents equipment calibration analytical results sample tracking training qualification audit reports corrective actions notebooks logbooks	Retain for at least 3 years or until dispositioned by YMP-USGS

Form DI-1
(Rev. April 1985)

**UNITED STATES
DEPARTMENT OF THE INTERIOR**

REQUISITION

To	Bureau/Office	Requisition No.
		Date
Appropriation/Allotment No.	Charge shipping costs to	
Vendor	Deliver to	

ITEM OR FORM NO.	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	AMOUNT

To Be Completed by Fiscal Authority Only			
FUND CERTIFICATION: Funds in the amounts shown are available and chargeable to the cost authorities shown above.			
Signature	Date	Approved by (Signature)	Date
Title		Title	
Requisitioned by (Signature)	Date	Bureau Officer (Signature)	Date
Title		Title	

Prepare in single space typing. Use double space between items. Fill out top of requisition completely, showing complete shipping instructions and appropriation if different from that to which requisition is chargeable.

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**YMP-USGS QA OFFICE PROCUREMENT REVIEW STAMP
(EXAMPLE)**

<p>REVIEWED YMP-USGS QA</p> <p>By: _____</p> <p>Date: _____</p> <p>Option Type: _____</p>

**CRITERIA FOR REVIEW OF PURCHASE DOCUMENTS FOR
APPROPRIATE TECHNICAL REQUIREMENTS**

1. Is there an appropriate Statement of Work to be performed by the supplier?
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?
3. Have appropriate tests, inspections, and acceptance requirements been specified? Have the methods(s) for USGS acceptance of services been specified?

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF 5 PAGES

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 14 Feb 1996	2. CONTRACT NO. (if any) 000001	3. ORDER NO. 1434-CR-96-SA-00452	4. REQUISITION/REFERENCE NO. 96-4889-6127
5. ISSUING OFFICE (Address correspondence to) US GEOLOGICAL SURVEY BRANCH OF ACQUISITION & FEDERAL ASSIST. PO BOX 25046 - M5204C DENVER, CO 80225 Linda L. Criger (303)236-5900 x343		6. SHIP TO: (Consignee and address, ZIP Code) US GEOLOGICAL SURVEY BLDG 25 ENT E-14 DFC DENVER, CO 80225	

7. TO: CONTRACTOR (Name, address, and ZIP Code):

00000182 CERTIFIED BALANCE SERVICE
6920 SOUTH JORDAN ROAD
UNITY J
ENGLEWOOD, CO 80112
303-680-6688

8. TYPE OF ORDER
 A. PURCHASE - Reference year _____
 B. DELIVERY - Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is bound subject to the terms and conditions of the above numbered contract.

Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheets, if any, including delivery as indicated. This purchase is negotiated under authority of:

9. ACCOUNTING AND APPROPRIATION DATA 96-4889-24001 BOC: 251A \$1,500.00	10. REQUISITIONING OFFICE
	11. BUSINESS CLASSIFICATION (Check appropriate boxes) <input checked="" type="checkbox"/> SMALL <input type="checkbox"/> OTHER THAN SMALL <input type="checkbox"/> DIS-ADVANTAGED <input type="checkbox"/> WOMEN-OWNED

12. F.O.B. POINT ORIGIN	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 02/14/97	16. DISCOUNT TERMS Net 030
13. PLACE OF INSPECTION AND ACCEPTANCE	17. SCHEDULE (See reverse for Rejections)		

ITEM NO. (U)	SUPPLIES OR SERVICES (S)	QUANTITY ORDERED (Q)	UNIT (U)	UNIT PRICE (P)	AMOUNT (A)	QUANTITY ACCEPTED (AC)
0001	<p>DELIVER TO GORDON BATTERY MS421</p> <p>BILLING CONTACT JOYCE COLOS 303-236-0516 X250</p> <p>AUTHORIZED CALLER GORDON BATTERY</p> <p>THIS PO IS A NOT TO EXCEED AMOUNT OF \$1500; BILLING AFTER EACH SERVICE</p> <p>THIS PROCUREMENT IS QUALITY AFFECTING AND ALL WORK SHALL BE PERFORMED IN ACCORDANCE WITH THE YMP-USGS QUALITY ASSURANCE REQUIREMENTS ATTACHED</p> <p>THIS IS A BLANKET PURCHASE ORDER FOR CALIBRATION OF BALANCE EQUIPMENT AND REPAIR OF 5 BALANCES CALIBRATED 2 TIMES A YEAR FOR THE PERIOD 02/14/96 THROUGH 02/14/97</p> <p>3 METTLER BALANCES MODEL PE16 MODEL PE24 MODEL PE160</p> <p>2 SARTORIUS BALANCES MODEL 1401 NAPS-1</p>	1.00	EA	1500.000000	1,500.00	

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.	0.00	17(II) TOT (Cont. Pages)
	21. MAIL INVOICE TO: (Include ZIP Code) USGS425 US GEOLOGICAL SURVEY, ATTN ADMINISTRATIVE OFFICER PO BOX 25046 M/S 425, DENVER, CO 80225			1,500.00	17(III) GRAND TOTAL
22. UNITED STATES OF AMERICA BY (Signature) <i>Linda L. Criger</i>			23. NAME (Typed) Linda L. Criger (303)236-5900 x343 TITLE: CONTRACTING/ORDERING OFFICER		

NSN 7540-01-182-8083

50347-101

OPTIONAL FORM 347 (10-83)
Prescribed by GSA
FAR (48 CFR) 53.213(e)

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USGS Order No. _____

U.S. GEOLOGICAL SURVEY
RECEIVING REPORT

IMMEDIATELY UPON RECEIPT OF SUPPLIES/SERVICES. perform necessary inspections, inform vendor of any shortages, damaged, or defective items, and annotate front of form to show quantities accepted. Failure to provide certification and invoices to OFM within 5 days of your receipt of invoice may result in payment of additional interest charges to the vendor.

This was a partial final delivery

All items delivered and/or services rendered were were not accepted. If you answered no, then please complete the rejection information at the bottom of this form.

Dates: _____
 goods received/ goods/services accepted Invoice received
 services rendered

I certify that the articles and/or services have been received, inspected, and accepted, except as otherwise noted.

Signature of Receiving Official Date Telephone No.

REPORT OF REJECTED ITEMS/DISALLOWED CHARGES

Item No.	Description of Supplies/Services	Quantity Rejected	Cost	Reason for Rejection/Disallowance

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 evaluate suppliers and support participants providing quality-affecting services, herein after referred to as suppliers, to determine that they have the capability to meet the Yucca Mountain Project (YMP)-U.S. Geological Survey (USGS) Quality Assurance (QA) requirements, and perform annual evaluations needed to maintain the supplier on the Office of Civilian Radioactive Waste Management (OCRWM) Qualified Suppliers List (QSL).
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 DOE/OCRWM. The QSL is maintained by the DOE/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.
 - 3.3 **Supplier Evaluation:** A documented evaluation that determines if the supplier is qualified to provide quality-affecting services in accordance with the procurement document requirements. The evaluation may be a desk-top evaluation, a supplier survey or a combination of both.
 - 3.4 **Supplier Surveillance:** An on-site review of a contracted supplier to verify conformance with specified procurement requirements, and evaluate their adequacy effectiveness. (See QMP-18.02).
 - 3.5 **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 survey 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.
 - 3.6 **Support Participant:** An organization providing a specific service under QMP-4.02 to the YMP-USGS.

4. **RESPONSIBILITIES.**

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

5. PROCEDURE.

5.1 Pre-award Supplier Evaluation: Upon determination of the need to evaluate a 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 desk-top supplier evaluation or by supplier survey, or combination of both, and shall consider the requirements identified in the applicable procurement document. 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. The evaluation and/or survey shall be documented on Attachment 1 to this QMP.

5.1.2 The evaluation shall be performed as soon as practical after a supplier has been selected in accordance with QMP-4.01, or QMP-4.02, but before the contract is awarded.

5.1.3 The QA reviewer performing the evaluation first determines if the potential supplier is currently on the QSL for the services being requested. If so, ensures the appropriate QA requirements are attached to the procurement document.

5.1.4 If the proposed supplier is not currently on the DOE/OCRWM QSL, the QA reviewer performs a pre-award supplier evaluation. The evaluation is documented by completing: 1) Attachment 1 to this QMP as it applies to the service requested and 2) the supplier evaluation documentation prepared in accordance with DOE/YMP AP-7.04 Q, Maintenance of the Office of Civilian Radioactive Waste Management Qualified Suppliers List. The QA Manager ensures the appropriate QA requirements are included in the procurement document.

5.1.5 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 procurement documentation to include the necessary QA controls to ensure that the requirements in QMP-4.01, Attachment 5, are satisfied. 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 and an alternate supplier will be selected.

5.1.5.1 Any variation to the QA requirements identified in the procurement document shall be based on criteria identified in Attachment 2, and evaluated by the QA Office to determine if the exceptions are appropriate. Consideration shall be given by the QA Office for the use of YMP-USGS Sample Analysis Quality Control Plan or Source Verification Plan described in Attachment 3 as a supplement to the supplier's QA program.

5.1.6 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.

5.2 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 and shall consider the following:

- 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 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 evaluate the 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, and one of the following actions shall be taken:

5.2.2.1 Delete the supplier from the QSL. The evaluation results shall be documented in the annual evaluation. 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. 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. 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 Coordinator 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/Individual Records

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

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:

- Quality Assurance Requirements Document
- DOE/YMP AP-7.4Q, Maintenance of the Office of Civilian Radioactive Waste Management Qualified Suppliers List
- DOE/YMP AP-17.1Q, Records Management
- QMP-17.01, Records Management
- YMP-USGS-QMP-4.01, Procurement Document Control/Receipt of Procurements
- YMP-USGS-QMP-4.02, Control of Agreements
- YMP-USGS-QMP-18.02, Surveillances

8. ATTACHMENTS.

- Attachment 1: YMP-USGS Supplier Checklist
Attachment 2: Grading Criteria
Attachment 3: Source Verification and Sample Analysis Quality Control

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
_____	_____
Senior 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	07/03/95	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 software programs perform as intended and provide evidence that data manipulation programs produce the intended results.				
Data shall be traceable to the software version preceding it.				
Software developed or modified for YMPB Site Characterization activities shall meet the requirements of YMP-USGS QMP-3.03.				
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				

Supplier QA Plan Checklist

Supplier: _____

Date: _____

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
The QA program shall include requirements to document the evaluation and selection of suppliers prior to the award of a contract.				
Methods shall be described to ensure that recieved services meet procurement requirements. Procurement documents for services directly supporting YMPB work shall incorporate appropriate YMP-USGS QA program 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 documments. The process must include methods for ensuring that only the latest revision is used.				
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 ttraceability 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 3 of 5

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, 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. i. An authenticating dated signature of the person responsible for the service. 				
<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: _____

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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 5 of 5

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
For Analytical Service Suppliers the following requirements shall be considered for inclusion instead of those in Para. 12.0:				
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 when a technical implementing procedure is not utilized.				
Data shall be identified in a manner that provides traceability to associated documentation and computer codes.				

GRADING CRITERIA

When a supplier needs its own QA program supplemented to ensure appropriate QA requirements are in place for the service to be provided, the following criteria shall be addressed to determine what QA requirements must be supplemented:

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 of 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 of the documentation supplied by the requestor. The QA Office evaluation shall be documented in accordance with QMP-7.04.

In cases where this graded approach is applied the supplier's supplemented QA program may be enhanced by either a YMP-USGS Sample Analysis Quality Control Plan, or a Source Verification Plan.

USE OF SOURCE VERIFICATION AND SAMPLE ANALYSIS QUALITY CONTROL

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.

Source verification 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 source verification 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 (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 Branch of Acquisitions and Federal Assistance who will advise the Supplier accordingly. The need for source verification should be identified and a plan developed prior to the award of the procurement.

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.

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 supplier'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 supplier's facilities will be conducted. The Requestor shall prepare the SAQC Plan (this Attachment) identifying the QC sampling method to be used, including acceptance criteria. QA sampling methods may include split samples, duplicate samples, known samples, etc. The SAQC Plan shall be prepared and approved prior to the 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.



YMP-USGS SAMPLE ANALYSIS QUALITY CONTROL PLAN

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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: _____

PROPOSED QARD EXCEPTIONS

The USGS with issuance of QMP-4.01, R8 and QMP-7.04, R3, is requesting the following two exceptions to the QARD requirements. Although the USGS believes that the QARD provides for these practices, recent interpretations of QARD requirements by YMQAD auditors have taken exception to these practices. Implementation of these exceptions does not diminish the documentation that would be used to support the evaluation of the quality of procured service.

Section 4:

4.2.1C - May not be met in all cases where analytical services are procured. In some cases the QARD requirements may be graded to justify the use of a Quality Control Sample Plan to augment the suppliers QA program. Suppliers will still need to be evaluated to ensure they are technically qualified and capable of performing the requested analyses.

Section 12:

12.2.7 - The USGS procedures allow that the required information be provided on the calibration certificate or that the certificate provide sufficient identification that the information is traceable to other documents supporting the calibration that contain the information.

Number	Requirement	USGS Implementation
4.1	GENERAL - This section establishes requirements to ensure that procurement documents, and any changes thereto, contain appropriate technical and quality assurance requirements.	
4.2	REQUIREMENTS	
4.2.1	Procurement Document Preparation - Procurement documents issued by each Affected Organization shall include the following provisions, as applicable to the item or service being procured:	
4.2.1A.	A statement of the scope of work to be performed by the supplier.	USGS_QMP-4.01 Rev 08 - Att4:pg1 :2bullet
4.2.1B.	Technical requirements including:	TRACE NOT REQUIRED
4.2.1B.1.	Design bases shall be identified or referenced.	USGS_QMP-4.01 Rev 08 - Att4:pg1 :2bullet
4.2.1B.2.:1 s	Specific documents (such as drawings, codes, standards, regulations, procedures, or instructions) that describe the technical requirements of the items or services to be furnished shall be specified.	USGS_QMP-4.01 Rev 08 - Att4:pg1 :2bullet
4.2.1B.2.:2 s	The revision level or change status of these documents shall also be identified.	USGS_QMP-4.01 Rev 08 - Att4:pg1 :2bullet
4.2.1B.3.	Tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.	USGS_QMP-4.01 Rev 08 - Att4:pg1 :2bullet
4.2.1C.	Quality Assurance Program Requirements including:	
4.2.1C.1.:1 s	A requirement for the supplier to have a documented Quality Assurance (QA) program that implements applicable Quality Assurance Requirements and Description (QARD) requirements prior to the initiation of work.	USGS_QMP-4.01 Rev 08 - Att5 :pg1 :ll
4.2.1C.1.:2 s	The extent of the QA program shall depend on the scope, nature, or complexity of the item or service being procured.	USGS_QMP-4.01 Rev 08 - Att5:pg1 :ll
4.2.1C.2.	A requirement for the supplier to incorporate the appropriate QARD requirements into any sub-tier supplier-issued procurement document.	USGS_QMP-4.01 Rev 08 - Att5 :ll 4

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Number	Requirement	USGS Implementation
4.2.1C.3.:1 s	When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another Affected Organization's QA program provided the work is adequately addressed.	USGS_QMP-4.01 Rev 08 - Att1 :pg1 :option1
4.2.1C.3.:2 s	In these cases, procurement documents shall specify that the purchaser's or another Affected Organization's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to them.	USGS_QMP-4.01 Rev 08 - Att1 See Note
4.2.1D.	Right of access to supplier facilities and records for inspection or audit by the purchaser, OCRWM, or other designee authorized by the purchaser.	USGS_QMP-4.01 Rev 08 - Att5 :IV
4.2.1E.	Provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.	USGS_QMP-4.01 Rev 08 - Att4 :pg1 :2bullet
4.2.1F.	Documentation required to be submitted to the purchaser for information, review, or acceptance:	USGS_QMP-4.01 Rev 08 - Att5 :V
4.2.1F.1.	The document submittal schedule shall be identified.	USGS_QMP-4.01 Rev 08 - Att5 :V
4.2.1F.2.	If the purchaser requires the supplier to maintain documentation that will become QA records, the retention times and disposition requirements shall be identified.	USGS_QMP-4.01 Rev 08 - Att5 :II 8.0
4.2.1G.	Purchaser requirements for the supplier to report nonconformances and the purchaser approval of the disposition of nonconformances.	USGS_QMP-4.01 Rev 08 - Att5 :II 10.0
4.2.1H.	Identification of any spare and replacement parts or assemblies and the appropriate technical and QA data required for ordering.	USGS_QMP-4.01 Rev 08 - Att4:pg1
4.2.2	Procurement Document Review and Approval	
4.2.2A.	Procurement document reviews in accordance with Subsection 2.2.10: Document Review, shall be performed and documented prior to issuance of the procurement documents to the supplier.	USGS_QMP-4.01 Rev 08 - 5.1.3a), 5.1.5a), 5.1.6a), 5.1.9.1a)
4.2.2B.	A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services will meet the governing requirements.	USGS_QMP-4.01 Rev 08 - 5.0 :5.1.5a), 5.1.6a), 5.1.9.1a)
4.2.2C.	Reviews shall ensure that all applicable technical and QA program requirements are included.	USGS_QMP-4.01 Rev 08 - 5.1.5a), 5.1.6a), 5.1.9.1a)

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Number	Requirement	USGS Implementation
4.2.2D.	Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement.	USGS_QMP-4.01 Rev 08 - 5.1.5), 5.1.6), 5.1.9)
4.2.2E.	Procurement document reviewers shall include representatives from the technical and QA organizations.	USGS_QMP-4.01 Rev 08 - 5.1.5a), 5.1.6a), 5.1.9.1a)
4.2.2F.	Procurement documents shall be approved.	USGS_QMP-4.01 Rev 08 - 5.1.5a), 5.1.6a), 5.1.7a)
4.2.3	Procurement Document Change	
4.2.3A.	Changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformances, hold points, and lists of spare and replacement parts delineated in procurement documents shall be subject to the same degree of control as used in the preparation of the original documents.	USGS_QMP-4.01 Rev 08 -2 :2p, 5.0
4.2.3B.:1s	Changes made as a result of proposal/bid evaluations or precontract negotiations shall be incorporated into the procurement documents.	USGS_QMP-4.01 Rev 08 - 2 :2p, 5.0, 5.1.8.2c):1), 5.1.8.2c) :4), 5.1.8.2c) :5), 5.1.9.1a)
4.2.3B.:2s	The evaluation of these changes and the resulting impact shall be completed before the contract is awarded.	USGS_QMP-4.01 Rev 08 - 2 :2p, 5.0, 5.1.8.2c):1), 5.1.8.2c):4), 5.1.8.2c):5), 5.1.9.1a)
4.2.3B.:3s	This evaluation shall consider:	
4.2.3B.:3s1	Appropriate requirements as specified in this section.	USGS_QMP-4.01 Rev 08 - 2. :2p, 5.0, 5.1.8.2c):1), 5.1.8.2.c):4), 5.1.8.2c) :5), 5.1.9.1a)
4.2.3B.:3s2	Additional or modified design criteria.	USGS_QMP-4.01 Rev 08 - 2. :2p, 5.1, 5.1.8.2c):1), 5.1.8.2c):4), 5.1.8.2c) :5), 5.1.9.1a)
4.2.3B.:3s3	Analysis of exceptions or changes requested or specified by the supplier and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished.	USGS_QMP-4.01 Rev 08 - 2. :2p, 5.0, 5.1.8.2c):5), 5.1.9.1a)

Number	Requirement	M&O Implementation
7.1	GENERAL - This section establishes requirements for planning and executing procurements to ensure that purchased items and services meet specified requirements. This section does not apply to direct-support services used for staff augmentation. The supplier selection and bid/proposal evaluation requirements of this section do not apply to situations where the Office of Civilian Radioactive Waste Management obtains the services of other Department of Energy offices or Federal agencies through Memoranda of Understanding, Memoranda of Agreement, Program Guidance Memoranda, Interagency Agreement or other documents containing appropriate technical and Quality Assurance (QA) requirements. Technical and QA requirements specified in these documents shall be verified to be satisfactorily incorporated into the applicable program prior to starting work subject to the Quality Assurance Requirements and Description (QARD).	
7.2	REQUIREMENTS	
7.2.1:1s	Procurement Planning - Procurements shall be planned and documented to ensure a systematic approach to the procurement process.	USGS-QMP-4.01 Rev 08 - 1.
7.2.1:2s	Procurement planning shall:	
7.2.1:2sA.	Identify procurement methods and organizational responsibilities.	USGS_QMP-4.01 Rev 08 - Att3, Att4:II
7.2.1:2sB.	Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.	USGS_QMP-4.01 Rev 08 - Att4:I, Att5
7.2.1:2sC.	Identify and document the sequence of actions and milestones needed to effectively complete the procurement.	USGS_QMP-4.01 Rev 08 - 5.
7.2.1:2sD.	Provide for the integration of the following activities:	TRACE NOT REQUIRED
7.2.1:2sD.1.	Procurement document preparation, review, and change control according to the requirements of Section 4.0, Procurement Document Control.	USGS_QMP-4.01 Rev 08 - 5.
7.2.1:2sD.2.	Selection of procurement sources.	USGS_QMP-4.01 Rev 08 - 5.1.8
7.2.1:2sD.3.	Proposal/bid evaluation and award.	USGS_QMP-4.01 Rev 08 - 5.1.8.1, 5.1.8.2
7.2.1:2sD.4.	Evaluation of supplier performance.	USGS_QMP-7.04 Rev 03 - 5.2
7.2.1:2sD.5.	Verifications including any hold and witness point notifications.	USGS_QMP-4.01 Rev 08 - Att4 :2bullet

Number	Requirement	M&O Implementation
7.2.1:2sD.6.	Control of nonconformances.	USGS_QMP-4.01 Rev 08 Att III 3.
7.2.1:2sD.7.	Corrective action.	USGS_QMP-4.01 Rev 08 - Att5 :II 7.0
7.2.1:2sD.8.	Acceptance of the item or service.	USGS_QMP - 4.01 Rev 08 - 5.1, 5.2
7.2.1:2sD.9.	Identification of QA records.	USGS_QMP-4.01 Rev 08 Att5, V.
7.2.1:2sE.	Be accomplished as early as possible, and no later than at the start of those procurement activities which are required to be controlled.	USGS_QMP-7.04 Rev 03, 5.1.2
7.2.1:2sF.	Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.	USGS_QMP-4.01 Rev 08 Att5, II.
7.2.1:2sG.	Include the involvement of the QA organization.	USGS_QMP-4.01 Rev 08
7.2.2	Source Evaluation and Selection	
7.2.2A.	Supplier selection shall be based on an evaluation, performed before the contract is awarded, of the supplier's capability to provide items or services in accordance with procurement document requirements.	USGS_QMP-7.04, Rev 3, 5.1.2
7.2.2B.:1s	The organizational responsibilities for source evaluation and selection shall be identified and shall include the QA organization.	USGS QMP-4.01 Rev 08 - 5.1.8.1a) :4), 5.1.8.1b) :2), 5.1.8.2b), 5.1.8.2c) :3) USGS QMP-7.04 Rev 03-4.1, 5.1.4
7.2.2.B.:2s	If a source evaluation board is established, then the QA organization shall have a voting member.	USGS_N/A
7.2.2C.	Measures for evaluating and selecting procurement sources shall include one or more of the following elements:	TRACE NOT REQUIRED
7.2.2C.1.	Evaluation of the supplier's history for providing an identical or similar product which performs satisfactorily in actual use.	USGS_QMP-7.04 Rev 03 - 5.14
7.2.2C.2.	Evaluation of supplier's current QA records supported by any documented qualitative and quantitative information.	USGS_QMP-7.04 Rev 03, 5.1, ATT1

Number	Requirement	M&O Implementation
7.2.2C.3.	Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and QA program implementation.	USGS_QMP-7.04 Rev 03, 5.1.1
7.2.2D.	The results of procurement source evaluation and selection shall be documented.	USGS_QMP-7.04 Rev 03, 5.1.4
7.2.3	Proposal/Bid Evaluation	
7.2.3A.:1s	The proposal/bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a::1), 5.1.8.2a):1), 5.1.8.2c):4):1s, 5.1.92
7.2.3A.:2s	This evaluation shall be performed by designated, technically qualified organizations including the QA organization.	USGS_QMP-4.01 Rev 08 - 5.1.8, 5.1.9.2
7.2.3B.	The evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:	TRACE NOT REQUIRED
7.2.3B.1.	Technical considerations.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c
7.2.3B.2.	QA program requirements.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c
7.2.3B.3.	Supplier personnel.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c
7.2.3B.4.	Supplier production capability.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c
7.2.3B.5.	Supplier past performance.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c
7.2.3B.6.	Alternatives.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c

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Number	Requirement	M&O Implementation
7.2.3B.7.	Exceptions.	USGS_QMP-4.01 Rev 08 - 5.1.8.1a&b, 5.1.8.2a.1, 5.1.8.2b, 5.1.8.2.c
7.2.3C.	Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.	USGS-QMP-4.01 Rev 08 - 5.1.9.1a USGS-QMP-7.04 Rev 03 - 5.1.5
7.2.3D.	Supplier QA programs shall be evaluated either before or after contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to the QARD.	USGS_QMP-7.04 Rev 03 - 5.1.5
7.2.3E.	Supplier QA programs shall be accepted by the purchaser before the supplier starts work subject to the QARD.	USGS_QMP-4.01 Rev 08 - 5.1.9.2
7.2.4	Supplier Performance Evaluation	
7.2.4A.:1s	The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance.	USGS_QMP-4.01 Rev 08 - 5.1.8.2 :1) USGS_QMP-7.04 Rev 03 - 5.2, 5.1.4, Att3
7.2.4A.:2s	The measures shall include:	
7.2.4A.:2s1.	Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents.	USGS_QMP-4.01 Rev 08 - 5.1.8.2a) :1)
7.2.4A.:2s2.	Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.	USGS_QMP-4.01 Rev 08 - 5.1.8.2a):1)
7.2.4A.:2s3.	Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements.	USGS_QMP-4.01 Rev 08 - 5.1.8.2a) :1)
7.2.4A.:2s4.	Identifying and processing necessary change information.	USGS_QMP-4.01 Rev 08 - 5.1.8.2a):1)
7.2.4A.:2s5.	Establishing the method to be used to document information exchanges between purchaser and supplier.	USGS_QMP-4.01 Rev 08 - 5.1.8.2a) :1)

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Number	Requirement	M&O Implementation
7.2.4A.:2s6.	Establishing the extent of source surveillance and inspection.	USGS_QMP-4.01 Rev 08 - 5.1.8.2a):1) USGS_QMP-7.04 Rev 03 - 5.1.4, 5.1.5, Att3
7.2.4B.	The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.	USGS_QMP-4.01 Rev 08 - 5.1.9.2 USGS_QMP-7.04 Rev 02 - 5.1.1
7.2.4C.:1s	Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement.	USGS_QMP-4.01 Rev 08 - 5.1.9.2
7.2.4C.:2s	Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's QA program.	AP-7.4Q
7.2.5	Control of Supplier Generated Documents	
7.2.5A.	Supplier generated documents shall be controlled, processed, and accepted in accordance with the requirements established in the procurement documents.	USGS_QMP-4.01 Rev 08 - Att5, II.8.0.V
7.2.5B.:1s	Measures shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements.	USGS_QMP-4.01 Rev 08 - Att 4, Att5, V
7.2.5B.:2s	These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria.	USGS_QMP-4.01 Rev 08 - 5.2.1
7.2.6	Acceptance of Items or Services	
7.2.6A.	The supplier shall verify that furnished items or services comply with the purchaser's procurement document requirements before offering the items or services for acceptance.	USGS_QMP-7.04 Rev 03 - Att1:10
7.2.6B.	The supplier shall provide the purchaser objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.	USGS_QMP-4.01 Rev 08 - Att4 :pg1
7.2.6C.	Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:	USGS_QMP-4.01 Rev 08 - Att4
7.2.6C.1.	Evaluating the supplier certificate of conformance.	USGS_N/A
7.2.6C.2.	Performing one or a combination of source verification, receiving inspection, or post-installation test.	USGS_QMP 7.04 Rev 03, ATT3

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Number	Requirement	M&O Implementation
7.2.6C.3.	Technical verification of the item or service.	USGS_QMP-7.04 Rev 03, ATT3
7.2.6C.4.	Surveillance or audit of the work.	USGS_QMP-7.04 Rev 03, 5.2
7.2.6C.5.	Review of objective evidence (such as certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.	USGS_QMP-4.01 Rev 8, 5.2.1
7.2.7	Certificate of Conformance - When a certificate of conformance is used to accept an item or service:	TRACE NOT REQUIRED
7.2.7A.	The certificate shall identify the purchased item or service to the specific procurement document.	NA
7.2.7B.:1s	The certificate shall identify the specific procurement document requirements met by the purchased item or service.	NA
7.2.7B.:2s	The procurement document requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.	NA
7.2.7C.	The certificate shall identify any procurement document requirements that have not been met together with an explanation and the means for resolving the nonconformances.	NA
7.2.7D.	The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose responsibilities and position are described in the supplier's QA program.	NA
7.2.7E.	The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's QA program.	NA
7.2.7F.:1s	Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item).	NA
7.2.7F.:2s	Verifications shall be conducted at intervals commensurate with the past quality performance of the supplier.	NA
7.2.8	Source Verification - The purchaser may accept an item or service by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.	USGS_QMP7.04, Rev 05, 5.1.5.1, ATT3

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Number	Requirement	M&O Implementation
7.2.8A.	Source verification shall be implemented consistent with the supplier's planned inspections, examinations, or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item.	USGS_QMP-7.04, Rev 03, Att3
7.2.8B.	Documented evidence of acceptance of source verified items or services shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.	USGS_QMP-7.04 Rev 03, ATT3
7.2.8C.	Source verification shall be performed by personnel qualified in accordance with Section 2.0, Quality Assurance Program.	USGS_QM-7.04, Rev 03, ATT3
7.2.9	Receiving Inspection - When receiving inspection is used to accept an item:	TRACE NOT REQUIRED
7.2.9A.	The inspection shall consider the results of source verifications and audits and the demonstrated quality performance of the supplier.	NA
7.2.9B.	The inspection shall be performed in accordance with established inspection implementing documents.	NA
7.2.9C.	The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.	NA
7.2.9D.	The inspection shall be planned and executed according to the requirements of Section 10.0, Inspection.	NA
7.2.9E.	Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.	NA
7.2.10	Post-Installation Testing	
7.2.10A.	When post-installation testing is used as a method of acceptance, the post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.	NA
7.2.10B.	The test shall be in accordance with the requirements of Section 11.0, Test Control.	NA
7.2.11	Control of Supplier Nonconformances - The purchaser and supplier shall establish and document the process for disposition of items that do not meet procurement document requirements according to the following requirements.	NA
7.2.11A.	The supplier shall evaluate nonconforming items according to the requirements of Section 15.0, Nonconformances.	NA

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Number	Requirement	M&O Implementation
7.2.11B.:1s	The supplier shall submit a report of nonconformance to the purchaser including supplier recommended disposition (e.g., use-as-is or repair) and technical justification.	NA
7.2.11B.:2s	Reports of nonconformances related to procurement document requirements, or documents approved by the purchaser, shall be submitted to the purchaser for approval whenever one of the following conditions exists:	TRACE NOT REQUIRED
7.2.11B.:2s 1.	Technical or material requirements are violated.	NA
7.2.11B.:2s 2.	A requirement in supplier documents, which have been approved by the purchaser, is violated.	NA
7.2.11B.:2s 3.	The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.	NA
7.2.11B.:2s 4.	The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.	NA
7.2.11C.	The purchaser shall disposition the supplier's recommendation.	NA
7.2.11D.	The purchaser shall verify implementation of the disposition.	NA
7.2.12	Commercial Grade Items - Where design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.	NA
7.2.12A.:1s	The commercial grade item shall be identified in an approved design output document.	NA
7.2.12A.:2s	An alternate commercial grade item may be applied, provided the responsible design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and the application.	TRACE NOT REQUIRED
7.2.12B.	Supplier evaluation and selection, when determined necessary by the purchaser based on the complexity and importance to safety, shall be in accordance with the requirements of the Subsection 7.2.2, Source Evaluation and Selection.	NA
7.2.12C.	Commercial grade items shall be identified in the procurement document by the manufacturer's published product description.	NA
7.2.12D.	After receipt of a commercial grade item, the purchaser shall ensure that:	NA

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Number	Requirement	M&O Implementation
7.2.12D.1.	Damage was not sustained during shipment.	NA
7.2.12D.2.	The item received was the item ordered.	TRACE NOT REQUIRED
7.2.12D.3.	Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.	NA
7.2.12D.4.	Documentation, as applicable to the item, was received and is acceptable.	NA

LMC 711-46-2-007

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Refer to Subsection 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. Identify the adverse condition.

The USGS procurement procedures provided for the use of vendors providing quality affecting services without having a documented QA program that met QARD requirements. Also, the links between the procurement procedures was not clear. See Car YM-96-C004.

2. Indicate *Where* the condition was found.

The condition was found at the USGS offices in Denver, CO.

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

The condition was found during Audit YM-ARC-96-10.

4. Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)

Potential repository.

5. Denote the specific area(s) or discipline(s) of the major program element the condition occurred. (e.g., engineering, design, ES&H)

Site Characterization

6. Determine if the condition is isolated or recurring.

Recurring

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

Programmatic - procedures

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

USGS

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

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

None

10. Determine the need for sketches or photographs.

N/A

11. Determine the need for laboratory tests.

N/A

12. Identify the physical evidence examined.

N/A

13. Note the relevant documents reviewed.

All FY96 USGS procurement documents, Horton letter 6/12/96 QSL Workshop Guidance.

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

N/A

15. Interviews conducted: Yes No

If Yes, refer to page 3 of this attachment.

No interviews were conducted.

RI or designee: (Print)

TOM CHANEY

Signature:

Date:

11/13/96

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ROOT CAUSE DETERMINATION QUESTIONNAIRE

Root Cause Code:
3AB

CAR No./DR No.
YM-96-C004

Root Cause:

Inadequate communication of Standards, Policies and Administrative Controls.

Justification or Rationale for Selected Root Cause:

The USGS had been issued deficiencies in this same area twice before. Each of these deficiencies were closed based on the revision of USGS procurement procedures. In addition the procedures were revised when the QARD was initially issued to address YMOQA comments. Because in each case DOE QA had reviewed and accepted the revised procedures, the USGS believed in each case it has procurement procedures that correctly addressed the QARD procurement requirements. Discussions with other technical program QA Managers identified that their procurement procedures also provide for the use of the methods used by USGS.

Designee: (Print)

N/A

Signature:

Date:

RI: (Print)

TOM CHANEY

Signature:

[Handwritten Signature]

Date:

11/15/96

OPEN PROCUREMENT DOCUMENT REVIEW

Attachment I

May 13 - 17, 1996

Purchase Order #	Supplier	QSL	Comments
96-SA-00192	Ball Aerospace System	Y	Calibration Services (Digital Multimeter). Standard QA Requirements for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00358	Ball Aerospace System	Y	Calibration Services (Hastings Power Supply). Standard QA Requirement for Suppliers of Calibration Services. Original PO had no acceptance reg'ts. Mod to PO required that calibration be done to manufacturer's specifications. Acceptance Reg'ts were added to P.O.: "Calibrate to USGS HP-271, RO"
96-SA-00259	Ball Aerospace System	Y	Calibration Services (Keithley Voltmeters, Voltage Sources, Voltage Dividers). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00200	Campbell Scientific Inc.	Y	Calibration Services (Dataloggers). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00203	Campbell Scientific Inc.	Y	Calibration Services (Dataloggers). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"

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Case 96-01-C-001

OPEN PROCUREMENT DOCUMENT REVIEW
May 13 - 17, 1996

Attachment I

Purchase Order #	Supplier	QSL	Comments
96-SA-00205	Campbell Scientific Inc.	Y	Calibration Services (Dataloggers). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00116	Eppley Laboratories	Y	Calibration Services (Radiometers & PSP Pyranometers). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate by comparing to appropriate standard and report results in accordance with Eppley procedures"
96-SA-1023	Golder Associates	N	PO contains a "QA Requirements" section which requires the supplier to implement applicable portions of the USGS QA Program (i.e.; QMP-201, QMP-2.08, QMP-3.03, QMP-5.01, QMP-5.05, QMP-6.01). PO reflects Extended Staff.
96-SA-00498	Desert Research Institute	Y	Analytical Services (Radiocarbon Age Dating). Standard QA Requirement for Suppliers of Analytical Services. Additional requirements specified in technical contract that DRI will perform analysis in accordance with the DRI QA Program as accepted by USGS, with the exception of QA Elements 4 and 18. Acceptance Requirements are included in the Statement of Work. SER prepared to delete requirements for QA Elements 4, 7 and Supp I from QSL.

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CAR KM-96-C-005

OPEN PROCUREMENT DOCUMENT REVIEW
May 13 - 17, 1996

Attachment I

Purchase Order #	Supplier	QSL	Comments
96-SA-00517	Beta Analytical Inc.	Y	Analytical Services (AMS Analysis C14). Standard QA Requirement for Suppliers of Analytical Services. No QA attachment in PO. This is covered by CAR YM-96-C004. Requirement that Beta work to own QA program.
96-SA-00561	Beta Analytical Inc.	Y	Analytical Services (AMS Analysis C14). Standard QA Requirement for Suppliers of Analytical Services.
96-SA-00070	Satec Systems	Y	Calibration Services (Load Frame). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00133	John Fluke Mfg.	Y	Calibration Services. (Multimeter). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00136	Environmental Research Assoc.	N	This P.O. is being canceled. USGS no longer needs the services of this supplier.
96-SA-00515	Scott Specialty Gases	Y	Material Supplier. (Speciality Gases & Standards). Standard QA Requirement for Suppliers of Calibration Services. Acceptance criteria documented in PO.

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CAR YM-96-C-004

OPEN PROCUREMENT DOCUMENT REVIEW
May 13 - 17, 1996

Attachment I

Purchase Order #	Supplier	QSL	Comments
96-SA-00156	Setra Systems, Inc.	Y	Calibration Services. (Barometers). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibrate to Manufacturer's Specifications"
96-SA-00230	University of Colorado	N	Analytical Services. (Pore-Water Samples). Supplier has no documented QA Program and USGS did not require supplier to implement USGS QA program requirements. USGS implemented QC Plan on this supplier. USGS 96-D002.
96-SA-00036	Huffman Labs, Inc.	N	Analytical Services. (Analysis of Cation, Anion, and Lithium Samples). Supplier has no documented QA Program and USGS did not require supplier to implement USGS QA Program requirements. USGS implemented QC Plan on this supplier. USGS 96-D003.
96-SA-00387	Setra Systems, Inc.	Y	Calibration Services. (Pressure Transducer). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. No action regarding acceptance requirements taken since PO is complete.
95-SA-00585	Intertyme Metrology Laboratory Inc.	Y	Calibration Services. (Decade AC/DC Resistor). Standard QA Requirement for Suppliers of Calibration Services.
96-SA-00452	Certified Balance Service	Y	Calibration Services. (Balance Equipment). Standard QA Requirement for Suppliers of Calibration Services. No acceptance requirements in PO. Acceptance Requirements were added to P.O.: "Calibration to Manufacturer's Specifications".
96-SA-00496	Mildred Murray	N	Augmented staff (i.e.; personal services contract) was used in the downsizing of the LRC.

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Car Ym-96-C-004

CLOSED PURCHASE DOCUMENT REVIEW
June 10 - 14, 1996

Attachment 2

PURCHASE ORDER #	SUPPLIER	QSL	COMMENTS
95-SA-01585 Modification	Intertyme Metrology Laboratory, Inc.	Y	Calibration Services (AC/DC Decade Resistor). Standard QA requirements for suppliers of calibrations. Acceptance requirements were referenced in PO.
1434-CR-95-SA-544	Intertyme Metrology Laboratory, Inc.	Y	Calibration Services (AC/DC Decade Resistor). Standard QA requirements for suppliers of calibrations. Appropriate quality and technical requirements included in PO.
1434-CR-95-SA-01715	Mountain States Micrographics	Y	Reprocess and duplication of film of seismic data. Quality and technical requirements referenced in PO. Removed from QSL, June 1996.
96-SA-00526	Barbara Hersch	N	Augmented Staff (i.e., personal services contract). Used for training and document control. QA requirements referenced in PO.
1434-CR-96-SA-00510	Certified Balance Service	Y	Calibration Services. Balance Calibration and Repair. Inadequate QA requirements in PO. QA requirements included in subsequent PO 96-SA-00452
1434-CR-SA-00434	Paul Vander Heijde	N	Augmented Staff (i.e., personal services contract). Used for technical review of ground water flow model. Qualification requirements missing. DR# USGS-96-D004.
94-PO-0078	NOSAMS McLean Laboratory	N	Analytical laboratory. Radiocarbon analysis. PO modification. July 19, 1994, canceled PO. Work never done.

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Case 96-96-C-009

CLOSED PURCHASE DOCUMENT REVIEW
June 10 - 14, 1996

Attachment 2

PURCHASE ORDER #	SUPPLIER	QSL	COMMENTS
1434-CR-96-SA-00307	Dr. John F. Schneider	N	Augmented Staff (i.e. personal services contract). Used for technical review of earthquake data. Qualifications not documented. DR# USGS-96-D004.
1434-CR-96-SA-00405	Norman Abrahamson	N	Augmented Staff (i.e., personal services contract). Used for technical review of earthquake data. Qualification not documented. DR# USGS-96-D004.
1434-CR-96-SA-00371	Beth Wildman	N	Augmented Staff (i.e., personal services contract). Used for technical review of thermoluminescence analysis of samples. Qualification not documented. DR# USGS-96-D004.
1434-CR-96-SA-00517	Beta Analytical	Y	Analytical Laboratory. Analysis 20-40 Calcium Carbonate samples. No QA requirements attached to PO. CAR# YMQAD-96-C004.
1434-CR-96-SA-496	Mildred Murray	N	Augmented staff (i.e., personal services contract). Used for review and oversight in elimination of duplicate records. Appropriate requirements in PO.
1434-CR-96-SA-00230	University of Colorado INSTARR	Y	Analytical laboratory. Analysis of PORE water extracted from UZ core. Inadequate requirements in PO. CAR# YMQAD-96-C004.
96-C-40098	Desert Research Institute	Y	Analytical Services. Radiocarbon Age Dating. No revisions or work done to contract after May 1993. Letter dated May 1996, terminated contract. Subsequent PO# 96-SA-00498 issued.

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Car Ym-96-C-004

CLOSED PURCHASE DOCUMENT REVIEW

June 10 - 14, 1996

Attachment 2

PURCHASE ORDER #	SUPPLIER	QSL	COMMENTS
95-C-40195	Pacific Western Technologies	N	Augmented Staff (i.e., personal services contract). Support studies 8.3.1.4.2.1, 8.3.1.4.2.2., 8.3.11.7.3.1, 8.3.11.7.4.5, and 8.3.1.5.1.4. Appropriate requirements referenced in PO.
94-C-40137	Foothill Engineering Consultants	N	Augmented Staff (i.e., personal services contract). Support studies 1.2.3.3.1, 8.3.1.2.3.1, 8.3.1.2.2.1, 8.3.1.2.1.1, and 8.3.1..2.2.3.1. Appropriate requirements referenced in PO.
96-SA-00453	Pacific Engineering & Analysis	N	Augmented Staff (i.e., personal services contract). Used for technical review of earthquake scenario motion data. Appropriate requirements referenced in PO.
96-SA-00510	Certified Balance Service	Y	Calibration Services (Balance equipment). Standard QA requirements for suppliers of calibrations services. No acceptance requirements in PO. Acceptance requirements added to subsequent PO# 96-SA-00452.
96-SA-00036	Huffman Laboratories	Y	Analytical Laboratory. Analysis of cation and ion concentrations in small water volumes by ICP/IC methods. Inadequate requirements in PO. CAR# YMQAD-96-C004.

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Car Ym-96-C-004

**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>1. Organization. QARD 1.2.3 - Quality shall be achieved and maintained by those who have been assigned responsibility for performing the work. Quality achievement shall be verified by persons or organizations not directly responsible for performing the work.</p>	<p>Provide a description of the supplier's organizational structure and define responsibilities for the personnel verifying quality achievement. Personnel who perform verification of quality achievement must be independent from those performing the work.</p>
<p>2. QA Program. A documented QA program shall be planned, implemented and maintained. The program shall identify the activities and items to which it applies. The establishment of the program shall provide control over activities affecting quality to an extent consistent with their importance.</p> <p>The program shall provide for indoctrination and training, as necessary, of personnel performing the activities affecting quality to assure that proficiency is achieved and maintained.</p>	<p>The supplier must have a documented QA program that addresses the topics presented in the purchase document to the degree appropriate for the nature, scope, and complexity of the activity.</p> <p>Provide for indoctrination, training, and qualification of personnel performing the activities to assure suitable proficiency is achieved and maintained prior to performing the work.</p>
<p>3. Design Control. N/A</p>	<p>N/A</p>
<p>4. Procurement Document Control. Procurement documents and changes thereof are reviewed and approved to insure inclusion of appropriate scope, technical and QA requirements. (QARD 4.2.1 applies to the extent necessary based upon an evaluation using QARD 2.2.4.)</p>	<p>Describe the approach used to assure that scope of work, technical and quality requirements are incorporated into procurement documents and changes to the documents. Include requirements to document the evaluation and selection of suppliers prior to the award of a contract/purchase order. Methods used to ensure that received services meet requirements shall be described. The procurement documents for services directly supporting this procurement work shall incorporate appropriate YMP USGS QA program requirements.</p> <p>The following documentation is required:</p> <p>Supplier QA Program document (Submit for acceptance prior to start of work) Calibration Certificate and calibration reports QA records such as: implementing documents; equipment calibration; analytical results; sample tracking; training; qualification; audit reports; corrective actions; notebooks; logbooks. (Retain at least 3 years).</p>

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100-7-96-001-244

COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>5. Implementing Documents. QARD 5.2 REQUIREMENTS Work shall be performed in accordance with controlled implementing documents</p> <p>5.2.1 Type of Implementing Documents: The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Implementing documents include documents such as procedures, instructions and drawings.</p> <p>5.2.2 Content of Implementing Documents: Implementing documents shall include the following information as appropriate to the work to be performed.</p> <ul style="list-style-type: none"> A. Responsibilities and organizational interfaces of the organizations affected by the document. B. Technical and regulatory requirements. C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and operations. The organization responsible for preparing the document shall determine the appropriate level of detail. D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished. E. Prerequisites, limits, precautions, process parameters, and environmental conditions. F. Quality verification points and hold points. G. Methods of demonstrating that the work was performed as required (such as provisions for recording inspections and test results, check-off lists, or sign-off blocks). H. Identification of QA records generated by the implementing document. I. Identification of associated items and activities. <p>5.2.3 Review and Approval of Implementing Documents: Implementing documents shall be reviewed, approved, and controlled in accordance with 6.</p> <p>5.2.4 Compliance with Implementing Documents: Individuals shall comply with implementing documents, however; When work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an undesirable situation, the work shall be stopped. Work shall not resume until the implementing document is changed to reflect the correct work practices.</p>	<p>Provide for conducting activities in accordance with documented approved implementing documents (e.g. procedures). These implementing documents shall consider the appropriateness of the following:</p> <ul style="list-style-type: none"> A. Responsibilities and organizations affected by the document. B. Technical requirements. C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and operations. The organization responsible for preparing the document shall determine the appropriate level of detail. D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished. E. Prerequisites, limits, precautions, process parameters, and environmental conditions. F. Quality verification points and hold points. G. Methods of demonstrating that the work was performed as required (such as provisions for recording inspections and test results, check-off lists, or sign-off blocks). H. Identification of QA records generated by the implementing document. I. Identification of associated items and activities. <p>Describe the methods used for preparation, review, approval and control of implementing documents. This process must include: methods used for ensuring that only the latest revision is used; and, methods used to ensure that documents are reviewed for adequacy, correctness, and completeness.</p>
<p>6. Document Control. Implementing documents and documents that specify technical requirements or quality requirements shall be controlled to ensure the current version is used. Those documents shall be reviewed against established criteria that consider applicability, correctness, technical adequacy, completeness, accuracy; and compliance with requirements established by documents such as standards, etc. The review shall be performed by individuals technically competent in the subject area; and review shall be performed by someone other than the preparer.</p>	<p>See 5. Above</p>

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UAE YMP-46-C-004

**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>7. Control of Purchased Items and Services. Application of the requirements in this section should be tailored to match the supplier's scope and importance and complexity of subtier procurements. QARD 2.2.4 should be used as the criteria for applying these requirements. Where possible, suppliers should be encouraged to procure from QSL suppliers.</p>	<p>See 4. Above</p> <p>Where possible sub-tier procurements should be with suppliers that are approved by the YMP-USGS QA Office.</p> <p>The supplier will identify any spare part or replacement parts or assemblies and the appropriate technical and QA requirements/information required for ordering.</p> <p>The supplier shall agree to allow YMP-USGS personnel, the NRC, the DOE or their representatives, upon reasonable notification, access to supplier facilities and records to perform inspections, audits, or surveillances to verify QA program compliance.</p> <p>YMP-USGS verification activities shall not relieve the supplier of the responsibility for verification of quality achievement.</p>
<p>8. Identification and Control of Items. N/A</p>	<p>Same</p>
<p>9. Control of Special Processes. N/A</p>	<p>Same</p>
<p>10. Inspection. N/A</p>	<p>Same</p>
<p>11. Test Control. N/A</p>	<p>Same</p>

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ARC YN1-96-C-001

**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS OMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>12. Control of Measuring and Test Equipment. M&TE including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards. Software developed or modified by the user shall be controlled in accordance with Supp. I. If no nationally recognized standards or physical constants exist, the basis of calibration shall be documented.</p> <p>Calibration standards shall have a greater accuracy than the M&TE being calibrated. If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements. The basis for calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.</p> <p>The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. For M&TE used in one-time-only applications, the calibration shall be done both before and after use.</p> <p>A calibration or calibration check shall be performed when the accuracy of the calibrated M&TE is suspect.</p> <p>Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration.</p> <p>Calibrated M&TE shall be uniquely identified to provide traceability to its calibration data.</p> <p>Updates to software contained in M&TE that effect calibration, require recalibration of the equipment prior to use.</p> <p>The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.</p> <p>M&TE shall be considered to be out-of-calibration and not used if any of the following exists: The calibration due date or interval has passed without recalibration; the device produces results known to be in error.</p>	<p>Describe the methods used to assure that M&TE, 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.</p> <p>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.</p> <p>NOTE: The following is applicable only to calibration suppliers: The supplier's calibration documentation (e.g. Certificate of Calibration) shall include the following: YMP-USGS Purchase Order Number Name of the organization (company) performing the calibration Name or identification of the person performing the calibration The date the calibration was performed The identification of the equipment being calibrated (such as manufacturer, type, model, serial number, or other unique identifier). Identification of calibration standard and NIST traceability or similar information when using other recognized standards and calibration procedure or method used. 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 out-of-calibration, as submitted, and a statement or clear indication that the recalibrated equipment is within tolerance in all operating ranges. An authenticating dated signature of the person who is responsible for the service.</p>

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Car Ym-46-26-004

**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>Out-of-calibration M&TE shall be controlled. The controls shall include the following: Out-of-calibration M&TE shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated; When M&TE is found out-of-calibration during recalibration, the validity of results obtained using the equipment since its last calibration shall be evaluated. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. The evaluation shall be documented. If any M&TE is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.</p> <p>When M&TE is lost, the validity of results obtained using the equipment since its last calibration shall be evaluated. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. The evaluation shall be documented.</p> <p>M&TE shall be properly handled and stored to maintain accuracy.</p> <p>Calibration and control shall not be required for rulers, tape measures, levels, and other normal commercial equipment that provides adequate accuracy.</p> <p>M&TE calibration documentation shall include: Identification of M&TE calibrated; Traceability to the calibration standard used for calibration; Calibration data; Identification of the individual performing the calibration; Identification of the date of calibration and the recalibration due date or interval, as appropriate; Results of calibration and statement of acceptability; Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE including evaluation results, as appropriate; Identification of the implementing document (including revision level) used in performing the calibration.</p>	

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Copy YMP-4.01-R8-004

**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>13. Handling, Storage, and Shipping. For Calibration Services see Sec. 12.2.5-M&TE shall be properly handled and stored to maintain accuracy.</p> <p>For Analytical Services see Supp II, 2.6: Handling, storage, cleaning, packageing, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents. If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, and preservation shall be identified.</p> <p>Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples as necessary to adequately identify, maintain, and preserve the sample.</p> <p>Markings and labels shall indicate the presence of special environments or the need for special contols if necessary.</p> <p>If required of particular samples, special equipment and special protective environments shall be specified and provided.</p> <p>Special Handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.</p>	
<p>14. Inspection, Test and Operating Status. N/A</p>	<p>Same</p>

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**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>15. Nonconformances. For Calibration Services see Sec. 12.2.3 Out-of-Calibration M&TE. M&TE shall be considered to be out-of-calibration and not used if any of the following exists: The calibration due date or interval has passed without recalibration; the device produces results known to be in error. Out-of-calibration M&TE shall be controlled. The controls shall include the following: Out-of-calibration M&TE shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated; When M&TE is found out-of-calibration during recalibration, the validity of results obtained using the equipment since its last calibration shall be evaluated. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. The evaluation shall be documented. If any M&TE is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.</p> <p>For Analytical Services see Supp II, 2.7 Disposition of Nonconforming Samples. Samples that do not meet requirements specified in work controlling documents shall be documented, evaluated, identified, and segregated in accordance with Sec. 15. The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is" or "discard."</p>	<p>The supplier shall 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>The supplier shall notify the YMP-USGS technical contact when the supplier identifies any nonconformances (deviations) from the procurement document. Nonconformances where the proposed disposition is "repair" or "use-as-is" require YMP-USGS approval.</p>
<p>16. Corrective Action. See Sec. 16.2.1 Identifying Conditions Adverse to Quality A condition adverse to quality shall be identified when the QARD or an implementing document requirement is not met.</p> <p>16.2.3 Conditions Adverse to Quality Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the QA organization for tracking. Responsible management shall determine the extent of the adverse condition and complete remedial action as soon as practical. The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied.</p> <p>16.2.5 Follow-up and Closure Action The QA organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.</p>	<p>Provide a control system for identifying and documenting deviations from technical and quality implementing documents. Adverse conditions shall be reported to appropriate management responsible for the condition who shall determine the extent of the condition and take remedial actions. The QA organization or other independent organization shall verify that the corrective actions have been completed.</p>

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**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS OMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>17. QA Records. Records that furnish documentary evidence of quality shall be specified, prepared, and maintained for a period of three years. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for records transmittal, distribution, retention, maintenance, and disposition shall be established and documented. Records that need to be maintained as lifetime project records should be acquired as part of the procurement.</p>	<p>Describe methods used 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, maintenance, and disposition shall be established and documented.</p> <p>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.</p> <p>QA records shall be reviewed to ensure that they are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.</p> <p>Corrections to previously transmitted QA records, including documents that will become QA records, shall include the initials or signature of the individual authorized to make the correction and the date the corrections were made.</p>
<p>18. Audits. Planned and scheduled audits shall be performed to verify compliance with all aspects of the QA program and to determine its effectiveness. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.</p>	<p>Planned and scheduled audits to verify compliance with the QA program requirements and determine its effectiveness shall be performed at least annually or once during the life of the contract. The audits shall be performed in accordance with prescribed procedures or checklists by qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to responsible management. Responsible management shall take action to correct identified deficiencies in accordance with Corrective Action (para 15 above) and follow-up action to verify corrective action shall be taken in accordance with Corrective Action (para 15 above)</p> <p>If the supplier does not have a means of providing for an annual audit, USGS may elect to request that DOE conduct the audit.</p>
<p>Supp. I Software. Calibration Services N/A. The software version used to support a calibration shall be traceable to the results and changes to software shall be checked to determine that the software produces correct results.</p> <p>Analytical Services: Applicable. Analytical results shall be traceable to the software version used to produce them and change to software shall be checked to determine that the software produces correct results. (NOTE: Supplement I of QARD is too long to place in this matrix)</p>	<p>Provide evidence that data manipulation programs produce intended results. Software to be developed or modified for YMPB site characterization activities shall meet the requirements of the YMP-USGS-QMP-3.03, Software.</p>

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LAB YMP-46-C-004

COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>Supp. II Sample Control. Calibration Services: N/A.</p> <p>Analytical Services: Applicable. Samples shall be controlled and identified in a manner consistent with their intended use. These controls shall identify responsibilities including interfaces between organizations for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use. Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.</p> <p>Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents. Sample traceability shall ensure that the sample can be traced at all times from its collection through final use.</p> <p>Identification shall be maintained on the samples or in a manner which ensures that identification is established and maintained. Samples shall be identified from their initial collection through final use. Sample identification is documented and checked before released for use. Sample identification methods shall include use of physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control).</p> <p>Physical markings, when used, shall be applied using materials and methods that provide a clear and legible identification; Not detrimentally affect the sample content or form; Be transferred to each identified sample part when the sample is subdivided.; and Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.</p> <p>The controls for samples shall address the following, as applicable: If documents contain specific identification or traceability requirements, those specified controls shall be implemented. If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life. If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with planned duration and conditions of storage. These methods shall provide for, as applicable: Maintenance or replacement of markings and ID tags damaged during handling or aging; Protection of ID markings subject to excessive deterioration resulting from environmental exposure; Updating related documentation.</p> <p>Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified</p>	<p>Describe the process for receiving, handling, tracking samples submitted by USGS. The disposition of samples that do not conform to conditions required for the requested analysis shall be documented, and provided to the USGS.</p> <p>Data (analysis) shall be properly recorded, received, stored, submitted to USGS requestor, and stored in accordance with QA Records Section above.</p> <p>Describe the methods for creation of standards, conduct of analyses, calibration of instruments, and documentation of software.</p> <p>Describe the supplier's internal and external quality control methods used to verify the analytical results are correct.</p> <p>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.</p> <p>Unless otherwise stated in the purchase document, it is not a requirement that the samples be returned to YMP-USGS.</p>

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**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>Handling, storage, cleaning, packageing, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents. If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, and preservation shall be identified.</p> <p>Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples as necessary to adequately identify, maintain, and preserve the sample.</p> <p>Markings and labels shall indicate the presence of special environments or the need for special contols if necessary.</p> <p>If required of particular samples, special equipment and special protective environments shall be specified and provided.</p> <p>Special Handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.</p> <p>Samples that do not meet requirements specified in work controlling documents shall be documented, evaluated, identified, and segregated in accordance with Sec. 15 .</p> <p>The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is" or "discard."</p>	
<p>Supp. III Scientific Investigation. N/A.</p>	<p>When technical or other implementing procedure are not utilized, scientific investigation activities shall be documented in a scientific notebook that provides a description of the work as performed and the results obtained.</p> <p>Data shall be identified in a manner that provides traceability to associated documentation and computer codes.</p>
<p>Supp. IV Field Surveying. N/A</p>	

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**COMPARISON OF QSL WORKSHOP GUIDANCE TO
YMP-USGS QMP-4.01, R8**

<p>WORKSHOP Calibration Services and Analytical Services are the same unless stated otherwise</p>	<p>YMP-USGS-QMP-4.01, Rev. 8</p>
<p>Supp. V Control of the Electronic Management of Data. Calibration Services: N/A</p> <p>Analytical Services: Applicable. This requirement should be met if the supplier is storing analytical results for the purchaser. Establish controls to ensure: completeness and accuracy of the data input; completeness and accuracy of subsequent changes to data input; security of the data is maintained including integrity of the data; and when data is retrieved using a query language, the query shall be checked to ensure it satisfies the purchaser's requirements for its intended use.</p>	

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Conclusion: CAR YM-96-C004 Corrective Action Verification

Based on this evaluation of the completed remedial actions, and implementation of the USGS Procurement Action Plan, CAR YM-96-C004 is closed. The remaining corrective actions identified in this verification report will be resolved and tracked via the referenced deficiency documents.

Verified by: *Kevin A. Hodges* Date: 5/28/97
QAR: *[Signature]* Date: 5/29/97

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CAR YM-96-C-004 Verification of Corrective Action

The following verification report addresses the CAR YM-96-C-004 Remedial Actions (Block 14) taken to correct the eight conditions documented in the Description of Condition (Block 6), and evaluates the implementation of the USGS procurement action plan, which was developed to address the Extent of Condition and Impact (Block 15), and the Action to Preclude Recurrence (Block 17).

Remedial Actions:

1. As committed, QMP-4.01, Revision 8, and QMP-7.04, Revision 3 were approved as part of the USGS procurement Action Plan, with an effective date of October 1, 1996. Based on the revision of QMP-4.01, the three alternative methods discussed in condition deficiency #1 are allowable only for acceptance of services, and not as an alternative to supplier approval. These procedures were evaluated by OQA and found acceptable via DOE letter YMQAD:RBC-2454, dated 8/21/96.

Based on review during Audit USGS-ARC-97-15, USGS procurement documents initiated since the effective date of QMP-4.01, Revision 8, were verified to be in compliance with that revision, with exception of two areas that are documented and tracked via USGS Deficiency Reports (USGS-97-D-003 and D-005). Also, at the time of this verification, the two subject procedures have been combined into a single draft QMP-4.01, Revision 9. This drafted procedure aims to further clarify the use of Source Verification Plans and Sample Analysis Quality Control Plans as methods of receipt. The remedial action for condition #1 is adequate to address the documented deficiency.

2. The finding documented that there was no evidence of a QA review of two USGS Purchase Orders (POs) for Kruger Enterprises and Huffman Labs, Inc. Evidence of a QA review of the Kruger procurement modification has been provided by the USGS. Apparently, the procurement was processed under QMP-4.01, Revision 6, which did not utilize the QA review stamp. Revision 6 required use of a "Final Procurement Review" form (Attachment 2). The provided form documents a QA review of the Kruger modification on 5/23/95, which was prior to issuance of this CAR.

However, no evidence could be produced documenting a QA review for the Huffman PO. As remedial action, and per the USGS procurement Action Plan, a review of all existing procurement documents (including Huffman) was conducted to ensure that the appropriate QA requirements had been imposed. Based on this review, DR USGS-96-D-002 was generated to document that the Huffman procurement was issued without evidence of a documented QA program or appropriate QA controls. A QC Sample Plan had been imposed, which was unacceptable based on the current QA requirements. A commitment was made in the DR to identify any impacts on technical data and to issue a FY97 Huffman PO in accordance with QMP-4.01, Revision 8. Based on the resolution of the DR, the FY96 PO was closed and an FY97 PO with appropriate QA requirements and reviews was issued. It was determined that there was no impact on technical data, since "The analysis of the QC sample results indicates that the analysis results were acceptable for their intended use."

Based on the status of Huffman and Kruger procurements, the remedial actions are complete. However, PR USGS-97-P-002 was issued on 4/2/97, documenting that a group of FY97 procurement modifications were issued without the required QA approval stamp. The PR was closed during Audit YM-ARC-97-15 and reissued as DR USGS-97-D-005, when an additional instance was identified by the audit team. Investigation during the audit revealed that USGS QA personnel were actively involved in these procurement modifications, as they involved addition of Attachment 5 QA requirements. Although the DR is similar to CAR condition #2, the failure to apply the QA stamp to these modifications was an oversight by a newly assigned USGS individual. OQA management has determined that the deficiency will be tracked and resolved independent of this CAR via DR USGS-97-D-005. The remedial action for condition #2 is adequate to address the documented deficiency.

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3. The cited Beta Analytic, Inc. PO contained a statement that Beta will work to the QA program as approved by USGS. This statement was considered adequate by USGS because Beta and its QA manual (Revision 1), dated 1/1/95, were listed on the OCRWM Qualified Suppliers List (QSL). Attachments 6, 7, and 8 were deleted from QMP-4.01 in Revision 8 and replaced by Attachment 5. Although a proceeding PO and modification issued to Beta (PO 1424-CR-96-SA-00561) was verified to contain Attachment 5 of QMP-4.01, Revision 8, no modification had been initiated for PO #1434-CR-96-SA-0517 to address the documented deficiency. During Audit USGS-ARC-97-15, a PO modification was generated by USGS, which appended the Attachment 5 QA requirements to the existing PO. The remedial action for condition #3 is adequate to address the documented deficiency.
4. This deficiency documented a supplier discrepancy that was identified but not documented per AP-16.1Q or AP-16.2Q. Although the discrepancy was not appropriately documented, the procurement was not pursued by USGS. However, a UNLV Harry Reid Center contract exists with the CRWMS M&O. The USGS notified the M&O of the identified deficiency via letter (Chaney to Ruth), dated 10/25/96. The Harry Reid Center is also part of DR YM-96-D051, which documents a failure by USGS to generate/complete/submit records, including supplier evaluation records. As part of the resolution of DR YM-96-D051, impact evaluations were generated by USGS QA for those records that could not be retrieved or regenerated. The remedial action for condition #4 is adequate to address the documented deficiency.
5. This deficiency documented that USGS procurement and calibration procedures failed to require that standards and procedures/revision levels used to perform calibrations be identified in the calibration documentation. Based on review of Attachment 5 of QMP-4.01, Revision 8, the identification of standards and calibration procedures or methods used are required to be included with the supplier's calibration documentation; e.g., Certificate of Calibration. Based on previous review by OQA during Surveillance YMP-SR-96-025, October 7 through 9, 1996, Certified Balance System (CBS) was verified to include a copy of the procedure used on the backside of its Certificates of Calibration. The noted deficiency regarding the State of Colorado Department of Agriculture was attributed to missing certification documentation, which was verified during the surveillance to have been retrieved. Calibration documentation reviewed during Audit USGS-ARC-97-15 contained standards used with NIST traceability, procedure/revision, and the technician performing the calibration. The remedial action for condition # 5 is adequate to address the documented deficiency.
6. Based on Surveillance YMP-SR-96-025, it was verified that updated SERs for all USGS suppliers had been completed and submitted to OQA. A procurement workshop conducted in Las Vegas, NV, April 15-16, 1996, established guidelines to be used as the basis for determining supplier qualification (Reference DOE letter: OQA:RBC 2008, dated 6/22/96). The USGS revised their procurement procedures to address these guidelines. On May 13-15, 1996, an OQA representative reviewed all USGS open POs and Memorandum of Agreements (MOAs) to determine if appropriate QA requirements had been imposed on suppliers (Reference SAIC letter: WWH: cmw:L96-034, dated 5/20/96). Although not clearly documented in the referenced report, discussion with the OQA representative who performed that review revealed that the review evaluated whether procurement documents imposed appropriate QA requirements on the supplier per QMP-4.01, Revision 7. Upon approval of Revision 8, a comparison was made between Revision 7 and Revision 8, and it was determined that there were no changes that impacted existing or previous POs. The remedial action for condition #6 is adequate to address the documented deficiency.
7. Updated SERs were submitted to OQA for both Beta Analytic, Inc., and Campbell Scientific, Inc., dated 3/28/96, 7/22/96, and 8/24/96 (Beta); and 3/28/96 and 12/22/96 (Campbell).

Per the Beta 8/24/96 SER, AMS Analysis is to be performed by LLNL-CAMS. This determination was made based on DR YM-95-D009, which, in part, documented that Beta had no program for the qualification and pass down of applicable QA program

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requirements to its sub-tier suppliers. Beta was utilizing LLNL as its supplier for AMS Analysis, but there was no contract between the two parties for performing this service. The DR was closed on 3/5/97, and LLNL-CAMs was added to the OCRWM QSL for providing the service as subcontracted by Beta.

The 3/28/96 Campbell SER imposed restrictions on Campbell until an acceptable response to DR YM-96-D035, issued 2/6/96, was received. The DR documented deficiencies in implementation of QA requirements by Campbell. An acceptable response was accepted on 4/22/96, and the OCRWM QSL restriction was then lifted. The 12/22/96 SER indicates qualification with no restrictions. The remedial action for condition #7 is adequate to address the documented deficiency.

8. This deficiency documented inadequacies of QMP-7.04, Revision 2, in providing sufficient qualitative and quantitative acceptance criteria for determining that activities were satisfactorily accomplished. Revision of the USGS procurement procedures was accomplished via the USGS Procurement Action Plan. QMP-4.01 and QMP-7.04 were revised to Revisions 8 and 3, respectively. These procedures were evaluated by OQA and found acceptable via DOE letter YMQAD:RBC-2454, dated 8/21/96. The remedial action for condition #8 is adequate to address the documented deficiency.

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Verification of Implementation of the "Action for U.S. Geological Survey (USGS) Procurement Activities Relative to Corrective Action Request YMQAD-96-C004"

The USGS Procurement Action Plan was developed as a collaborated effort between OQA and the USGS, with the intent of preventing recurrence of the conditions identified in the CAR. The implementation of the plan for each committed action is as follows:

A. Revisions to USGS Procedures

1 & 2) QMP-4.01, Revision 8 and QMP-7.04, Revision 3 were evaluated by OQA and found acceptable via DOE letter YMQAD:RBC-2454, dated 8/21/96. The procedures were issued with an effective date of 10/1/96.

B. Corrective Actions for New or Amended Existing Quality-Affecting Procurements

1) During Audit USGS-ARC-97-15, recent procurements, including modifications issued since the effective date of QMP-4.01, Revision 8 and QMP-7.04, Revision 3 (10/1/96), were evaluated for compliance with the new revisions. Based on the review, it was determined that USGS is satisfactorily implementing the revised procedures in regard to imposing appropriate QA requirements on its suppliers. Reviewed procurement files included QMP-4.01, Attachment 5, for suppliers of calibration and analytical services, which is based on the procurement workshop conducted in Las Vegas, NV, on April 15-16, 1996.

2) Updated SERs were generated and submitted to OQA, as committed.

3) As committed, the USGS submitted and obtained concurrence from OQA prior to issuance of any POs. This condition was lifted based on OQA Surveillance YM-SR-97-04, which stated, "Based on the reviews to date, OQA is satisfied that appropriate QA requirements are being incorporated into the POs. Consequently, the USGS is relieved of the responsibility to send POs to OQA for that review."

4) The USGS committed to submitting a copy of the PO and a copy of the documentation received from a supplier to OQA upon receipt and acceptance by USGS of analytical, calibration, and/or other services. USGS QA initiated a surveillance (USGS-97-003-IS) of receipt inspection. The surveillance resulted in issuance of DR USGS-97-D003, which documented failure to complete receipt documentation in accordance with QMP-4.01, Revision 8. The DR response extended the deficiency to QMP-4.02, which covers USGS Work Agreements, including MOAs. Although this item of the action plan has not been completed, OQA management has determined that the remaining action will be better tracked and resolved via the open DR USGS-97-D003.

C. Corrective Actions for Procurements Already in Existence

1,2) On May 13-17, 1996, an OQA representative, in collaboration with USGS QA staff, reviewed all open POs and MOAs to determine QA classification, and if the supplier is: 1) on the OCRWM QSL; 2) working directly to its own approved QA program or working directly to the USGS QA program; and 3) not on the OCRWM QSL and/or not working directly to the USGS QA program, but has been found acceptable by other means. This review is documented on SAIC letter WWH:cmw:L96-034 (Hudson to Spence), dated 5/20/96.

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The review, which included suppliers of calibration and analytical services, verified that calibration procurements included appropriate QA requirements, with exception of receipt inspection requirements. Deficient POs were revised to include appropriate receipt inspection requirements prior to completion of the review. DRs (USGS-96-D002 and USGS-96-D003) were issued to document that two USGS suppliers of analytical services were not listed on the OCRWM QSL and had only a QC Sample Plan imposed by USGS. All other open procurements were found to contain appropriate QA requirements. Both DRs were closed prior to this verification.

The USGS performed its own procurement document review, which is largely based on the preliminary findings of the OQA reviewers; however, the USGS review, documented in USGS letter THC/RWC/aa (Craig to Horton), dated 11/14/96, reflects the updated status of the OQA reviewer's preliminary findings.

3) In addition to the reviews discussed above, OQA temporarily assigned an on-site representative to assist USGS with implementation of this action plan. During the months of July and August 1996, the representative assisted USGS in revision of its procurement procedures, and with review of existing procurement documents to ensure that appropriate technical detail and quality requirements were included.

4) Per the action plan, the USGS coordinated with the OCRWM QSL Coordinator to ensure that audits were scheduled and performed of USGS suppliers listed on the OCRWM QSL. Although there were deficiency documents issued to USGS suppliers, there were no disqualifying deficiencies; therefore, there were no instances of USGS suppliers being removed from the OCRWM QSL, and no evaluations performed for impact on completed work were required. As discussed earlier, updated SERs were submitted by the USGS to reflect the current status of its suppliers.

5) The reviews discussed in 1,2) above ensured that appropriate requirements were imposed on USGS suppliers that were not listed on the OCRWM QSL, and were indicated as working directly to the USGS QA program and procedures.

6) USGS deficiency documents were generated for two suppliers of analytical services (Huffman Labs, Inc. and the University of Colorado) that were not listed on the OCRWM QSL but implemented QC Sample Plans. The deficiencies (USGS-96-P016 and P017 superseded by USGS-96-D002 and D003) were resolved and closed during the implementation of the action plan.

7) This action plan commitment is the same as was stated in B.4 above. Although this item has not been completed, OQA management has determined that the remaining action will be better tracked and resolved via DR USGS-97-D003.

D. Actions for Completed Procurements

On June 10-14, 1996, another OQA representative, in collaboration with USGS QA staff, reviewed all closed POs and MOAs for the same criteria indicated in C.1 & 2 above. The review, documented on SAIC letter WWH:jkm:L96-042 (Hudson to Spence), resulted in identification of several problems. Those that could not be immediately resolved were related to personnel qualification and were documented by USGS on DR USGS-96-D004. At the time of this verification, the DR is open with a corrective action completion date of 5/30/97. OQA management has determined that the remaining corrective action will be better tracked and resolved independent of this CAR via DR USGS-96-D004.