



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
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AUG 21 1996

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Technical Project Officer
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EVALUATION OF U.S. GEOLOGICAL SURVEY'S (USGS) SUBMITTAL OF QUALITY MANAGEMENT PROCEDURES QMP-4.01, REVISION 8 AND QMP-7.04, REVISION 3

The Yucca Mountain Quality Assurance Division staff has evaluated subject USGS procurement procedures revised in response to Corrective Action Request (CAR) YM-96-C-004. In general, the procedures were found to be acceptable as submitted. As per your request, YMQAD has provided a verbal and a Lotus Notes concurrence to you on August 15, 1996 as to the acceptability of the procedures. Based on concurrence and notification, it is expected that Action Plan steps C.3 and D.2 will be completed on or before September 14, 1996. Additionally, in accordance with the original accepted USGS response relative to CAR YM-96-C-004, it is expected that all corrective actions by USGS will be completed on or before September 30, 1996.

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

Robert B. Constable

YMQAD:RBC-2454

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

Enclosure:
CAR YM-96-C-004

cc w/encl:
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rec'd, J Spraul

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8
CAR NO. **YMQAD-96-C004**
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QA: LOS

CORRECTIVE ACTION REQUEST

1 Controlling Document:

See various documents listed below

2 Related Report No.:

YM-ARC-96-10

3 Responsible Organization:

U.S. Geological Survey (USGS)

4 Discussed With:

T. Chaney / R. Craig

5 Requirement:

The following Quality Assurance program and procedural implementation deficiencies were found during the course of Audit YM-ARC-96-10. The requirements and the associated deficiencies correspond to the numbers given for each item.

1) QARD Section 4.0, paragraph 4.2.1, states: "Procurement documents issued by each Affected Organization shall include the following provisions, as applicable to the item or service being procured".

Paragraph 4.2.1.C (1), states: " A requirement for the supplier to have a documented QA Program that implements applicable QARD requirements prior to initiation of work. The extent of the QA Program shall depend on the scope, nature, or complexity of the item or service being procured".

6 Description of Condition:

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

2) Contrary to the above, the final Purchase Order (P.O.) # 1434CR-96-SA-00036 for Huffman Labs, Inc. and P.O. 1434CR-95-SA-0610 Amendment dated 23 May, 1995 for Kruger Enterprises provides no documented evidence of having received a review by the QA Office.

3) No documented evidence exists to show that Quality Assurance Requirements stipulated on Attachments 6, 7, or 8 were attached to the DI-1 Form United States Department of Interior Requisition within P.O. 1434CR-96-SA-0517 as procedurally required. Subject P.O. was issued to Beta Analytic, Inc..

4) Supplier Evaluation/Surveillance performed 9 August, 1995 documented on USGS letter dated 17 November, 1995 from T. H. Chaney Quality Assurance Manager Yucca Mountain Project to MS. Amy Smiecinski, QA Office Harry Reid Center for Environmental Studies documents a programmatic discrepancy that was not documented in accordance with AP-16.1Q or AP-16.2 Q.

7 Initiator:

John S. Martin

Date 03/29/96

9. Does a stop work condition exist?

Yes ___ No ☒ ; If Yes, Attach copy of SWO
If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

Describe those action necessary to correct those deficiencies identified within the CAR.

Implement those actions imposed by Attachment 1, "Corrective Actions To Be Performed Prior to Issuing New or Amending Existing Quality-Affecting Procurements."

Determine the root cause of the deficient conditions identified.

Determine those actions necessary to preclude recurrence for the deficiencies identified.

11 QA Review:

Date 4-5-96

12 Response Due Date:


10 ~~21~~ 4-5-96
20 Working Days from Issuance

13 Affected Organization QA Manager Issuance Approval:

Printed Name

RICHARD E. SPENCE

Signature



Date

4.8.96

ORIGINAL

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CORRECTIVE ACTION REQUEST

¹⁴ Remedial Actions:

SEE ATTACHED SHEET

¹⁵ Investigative Actions:

SEE ATTACHED SHEET

¹⁶ Root Cause Determination:

SEE ATTACHED SHEET

¹⁷ Action to Preclude Recurrence:

SEE ATTACHED SHEET

¹⁸ Response by:

Date 4/24/96

¹⁹ Corrective Action Completion Due Date

See attached sheet

²⁰ Response Accepted
QAR

Date 5/13/96

²¹ Response Accepted
AOQAM

Date 5/8/96

²² Amended Response Accepted
QAR

Date

²³ Amended Response Accepted
AOQAM

Date

²⁴ Corrective Actions Verified
QAR

Date

²⁵ Closure approved by:

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8 ☒ Corrective Action Request
☐ Stop Work Order

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CAR/SWO CONTINUATION PAGE

Block 5, Requirement, cont'd.

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

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

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

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

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

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

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

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

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

B. Traceability to the calibration standard used for calibration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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CAR/SWO CONTINUATION PAGE

Block 6, Description of Condition, cont'd

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

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

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

- (CBS) - weight 307.1 K. Futa 10/15/95

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.

8/12/96 Chris de France

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 clairified 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	Change to Attachment 8 and add a new Attachment 7 that reads: CRITERIA FOR REVIEW OF PURCHASE DOCUMENTS FOR APPROPRIATE QA REQUIREMNTS 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

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

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

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

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

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/NCLZ 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

Page _____ of _____

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

YMP USGS-QMP-4.01, R8

ATTACHMENT 7 TO FOLLOW

Page 1 of 1

PER JOHN MARTIN

**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. 96-4889-6227
5. ISSUING OFFICE (Address correspondence to) US GEOLOGICAL SURVEY BRANCH OF ACQUISITION & FEDERAL ASSIST. PO BOX 25046 - MS204C DENVER, CO 80225 Linda L. Criger (303)236-5900 x343		6. SHIP TO: (Consignee and address, ZIP Code) US GEOLOGICAL SURVEY BLDG 25 EXT E-14 DFC DENVER, CO 80225 SHIP VIA:	

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

00000182
CERTIFIED BALANCE SERVICE
4920 SOUTH JORDAN ROAD
UNIT 3
ENGLEWOOD, CO 80212
303-680-6608

8. TYPE OF ORDER

☒ A. PURCHASE -- Reference year _____

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:

☐ 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 issued subject to the terms and conditions of the above numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA

96-4889-24001

BOC: 253A

\$1,500.00

10. REQUISITIONING OFFICE

11. BUSINESS CLASSIFICATION (Check appropriate box(es))

☒ SMALL ☐ OTHER THAN SMALL ☐ DIS-ADVANTAGED ☐ 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. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	\$	AMOUNT (F)	\$	QUANTITY ACCEPTED (G)
0001	<p>DELIVER TO GORDON RATTRAY MS421</p> <p>BILLING CONTACT JOYCE GOLOS 303-236-0516 X250</p> <p>AUTHORIZED CALLER GORDON RATTRAY</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 PE16 MODEL PE160</p> <p>2 SARTORIUS BALANCES MODEL 1601 AMP-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

1700.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

1701.
\$ GRAND
TOTAL

22. UNITED STATES OF AMERICA
BY (Signature)

Linda L. Criger

23. NAME (Typed)

Linda L. Criger (303)236-5900 x343

TITLE: CONTRACTING/ORDERING OFFICER

NSN 7540-01-152-8083

50347-101

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

[illegible]

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

Page 1 of 5

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: _____

Page 2 of 5

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 documuments. 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 traceability to nationally recognized standards. Calibration standards shall have a greater accuracy than that required of the M&TE being calibrated.				
Calibration M&TE shall be uniquely identified to provide traceability to calibration data. The use of M&TE shall be documented. Measures shall be established to prevent the use of out-of-calibration M&TE. When M&TE is found to be out-of-calibration the validity of results using that equipment since its last calibration shall be evaluated.				

Supplier QA Plan Checklist

Supplier: _____

Date: _____

Page 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. 				
What are the supplier's calibration capabilities? What M&TE can be calibrated? Over what ranges? To what accuracies?				
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?				
Does the supplier have established methods for receiving, handling, storing, shipping and otherwise controlling YMP-USGS M&TE?				
Is the supplier willing to calibrate equipment in its as-received condition as well as after maintenance (before and after calibration)?				

Supplier QA Plan Checklist

Supplier: _____

Date: _____

Page 4 of 5

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
QUALITY ASSURANCE
SOURCE VERIFICATION PLAN

SVN: _____

Date: _____

Page 1 of 1

COMPLETE ONLY APPLICABLE ITEMS:

SUPPLIER: _____

P.O. _____
Number Date

DESCRIPTION: _____

Prepared by: _____ Date: _____

QA Manager Approval: _____ Date: _____

Technical Approval: _____ Date: _____

ELEMENTS TO BE VERIFIED:

ACCEPTABLE

UNACCEPTABLE

Verification has confirmed that the preceding activities are:

☐ Acceptable ☐ Unacceptable Ref: QDR _____

Verified by: _____ Date: _____

QAO Approval: _____ Date: _____



YMP-USGS SAMPLE ANALYSIS QUALITY CONTROL PLAN

Page 1 of

COMPLETE ONLY APPLICABLE ITEMS:

SUPPLIER: _____ PURCHASE ORDER NO. _____ DATE: _____

DESCRIPTION OF PLAN: _____

PURPOSE OF PLAN: _____

SCOPE OF PLAN: _____

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

PLAN DESCRIPTION

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

Results Reviewed By: _____ Date: _____

Reviewed By (QAO): _____ Date: _____

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.:1s	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.:2s	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.:1s	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 :II
4.2.1C.1.:2s	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 :II
4.2.1C.2.	A requirement for the supplier to incorporate the appropriate QARD requirements into any supplier-issued procurement document.	USGS_QMP-4.01 Rev 08 - Att5 :II.4

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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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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, 5.1.9.2
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

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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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

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

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

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

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