



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

AUG 30 1995

Robert W. Craig  
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for Yucca Mountain  
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U.S. Geological Survey  
101 Convention Center Drive  
Suite 860  
Las Vegas, NV 89109

EVALUATION OF SUPPLEMENTAL RESPONSE TO CORRECTIVE ACTION REQUEST  
(CAR) YM-95-041 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE  
DIVISION'S (YMQAD) AUDIT YM-ARP-95-09 OF U.S. GEOLOGICAL SURVEY  
(USGS) (SCPB: N/A)

The YMQAD staff has evaluated the supplemental response, inclusive of verification information, to CAR YM-95-041. The response has been determined to be satisfactory, based on the supplemental response and agreements reached in a meeting in Las Vegas, Nevada, on August 24, 1995. Those present at the meeting were the YMQAD Supplier Evaluation Group, Donald Harris, YMQAD staff member, and USGS's Quality Assurance Program organization representatives Thomas Chaney, Larry McInroy, and Robert Scavuzzo. The agreement was that USGS would do the following:

1. Review their procurement procedure for the language provided in the meeting handout.
2. Ensure that the USGS Source Verification Plan requires the recommended Quality Assurance Requirements and Description Document program section requirements are addressed.

Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Donald J. Harris at 794-7356.

*Robert B Constable*

YMQAD:RBC-4407

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

Enclosure:  
CAR YM-95-041

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Robert W. Craig

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cc w/encl:

~~D. G. Spraul, NRC, Washington, DC~~  
S. W. Zimmerman, NWPO, Carson City, NV  
T. H. Chaney, USGS, Denver, CO  
D. D. Porter, SAIC, Golden, CO

cc w/o encl:

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

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

8. CAR NO. **YM-95-041**  
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**CORRECTIVE ACTION REQUEST**

1. CONTROLLING DOCUMENT: **QARD, DOE/RW-0333P, Revision 2**      2. RELATED REPORT NO.: **YM-ARP-95-09**

3. RESPONSIBLE ORGANIZATION: **U.S. Geological Survey**      4. DISCUSSED WITH: **T. Chaney, B. Parks**

5. REQUIREMENT:  
**SECTION 4.0, "Procurement Document Control," Paragraph 4.2.1 C.1, states in part, "a requirement for the supplier to have a documented Quality Assurance Program that implements applicable QARD requirements prior to the initiation of work.**

6. ADVERSE CONDITION:  
Contrary to the cited requirement:

1. Geometrics Incorporated performed calibration of magnetometer for USGS with past due Annual performance evaluation and the Triennial audit. The calibrations were performed and witnessed by USGS on surveillance 95002 SV (11/2/94) and 95027 SV (3/15/95) for Purchase Orders (PO) 1434 CR-94-PO-0331, 1434 CR-95-SA-0930, and 1434 CR-95-SA-0958.

2. PCI Sales (unapproved supplier) performed calibration of MICROMETER Model MW-506 Flowmeter for USGS with USGS witnessing of the calibration on surveillance 95035 SV (4/13/95) for PO 1434 CR-95-SA-1048.

9. Does a Significant Condition Adverse to Quality exist?  Yes  No  
If Yes, Check One:  A  B  C  D  E

10. Does a stop work condition exist?  Yes  No; If Yes, Attach copy of SWO  
If Yes, Check One:  A  B  C

13. Response Due Date: **20 Working Days From Issuance**

11. Required Actions:  Remedial  Extent of Deficiency  Preclude Recurrence  Root Cause Determination

12. Recommended Actions:

7. Initiator: **Donald J. Harris**      14. Issuance Approved by: **[Signature]**      Date: **5-17-95**

15. Response Accepted: **QAR**      Date:      16. Response Accepted: **QADD**      Date:      **5-17-95**

17. Amended Response Accepted: **Donald J. Harris**      Date: **8/28/95**      18. Amended Response Accepted: **[Signature]**      Date: **8/28/95**

19. Corrective Actions Verified: **QAR**      Date: **7/10/95**      20. Closure Approved by: **QADD**      Date: **7-13-95**

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

**1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95-041**

**Background** - This approach was undertaken to provide a method that supplement suppliers programs that are weak in the area of formal quality program documentation. It is the USGS position that Paras. 4.2.1 c 3 and 7.2 4 a of the QARD, as well as NQA-1 and 10 CFR 50, Appendix B, allow for this flexibility in selecting suppliers by responsibly managing and planning the overall procurement process.

This approach was developed because it is occasionally necessary for the USGS to obtain unique services from suppliers that do not maintain fully documented quality programs. In some situations, the service is one-time-only or very infrequent, or a very low dollar amount, for which there is little or no incentive for the supplier to invest in a more formal quality program. In other circumstances, the service is so unique that the number of suppliers is extremely limited.

The USGS plans to exercise this option on a limited basis, and to normally select suppliers with fully documented quality programs. To implement a more rigid approach would severely compromise the USGS's ability to provide a product that meets our technical standards.

**A. REMEDIAL ACTION:** Both of the instances identified, Geometrics and PCI/Micrometer, fit the circumstances described in the background information.

Geometrics had been maintained by the USGS as an Approved Supplier since 1989. As a result of CAR YM-94-050, the USGS removed Geometrics from the Approved Suppliers List (ASL) in November of 1994. Geometrics declined to develop a formal QA program citing that our work with them is extremely limited and it would not justify the expense. At this time, the USGS is unaware of other suppliers who can calibrate the magnetometers which were manufactured by Geometrics. However, it is the USGS position that the comprehensive Source Verification (copy attached) performed by the USGS demonstrated that the calibration work performed by Geometrics was completed with adequate quality.

PCI Sales/Micrometer - PCI Sales is merely the local (Denver area) representative for Micrometer, the company who manufactured the flow meter and performed the calibration. The flow meter was borrowed from REECO only to learn just before the flow test was to be performed, that it had not been calibrated. The meter was returned to the manufacturer for calibration. Again, the comprehensive Source Verification (copy attached) performed by the USGS demonstrates that the calibration was completed with adequate quality.

Certified Balance Services, Inc. (CBS) - Although not identified in the CAR, investigative action identified CBS as a supplier that does not have a documented quality program and that Source Verification was used to accept CBS work. CBS has been on the USGS ASL since 1991, but as a result of CAR YM-94-050, CBS will be deleted from the ASL. As a matter of note, CBS calibration standards are traceable to National Institute of Standards and Technology (NIST) through the Colorado Department of Agriculture. Also, NIST certifies the Colorado Department of Agriculture for the State of Colorado. All work in this one-man shop is done to manufacturer's procedures.

*10/15/95* *diagram* *See...*

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

As a result of the comprehensive Source Verifications performed on the suppliers during their performance of the work, it is not believed that any Remedial Action is required. In all cases, it has been demonstrated that the work was performed in an adequate manner.

- B. EXTENT OF THE DEFICIENCY:** As noted above, one additional Source Verification, beyond those identified in the CAR has been performed. See Attachment A for all Source Verifications performed by the USGS. Only those identified as Quality Related are subject to this CAR.
- C. ROOT CAUSE DETERMINATION:** The root cause of the identified condition relates to the manner in which the QARD has been interpreted by the USGS and incorporated into Revision 7 of QMP-4.01.
- D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** As noted in the Background Information, the approach to supplier selection and procurement planning is a planned process developed and implemented in a responsible manner. It is therefore the USGS position that no Corrective Action is required to preclude recurrence.

**NOTE:** If it is determined from the planned workshop with the DOE that the USGS approach is totally unsatisfactory, the flexibility provided by Revision 7 of QMP-4.01 will be removed. Alternatives to the approach have not yet been evaluated.

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

None.

3. RESPONSE APPROVED:

Martha H. Mustard  
for Thomas H. Chaney  
YMP-USGS Quality Assurance Manager

6-15-95  
Date

Robert W. Craig  
for Larry R. Hayes  
Chief, Yucca Mountain Project Branch

6/15/95  
Date

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

**1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95-041**

As a result of discussions held with YMQAD representatives on June 27, 1995, it is necessary to amend our response to CAR YM-95-041. This meeting resulted in the consensus that using alternate procurement acceptance methods identified in the CAR, such as source verification, laboratory quality control plans and comprehensive receipt inspection to supplement incompletely documented QA programs is not provided for in the QARD. As a result, the USGS will submit to YMQAD a justification for using these methods in support of an exception to QARD requirements. The USGS will also provide specific criteria for their applications.

**2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.**

1. L.L. McInroy/T.H. Chaney 7/30/95

**3. RESPONSE APPROVED**

  
\_\_\_\_\_  
Thomas H. Chaney, YMP-USGS  
Quality Assurance Manager

6/28/95  
Date

  
\_\_\_\_\_  
for Larry R. Hayes, Chief,  
Yucca Mountain Project Branch

6/28/95  
Date

*12/2/95* *at least 10 days*

**YMP-USGS JUSTIFICATION FOR  
SECTIONS NOT APPLICABLE TO THE USGS**

Requirements 4.2.1C.1:1s through 4.2.1C.2: USGS quality-affecting procurements will be controlled by one (or a combination) of the following procurement options: (1) Suppliers Approved QA Program; (2) USGS QA Program; (3) Source Verification; (4) Comprehensive Receipt Acceptance Plan; and (5) Sample Quality Control Plan. The selection of the appropriate procurement option is made based on the scope, nature, or complexity of the service being procured and is approved by the USGS QA Office prior to commencement of the service.

Options (3), (4), and (5) coupled with a supplier evaluation will be used to supplement supplier QA programs. These options will be typically utilized for suppliers with a narrow scope of service and/or limited involvement with the YMP.

7/28/95  
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## CRITERIA FOR ALTERNATIVE SUPPLIER ACCEPTANCE

### SOURCE VERIFICATION

Source verification will be used to accept service products when more than one of the following conditions exist:

- the vendor does not have a documented QA program that meets all the appropriate QARD criteria for the service;
- the task to be performed by the vendor can be monitored;
- the task is of limited scope (*ie.*, short duration);
- the vendor is the only source available for the service;
- the vendor has a known history of providing the same or similar service;
- the method(s) used are documented.

When source verification is to be used to supplement a suppliers QA program, an evaluation will be performed along with the verification that includes the following elements:

- personnel qualifications and training;
- procedure documentation;
- past history;
- calibration traceability;
- audits or other reviews (closure of discrepancies);
- maintenance of records;
- identification of key hold and witness points.

### RECEIPT INSPECTION

Receipt inspection will be used for acceptance of made to order items or services when more than one of the following conditions are met:

- the vendor does not have a documented QA program that meets the appropriate QARD requirements;
- the acceptability of the product can be fully verified through inspection;
- the product is a one time only task of short duration;
- the vendor is the only source available;
- there is a known quality history;
- the product is produced using documented methods;

When receipt inspection is to be used it will be performed in conjunction with an evaluation that includes the following:

**CRITERIA FOR ALTERNATIVE  
SUPPLIER ACCEPTANCE**  
(Continued)

- personnel qualifications and training;
- procedure documentation;
- past history;
- calibration traceability;
- audits or other reviews (closure of discrepancies);
- maintenance of records;
- identification of key hold and witness points;

**SAMPLE ANALYSIS QUALITY CONTROL PLAN**

A sample analysis quality control plan will be used to accept analytical services when one or more of the following conditions exists:

- vendor does not have a documented QA program that meets all the appropriate QARD requirements;
- limited types of sample analysis;
- small number of samples;
- unique analysis method;
- need to maintain consistency of data;
- supplier participates in a round robin testing program;
- documented analysis method is available.

When a QA Plan is to be used to accept analytical services, the QC Plan will be prepared in accordance with the attached guidance document and approved by the QA Office prior to issuance of the.

In addition an evaluation will be performed that includes the following:

- personnel qualifications and training;
- documented methods;
- calibration practices;
- sample handling;
- laboratory facilities;
- past history;
- results of participation in round robin programs.

## QUALITY CONTROL PLAN GUIDANCE FOR THE USE OF ANALYTICAL LABORATORIES

The acceptability of analytical laboratory services may be validated through the use of a quality control (QC) plan. A QC plan is an alternative to, or may be used in addition to an on-site vendor qualification process. The vendor qualification process can establish that a laboratory has the capability to perform the required service and the QC plan can be used to verify that an acceptable service has or has not been performed. This guidance is intended to help in the preparation of a quality control plan that will ensure that the services provided by an analytical laboratory are of known and acceptable quality.

QC plans must be reviewed and approved according to QMP-7.01. Procurements must be initiated according to QMP-4.01 and sample requirements must be addressed according to QMP-8.01. QC plans should be referenced in or incorporated into new technical procedures; existing procedures should be similarly revised according to QMP-5.01. When the best method for analysis has not yet been determined, or data quality objectives are unclear, QMP-5.05 (scientific notebooks) may be applicable for QC plan methods development.

### Purpose and Content of a QC Plan

The purpose of a QC Plan is to establish methods and criteria by which the acceptability of results provided by an analytical laboratory can be measured. Quality control is a process that measures actual quality performance *after the fact* by comparison to established criteria. Since samples may be totally consumed during analysis, there is a risk that upon evaluation, the results will be found to be unacceptable with no way to recover the data.

A QC plan should describe the methods that will be used to determine if sample analysis was performed correctly and the quality standard that must be met for the results to be acceptable for the intended use. The QC plan should tell the laboratory what types of samples they will receive, what types of analytical methods can be used by them, the expected accuracy of results, and how those results are to be verified and reported. To provide a fill-in-the-blanks format for all QC plans would be counterproductive as each plan will be unique based on an assessment of such factors as familiarity with the lab and the complexity of the analysis. Therefore, this guidance provides a shopping list of topics to be considered when plans are prepared.

### Definitions

QC samples — samples that are used to give an indication of laboratory performance that include, but are not limited to:

- Blank samples — a sample for which a specified component is not present.
- Blind samples — a sample submitted for analysis whose composition is known to the submitter but *unknown* to the analyst.

**QUALITY CONTROL PLAN GUIDANCE  
FOR THE USE OF  
ANALYTICAL LABORATORIES  
(Continued)**

- Spike samples — a sample to which known concentrations of specific analytes have been added in such a manner as to minimize the change in the matrix of the original sample.
- Split samples — a replicate portion or sub-sample of a total sample obtained in such a manner that it is not believed to differ significantly from other portions of the same sample.
- Reference material — a material or substance, one or more properties of which, are sufficiently well established to be used for the assessment of a measurement method or for assigning values to materials.
- Standard reference material — a certified reference material produced by the U.S. National Institute of Standards and Technology.

**Preparation of a QC Plan**

- Title page with review and approval signatures.
- General description of project, sampling, analysis, and end use of data.
- Objectives for quality of data.
- Analytical methods.
- Quality control checks.
- Data analysis, acceptance criteria and reporting.

The following items, as applicable, should be addressed in the QC Plan:

- Detection limits of the analytical method.
- Precision (repeatability) between results.
- Bias of the analytical method.
- Expected accuracy of results.

**QUALITY CONTROL PLAN GUIDANCE  
FOR THE USE OF  
ANALYTICAL LABORATORIES  
(Continued)**

- Predetermined limits for data criteria acceptability that, if not met or are exceeded, require remedial action.
- Procedures for remedial action.
- Evaluation of results, methods, and evaluation report format.
- Evaluation of QC sample results.
- Use of results from another lab (same sample or split run by 2 labs).
- If an intact, timely, and representative sample of proper size and composition is not delivered to the laboratory, the analytical methods and QC efforts cannot yield meaningful results. Sample collection, preservation, and handling are part of the sample program.
- Types of samples.
- QC samples prior to use for new labs.
- Description of QC samples, identification, methods for preparation, and frequency of analysis.
- Availability and use of NIST SRMs.
- System for QC sample tracking, traceability.
- Sample holding time — collection to analysis.
- Associated technical procedures or scientific notebooks that address QMP-8.01.
- Participation in USGS interlaboratory evaluation program (SRWSP).