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.

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5.1 Pre-awards 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 I 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 attaches the appropriate QA requirements to 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 satified. 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 Vertification 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.

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

YMP-USGS
SUPPLIER CHECKLIST

SUPPLIER NAME: _____

DOCUMENT TITLE: _____

REVIEWED BY: _____ DATE: _____

REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
1.0 Organization				
The supplier shall include a description of the organizational structure and define responsibilities for verifying quality that are independent from those performing work.				
The supplier shall agree to allow YMP personnel, including the NRC, DOE, USGS, and other authorized personnel, upon reasonable notification, to perform audits and/or surveillances of the supplier's facilities, personnel, and QA implementation?				
2.0 Quality Assurance Program				
A program shall be established for indoctrination, training, and qualification of personnel performing quality-affecting activities to assure proficiency is achieved and maintained.				
The program shall include the documentation of personnel qualifications, indoctrination, and training prior to performing work.				
3.0 Software				
Methods shall address that software programs perform as intended and provide evidence that data manipulation programs produce the intended results.				
Data shall be traceable to the software version preceding it.				
Software developed or modified for YMPB Site Characterization activities shall meet the requirements of OCRW QARD (DOE/RW-0333P) Supplement I.				
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 orginal procurement documents and modifications to them shall be reviewed for inclusion of technical and quality requirements				

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

Supplier QA Plan Checklist
Supplier: _____
Date: _____
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REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
Does the supplier's calibration documentation 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 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) 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, range, accuracy, traceability, and the procedure or method used. h. Records of actual calibration data values, when applicable, both before and after any adjustments, enabling the determination of whether the equipment was, and is, within required tolerance or accuracy. If adjustments are not performed, a second set of data is not required. Clear indication of condition when instrument is found to be out of calibration, as submitted, and a statement or clear indication that the recalibrated equipment is within tolerance in all operating ranges.				
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: _____
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REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
Does the supplier maintain records of all actions affecting calibrations? For how long? Is the supplier willing to provide YMP-USGS with originals or copies of those records?				
16.0 Corrective Action				
The QA Program shall provide a control system for identifying and documenting deviations from technical and quality procedures.				
Adverse conditions shall be reported to appropriate management responsible for the condition who shall determine extent of the condition and take remedial actions.				
The QA organization or other independent group shall verify that corrective actions have been completed.				
17.0 QA Records				
The QA Program shall provide for specifying, preparing, and maintaining records that provide evidence of quality.				
The records shall be protected from damage, deterioration, or loss.				
The requirements and responsibilities for record transmittal, distribution, retention (3 years Minimum), maintenance, and disposition shall be established and documented				
18.0 Audits				
The QA Program shall provide for planned and scheduled audits to verify compliance with its requirements and determine its effectiveness.				
The audits shall be performed by independent personnel to perform the audits in accordance with prescribed procedures or checklists.				
Audit results shall be documented and reported to responsible management.				
Follow-up action to verify corrective action shall be taken where indicated.				

Supplier QA Plan Checklist
Supplier: _____
Date: _____
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REQUIREMENT	INCLUDED			COMMENTS
	YES	NO	N/A	
For Analytical Serivce Suppliers the following requirements shall be met 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.				
Data shall be indentified 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 sampling method to be used, including acceptance criteria. 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.