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U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

UNITED STATES GEOLOGICAL SURVEY

DENVER, COLORADO

AUDIT YMP-93-10
JUNE 14 - 18, 1993

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Donald G. Horton
Director
Office of Quality Assurance

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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMP-93-10, the audit team determined that the United States Geological Survey (USGS) is satisfactorily implementing an effective QA program in accordance with the USGS Quality Assurance Program Plan (QAPP -01, Revision 5) and implementing procedures for the QA program elements defined in Section 2.0 of this report.

The audit team identified eight deficiencies during the course of the audit. Of those, six were corrected prior to the close of the postaudit meeting. Therefore, two of the deficiencies resulted in the issuance of Corrective Action Requests (CAR). CAR YM-93-052 related to the lack of management controls for timely closure of corrective action documents. CAR YM-93-053 related to inadequate passdown of USGS QA Program requirements to subtier suppliers and contractors. The external audit process could be improved, see Section 6.0, Recommendations, of this report for details.

2.0 SCOPE

The audit evaluated compliance to and the effectiveness of the USGS QA Program as described in the USGS QAPP and implementing quality procedures.

The QA program elements/requirements evaluated during the audit are in accordance with the published audit plan and are as follows:

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0 Organization
2.0 Quality Assurance Program
5.0 Instructions, Procedures, Plans, and Drawings
6.0 Document Control
12.0 Control of Measuring and Test Equipment
13.0 Handling, Shipping, and Storage
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits

During the course of the audit, it was determined that the scope needed to be expanded due to concerns in the procurement area. Subsequently, the following QA program element was added to the audit scope:

4.0 Procurement Document Control (Limited to procurement documents for calibration services)

The following QA program element/requirement was not reviewed during the audit because USGS has no activity for which this element applies.

9.0 Control of Processes

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, their assigned area of responsibility, and observers:

Individual	QA Program Element/Requirement
AUDITORS:	
Richard L. Maudlin, Audit Team Leader (ATL), Yucca Mountain Quality Assurance Division (YMQAD)	18.0, 4.0
James Blaylock, Auditor, YMQAD	16.0, 17.0
Robert E. Harpster, Auditor, YMQAD	1.0, 5.0, 6.0
Charles C. Warren, Auditor, YMQAD	2.0, 12.0, 13.0
OBSERVERS:	
None	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at USGS offices in Denver, Colorado on June 14, 1993. A daily debriefing and coordination meeting was held with USGS management and staff, and daily team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at USGS offices in Denver, Colorado on June 18, 1993. Personnel contacted during the audit are listed in Attachment 1 to this report. The list includes an indication of those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

Overall, USGS is implementing an adequate and effective QA program for those areas audited. However, one aspect of QA Program Element 16.0 was considered unsatisfactory. CAR YM-93-052 was generated to document that there was a lack of management controls to effect timely closure of open

items. Also, during the course of the audit, two areas for improvement in the external audit evaluation process were identified. These areas are documented as a recommendation in Section 6.0 of this report. In addition, one CAR (YM-93-053) was generated in the area of procurement relating to the passdown of QA requirements to sub-tier contractors/vendors.

Positive observations that were noted by the audit team were in the area of records retrievability and documenting of conditions adverse to quality. USGS retrievability of records during the course of the audit was considered above average. Also, USGS should be commended on their past practices of identifying and documenting deficiencies.

5.2 Stop Work or Immediate Corrective Actions or Additional Actions

None

5.3 QA Program Audit Activities

Details of the QA program audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

5.4 Technical Activities

None

5.5 Summary of Deficiencies

The audit team identified eight deficiencies during the audit. Six of the deficiencies were corrected prior to the postaudit meeting.

A synopsis of the deficiencies documented as CARs and those corrected during the audit are detailed below. Information copies of the CARs are included in Attachment 4.

5.5.1 Corrective Action Requests (CARs)

As a result of the audit, the following CARs were issued:

CAR YM-93-052

QMP-16.01, Revision 3 does not have sufficient management controls for timely closure of CARs.

CAR YM-93-053

Purchase orders for calibration suppliers do not include applicable QA program requirements such as: QA Program Element 2.0 (Personnel Qualifications), QA Program Element 5.0 (Procedures to perform calibrations), etc.

5.5.2 Deficiencies Corrected During the Audit

Deficiencies which are isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit.

1. YMP-USGS-QMP-2.07, Revision 1, Section 5.5, requires that all YMP-USGS instruction be documented to provide a record of completion, and forwarded to the Technical Project Officer's (TPO's) office. Contrary to this requirement, Technical Procedure Instruction Assignment forms are not being forwarded to the TPO's office. These forms are being forwarded to the Training Coordinator in accordance with instructions on the form. This condition was corrected during the audit by the TPO issuing a memorandum delegating the Training Coordinator to receive these forms for the TPO. Delegation is permitted by Section 4.1 of the procedure.

2. YMP-USGS-QMP-2.07, Revision 1, Section 5.1.2, requires an orientation session be completed by all new employees within 30 calendar days of employment or, if not within 30 calendar days, before the start of quality affecting activities. Contrary to this requirement, a USGS employee was employed on 04-27-92 and orientation was not completed until 06-19-92 with no indication of whether the employee had performed quality-affecting work prior to orientation. This condition was corrected during the audit by the Principle Investigator (PI), who supervises the employee, issuing a memorandum stating that no quality-affecting work had been performed by the employee prior to completing orientation and that the PI had intentionally scheduled the employee for orientation on June 19, 1992.

3. NWM-USGS-GCP-03, Revision 2, requires that calibration of analytical balances be performed by a Yucca Mountain Site Characterization Project Office (YMPO) approved vendor on an annual basis. Contrary to this requirement, Notice of Status of

Calibration forms and the Calibration Record For Calibration Status indicated calibration of balances (Serial Nos. 2709742 and 3404218) was performed by USGS personnel. This condition was determined to be an error in documentation as a review of calibration certificates for these balances indicated calibration was performed by an approved vendor. Documentation was corrected by USGS personnel during the audit to accurately identify the vendor organization that performed these calibrations.

4. YMP-USGS-QMP-18.01, Revision 6, Section 5.1, Paragraph 5.1.3 requires that the applicable elements of the QA program for organizations on the approved vendors list shall be audited at least triennially. Contrary to this requirement, a memo had been drafted which extended the triennial audit date of Ocala Water Quality Service Unit from July 13, 1993 to August of 1993. This was resolved prior to the conclusion of the audit by USGS issuing Nonconformance Report (NCR) USGS-NCR-93-31 to document the deviation.

5. YMP-USGS-QMP-18.01, Revision 6, Section 5.7, Paragraph 5.7.1 requires that surveillance reports include a statement regarding effectiveness. Contrary to this requirement, Surveillance Report USGS-93-S03 did not include an effectiveness statement. Prior to the postaudit conference, the surveillance report was corrected to include a statement of effectiveness.

6. YMP-USGS-QMP-18.02, Revision 6, Section 5.0, Paragraph 5.1 requires that a schedule of annual surveillance activities be prepared and issued by the QA Manager. Paragraph 5.1.1 requires that the schedule reflect the surveillance subject and date. Contrary to this requirement, the surveillance schedules for January 1993 and April 1993 did not identify surveillances to be performed through the end of FY93. Also two of the surveillances listed had "TBD" instead of a date. Prior to the close of the audit, a procedure change to QMP-18.02, Revision 6 was initiated and approved on June 17, 1993 which changed the requirement to statusing surveillances instead of scheduling.

5.5.3 Follow-up of Previously Identified CARs

CAR YM-91-053 was closed on August 8, 1991. Because this CAR documented inadequate calibration documentation for mass spectrometers, follow-up was performed by including Mass

Spectrometer G-372674 in the instruments sampled during the audit. Documentation for the mass spectrometer was acceptable although a recommendation to develop a consistent method of compiling documentation for all calibrations performed by USGS personnel was issued based on the review of calibration documentation for Mass Spectrometer G-372674.

CAR YM-93-025 was closed on March 10, 1993. This CAR documented a procedural noncompliance in the area of affixing Calibration Status Stickers to equipment. During the audit, it was verified that proper calibration stickers are being affixed to calibrated equipment, as required by procedure.

CAR YM-93-015 was closed on May 12, 1993. As of the time of the original schedule of this audit, the CAR tracking system did not indicate closure for YM-93-015. Therefore, during audit YMP-93-10, documentation was obtained at the USGS office in Denver, Colorado, to verify the proper closure on May 12, 1993. Subsequent checks of objective evidence at the YMQAD office in Las Vegas, Nevada, also verified the closure of CAR YM-93-015.

6.0 RECOMMENDATIONS

The following recommendation resulted from the audit and is presented for consideration by the USGS management.

Two areas that need improvement regarding the audits of calibration suppliers/vendors were identified. One area is the basis for acceptance of the suppliers' QA program. Of the recent external audits performed (i.e. USGS 93-01, 93-03, 93-04, and 93-05), one audit identified the basis for the QA program as a Mil Standard. Other audit reports for calibration services either indicated that they had no QA program or the program in place was not supported by any standard. The second area that needs improvement is related to the thoroughness of the assessments. Each checklist reviewed had a question regarding personnel qualifications; however, the response to this question only dealt with the fact that personnel training was required or training was performed, with no indication if personnel were qualified and to what criteria. Also, environmental controls at the Colorado State Department of Agriculture calibration laboratory were evaluated, but the auditor did not determine if the readings on the instrumentation met established requirements (i.e. implementation not verified).

It is recommended that USGS take immediate action to determine what measures need to be taken to assure that pertinent (i.e. determinations of personnel qualifications, implementation of procedures, etc.) elements of the QA program are being implemented and that personnel are qualified. The checklists should clearly reflect substance and depth so that adequacy and satisfactory compliance by the supplier/vendor, can be demonstrated through the documented evaluation. Also, future supplier/vendor audit reports should clearly indicate the basis (i.e. QA requirements document) for qualification.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Audit Details
Attachment 3: List of Objective Evidence Reviewed During the Audit
Attachment 4: Information Copies of CARs

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization/Title	Preaudit Meeting	Contacted During Audit	Postaudit Meeting
Appel, D.	Chief, (USGS/HIP)	X	X	X
Blaylock, J.	Auditor (YMQAD)	X		X
Brown, G.	QA Specialist (USGS/SAIC)	X		X
Boucher, M	QA Specialist (USGS/HIP)	X		X
Burgess-Kohn, K.	Trng Coord. (USGS/SAIC)	X	X	X
Causseaux, W.	Sr. QA Spec. (USGS/HIP)	X		X
Chaney, T.	QA Manager (USGS)	X	X	X
Ciesnik, M.	QA Specialist (USGS/HIP)	X		X
Cloutier, K.	Records Tech. (USGS/SAIC)			X
Ducret, L.	Asso. Chief (USGS/YMPB)	X	X	X
Dudley, B.	Scientific Advisor (USGS)		X	
Fridrich, C.	Hydrologist (USGS)		X	
Gockel, D.	QA Specialist (USGS)	X	X	X
Handy, A.	QA Specialist (USGS)	X	X	X
Harpster, R.	Auditor (YMQAD/QATSS)	X		X
Hayes, L.	Technical Project Officer	X	X	
Hersh, B.	Doc. Control (USGS/SAIC)	X	X	
Hovenden, C.	QA Specialist (USBR-QA)	X		
Karas, N.	QA Specialist (USGS/SAIC)	X	X	
McInroy, L.	QA Audits (USGS/SAIC)	X		X
McKinley, P.	Data Coordinator (USGS)	X		
Ludwig, K.	Geologist (USGS)		X	
Lykins, A.	QA Specialist (USGS)	X	X	X
Maudlin, R.	ATL (YMQAD/QATSS)	X		X
Mendez-Vigo, T.	Sr. QA Specialist (USGS/SAIC)	X	X	X
Oliver, T.	Hydrologist (USGS)		X	
Ortiz, H.	Trng Coord. (USGS/SAIC)	X	X	
Pabst, M.	QA Specialist (USGS-HIP)	X		X
Paces, J.	Geologist (USGS)	X	X	X
Parks, B.	Chief, Paleoclimate Sec. (USGS)	X		X
Porter, D.	Project Manager (USGS/SAIC)	X	X	X
Reilly, P.	QA Specialist (USGS)	X	X	X
Reinhart, N.	Manpower Assist. (USGS/SAIC)			X
Rodman, W.	QA Specialist (USGS)	X	X	X
Rodriguez, P.	QA Auditor (USGS/SAIC)	X	X	X
Stuckless, J.	Chief, GSP (USGS)		X	
Velega, D.	QA Auditor (USGS/SAIC)	X	X	X

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT
(Continuation)

Name	Organization/Title	Preaudit Meeting	Contacted During Audit	Postaudit Meeting
Wallendorf, M.	SCM Coord. (USGS/SAIC)			X
Watson, J.	QA Specialist (USGS-HIP)	X		X
Watt, L.	Records Coord. (USGS/SAIC)	X	X	X
Warren, C.	Auditor (YMQAD/QATSS)	X		X
Whiteside, A.	YMPB Auditor (USGS/SAIC)	X	X	X
Woolverton, J.	QA Specialist (USGS)		X	
Ziemba, J.	Lead Auditor (USGS/SAIC)	X	X	X

Legend:
GSP = Geologic Studies Program
HIP = Hydrologic Investigations Program
SAIC = Science Applications International Corporation
USBR = United States Bureau of Reclamation
YMPB = Yucca Mountain Project Branch

ATTACHMENT 2

AUDIT DETAILS

The following is a summary of the YMP QA Program activities covered during the audit. The list of objective evidence reviewed and specific procedures audited, are provided in Attachment 3.

1.0 ORGANIZATION

The evaluation of this QA program element was based on the review of selected organizational responsibilities from implementing procedure Quality Management Procedure (QMP)-1.01 with the managers of the USGS YMPB and the Yucca Mountain Site Characterization Project (YMP) USGS QA Manager. Review discussion was verified through objective evidence produced by the managers.

The selected responsibilities are listed below:

- QA Manager: Functional responsibilities, level of authority and level of communication.
- Chief, YMPB: Planning and directing work, complying with quality requirements, approving and implementing YMP-USGS QAPP and YMP-USGS implementing procedures.
- QA Implementation Advisor: Assisting in integration of quality requirements into technical activities.
- Chief, Programs and Plans: Reporting relationships, responsibilities for YMP planning and control activities.
- Chief, Nevada Operations Program: Identification of person assigned.
- Chief, Geological Studies Program: Assuring work is performed in accordance with QA documents.
- Chief, HIP: Assuring HIP Participants perform work in accordance with QA documents.

The results of the review of the responsibilities stated in QMP-1.01 were satisfactory. Interviews with all key USGS organizational management personnel were conducted. Questions were asked regarding both specified responsibilities, requirements and about

methods of implementation. When appropriate objective evidence was requested and discussed with the responsible manager.

Based on the above interviews, reviews of requirements, and obtained objective evidence, implementation of QA Program Element 1.0, "Organization," is considered satisfactory.

2.0 QUALITY ASSURANCE PROGRAM

This QA program element was evaluated based on the review of selected requirements from implementing procedures QMP-2.01, QMP-2.02, QMP-2.05, QMP-2.07 and QMP-2.08. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

Management Assessment (QMP-2.01)

- At least one Management Assessment is completed annually examining activities from the previous year.
- Management Assessment Reports are prepared by a committee composed of required personnel.
- Management Assessment Reports are submitted for approval to the Assistant Chief Hydrologist for Program Coordination and Technical Support.
- Management Assessment Reports are reviewed for adequacy by the Assistant Director for Engineering Geology.
- Copies of Management Assessment Reports are provided to the Project Manager and YMP QA Division Director.

Personnel Qualification (QMP-2.02)

- USGS personnel qualifications are evaluated and verified by the USGS Servicing Personnel Office.
- Copies of personnel Position Descriptions are submitted to the TPO.
- Resumes containing education and experience pertinent to YMP and USGS responsibilities are prepared, verified, and filed in personnel folders.
- Project specific documentation for qualification consists of a Statement of Attestation documenting supervisor's evaluation of employee qualifications.

- Records generated as a result of this procedure are maintained as project lifetime records.

Qualification of Audit and Surveillance Personnel (QMP-02.05)

- Prospective Auditors or Lead Auditors initiate a Qualification Record.
- Competence of audit personnel is developed by one of the required methods.
- Auditor Qualification Records are maintained for each auditor.
- Lead Auditor Qualification Records are completed by the QA Manager.
- Prospective Lead Auditors pass an examination to evaluate comprehension and ability.
- Lead Auditors maintain their proficiency and have Qualification Records updated annually.

YMP-USGS Instructions (QMP-2.07)

- Supervisors/Managers promptly notify the TPO regarding personnel newly assigned to YMP and USGS activities.
- Orientation sessions are completed by new employees within 30 days or prior to performing quality-affecting activities.
- YMP and USGS instruction of employees is documented as required and forwarded to the TPO.
- Records of employee instruction are maintained by the Local Records Center (LRC).
- Submittal of records packages by topic is performed within the required time frame.

Non-Federal Contractor Personnel (QMP-2.08)

- Contractor personnel performing activities affecting quality have their qualifications verified.
- Position descriptions are approved by the applicable YMP-USGS manager.

- Contractor personnel performing activities affecting quality meet the minimum requirements for each position.

- The Contract Project Manager provides a statement attesting to personnel education, experience, and qualifications to the TPO.

- Records of contractor personnel qualification are maintained as lifetime records by the TPO.

Evaluation of Management Assessment activities for procedural compliance consisted of review of the most recent, approved Management Assessment Report in addition to one report that has been drafted but has not yet been approved. The results of this evaluation indicated satisfactory compliance with procedural requirements.

During the evaluation of procedure implementation for qualification of USGS and non-federal contractor personnel, objective evidence from a sample of personnel files was reviewed. File documentation included position descriptions, resumes, statements of verification of employee education and experience, and memorandums of attestation to employee qualifications. The results of the evaluation indicated satisfactory compliance to procedural requirements.

Training files containing completed Indoctrination Assignment, Technical Procedure Instruction Assignment, and Record of Instruction forms were reviewed during the evaluation of procedure implementation for YMP-USGS personnel instruction. The results of this evaluation indicated two areas of noncompliance with procedural requirements. One noncompliance involved not forwarding completed Technical Procedure Instruction Assignment forms to the TPO as required. The second noncompliance involved a USGS employee that did not complete project orientation within the time limitations specified in the procedure. Both of these noncompliances were corrected during the audit and are noted in Section 5.5.2, Items 1 and 2. The results of all other evaluations in the area of personnel instruction indicated satisfactory compliance to procedural requirements of this report.

An evaluation of qualification records for audit personnel who performed as Auditors or Lead Auditors in internal and external audits listed in Attachment 3 under QA Program Element 18.0 were reviewed. The results of the evaluation indicated satisfactory compliance with procedural requirements for qualification of Auditors and Lead Auditors.

Based on the results of the above evaluations, implementation of QA Program Element 2.0 is considered satisfactory.

4.0 PROCUREMENT DOCUMENT CONTROL

Due to concerns that were noted during the evaluation of QA Program Element 18.0, the audit scope was expanded to cover a small portion of procurement documents relating the pass down of QA requirements to subcontractors and suppliers. The requirements evaluated were selected from the USGS QAPP and QMP-4.01 and are as follows:

QAPP

- Procurement documents shall require that suppliers have a documented program that implements either part or all of the requirements of this document.

Procurement Document Control (QMP 4.01)

- The requester shall initiate a procurement action through a purchase requisition. Topic to be considered shall include QA requirements.

A sample of calibration supplier purchase orders was selected to evaluate compliance to the above. The results of the evaluation concluded that the appropriate QA program requirements were not being adequately identified in the Purchase Order (PO). This condition was documented on CAR YM-93-053.

The evaluation in this area was limited to POs dealing with calibration services.

Based on objective evidence reviewed for the areas audited, implementation of QA Program Element 4.0 is considered satisfactory.

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

This QA program element was evaluated by objective evidence obtained through the YMP response to selected requirements from implementing procedures, QMP-5.01, QMP-5.03, and QMP-5.04. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

Preparation of Technical Procedures (QMP-5.01)

- Technical procedures are not to address activities: (1) beyond the state of the art, (2) requiring professional judgment, or (3) requiring trial and error.

- Technical procedures shall comply with identification requirements.

- Technical procedures shall incorporate minimum required topics.

- Software used to perform data acquisition data resolution shall be identified in procedure.

- Technical review of technical procedures and revisions shall be performed and documented in accordance with requirements.

- Technical review shall show evidence review criteria has been considered.

- Major technical review comments shall be evaluated and resolved by the procedure's preparer in coordination with reviewer.

- QA review at a minimum shall show evidence of consideration for review criteria.

- All documentation of review comments and resolution shall be attached to original review copy, submitted to PI for concurrence.

- Technical procedure shall be signed by the PI, technical reviewer, Chief GSP/Chief HIP, Chief YMPO, and USGS QA Manager.

- Effective date shall be assigned by the QA office. Effective date should be subsequent to approval date and allow time for training.

- A modification to technical procedure determined to be permanent shall cause the procedure to be revised within 90 calendar days from date of the modification.

- Records associated with this procedure shall be submitted to YMP USGS LRC in accordance with requirements for technical procedure record package or technical procedure modification records.

Development and Maintenance of Quality Management Procedures (QMP-5.03)

- The QA manager, with concurrence of the Chief, YMPB shall document the allowed use of Administrative Procedures-Quality (AP-Qs) and distribute document in accordance with requirements.

- The organization, format, and content of each QMP shall be divided into nine specific required topics.

- The GSP and the HIP shall review the QMP and resulting comments shall be reviewed by the Chief, YMPB.

- Procedure comments shall be resolved in accordance with requirements.
- The QA Manager shall review the draft QMP or modification and sign document.
- The Chief, YMPB shall approve the QMP of modification based on technical management review and sign document for approval.
- Assistant Chief Hydrologist for Program Coordination and Technical Support and USGS Assistant Director for Engineering Geology shall review QMP and revision.
- QA Manager shall assign an effective date to QMP, revision or modification.
- Major changes either as modifications or as a revision shall be subject to QMP requirements.
- Individual or packages of QA records shall be submitted to USGS LRC in accordance with content requirements.

Quality Assurance Program Plan (QMP-5.04)

- USGS QAPP shall include required elements.
- QAPP revisions or changes shall be by issuing entire document at a higher revision number or by an Interim Change Notice (ICN).
- When an ICN is issued, the change shall indicate the document revision number, state the full change being made, and identify what part of the document is being changed in accordance with requirements. The ICN shall be approved by Chief, YMPB and YMP USGS QA Manager with concurrence by the Assistant Chief Hydrologist for Program Coordination and Technical Support and Assistant Director for Engineering Geology. The ICN shall be given controlled distribution and table of contents shall identify changes. Interim changes shall be incorporated into the next document revision.
- QA records associated with QMP-5.04 shall be submitted to USGS LRC in accordance with requirements.

For the review of technical procedures, five recent procedures were selected for auditing. Record packages were retrieved and reviewed for objective evidence supporting completion of requirements. No problems were encountered.

For the review of QMPs, recent modifications were reviewed with regard to requirements. Four procedures with modifications made within the last year were selected for audit. Record packages were retrieved and reviewed for objective evidence of compliance. No problems were encountered.

For review of the QAPP, one issued QAPP was selected for audit. Also, the records package for the QAPP and different revisions and ICNs, were reviewed against the requirements. No problems were encountered.

Based on the results of the above evaluations, implementation of QA Program Element 5.0 is considered satisfactory.

6.0 DOCUMENT CONTROL

This QA program element was evaluated based on objective evidence obtained through the YMP response to selected requirements from implementing procedure QMP-6.01. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

- Controlled documents shall be transmitted under cover of a USGS Document Transmittal Notice (DTN). The document receiver shall place new document in proper manual for file, sign DTN and return the DTN to the QA Manager within 30 calendar days from issuance.

- Overdue notices shall be issued by the QA office in the form of a follow-up DTN to participants who have not returned signed DTNs within the required 30 calendar days. If no response is received after another 30 calendar days, upon concurrence of QA Manager based upon need of participant to retain the document, a letter shall be issued instructing holder to return documents or mark them uncontrolled.

- At a minimum, a configuration check shall be performed annually by distribution of a current full index of all controlled documents with an indication of specific documents the holder should possess. The participant shall return configuration check document completed as directed within 30 calendar days to document control. Delinquent accounts shall be handled in accordance with requirements.

- Control distribution of technical procedures exempted that use an alternate control system that allows distribution of technical procedure for personnel under PIs direction, shall be controlled by check-out to technical personnel by check-out Log in accordance with requirements.

- Document distribution record packages transmitted to LRC shall contain the specified documents.

- Configuration check packages transmitted to LRC shall contain the specified documents.

Four record packages were retrieved and checked for compliance with the requirements of QMP-6.01. Also, three individuals were interviewed and their controlled documents checked for completion of the control of documents assigned to them. No problems were encountered.

Based on the results of the above evaluation, implementation of QA Program Element 6.0 is considered satisfactory.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

This QA program element was evaluated based on the review of selected requirements from implementing procedure QMP-12.01. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

- Calibration procedures for individual equipment have been established as required.

- Calibration procedures are readily accessible at the site when performing calibrations.

- Standards used for equipment calibration are traceable to National Institute of Standards Technology (NIST).

- Calibrating standards have equal or greater accuracy than equipment being calibrated.

- Calibrations are recorded as required by technical procedures and/or scientific notebooks.

- When calibrations are performed by other than YMP-USGS or contractor personnel, these organizations are identified on the Approved Vendor's List.

- Calibration stickers are affixed to calibrated equipment used for QA graded work.

- Notification of Calibration forms are sent to the QA Office by PIs when calibrated equipment is to be used for QA Work.

- Calibration Tracking System is maintained by the QA Office for all equipment calibrations and equipment status.

- Equipment that is documented on an NCR is hold tagged and/or segregated per QMP-15.01.

- Out-of-tolerance calibration documentation is evaluated by PIs for impact on previously collected YMP data.

- The calibration tracking system reflects the current status, location and control number of instruments.

During the evaluation of QA Program Element 12,0, the USGS Calibration Record for Calibration Status, vendor calibration certificates, and documentation of calibrations performed by USGS were reviewed. The results of the evaluation indicated satisfactory compliance to procedural requirements with exception of one procedural deficiency involving an error in calibration documentation for two instruments. This deficiency was corrected during the audit and is noted in Section 5.5.2, Item 3 of this report.

Overall, the implementation of QA Program Element 12.0 is considered satisfactory.

13.0 HANDLING, SHIPPING, AND STORAGE

This QA program element was evaluated based on the review of requirements taken from the USGS QAPP, Section 13 and associated implementing procedures. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

- Measures to control proper handling, shipping and storage of equipment described in documented procedures.

- Special equipment and special environments are utilized, when required.

- Marking and labeling are employed, when necessary.

The results of this evaluation indicated satisfactory compliance to QAPP and procedural requirements. Overall, implementation of QA Program Element 13.0 is satisfactory.

16.0 CORRECTIVE ACTION

An evaluation was performed to determine if USGS was implementing the applicable requirements of QMPs 16.01, 16.02, and 16.03. The selected requirements that were evaluated are as follows:

Corrective Action (QMP 16.01)

- All information must be noted on closed CARs. The description section of Part 4 of USGS CARs is to include a statement of immediate actions taken to remedy the specific condition.

- Response dates to CARs not to exceed 30 days from initiation date. Responsible managers to notify affected personnel at all levels of adverse condition(s) and of lessons to be learned.

Stop Work (QMP 16.02)

- No implementation since last audit.

Trend Analysis (QMP 16.03)

- The following information is to be entered into the Trend Analysis Data Base from the USGS deficiency document: cause, root cause, date of last action, due date, action text, and action status.

- The root cause to be determined by the QA Manager using attachment 2 and the results entered in the Trend Analysis Data Base. On a monthly basis, the status of open items is addressed in the Trend Analysis Report and distributed to technical management.

- Specific items to be tracked include: (1) USGS Stop Work Orders (SWOs), NCRs, Audit Finding Reports (AFRs), CARs, Audit/Surveillance Observations, and (2) YMP SWOs, Standard Deficiency Reports, NCRs, Corrective Action Reports, and Audit/Surveillance Observations.

In relation to the implementation of QMP-16.01, since the last audit, two CARs have been closed (CAR 91-01 and CAR 92-01). The closed CARs met procedural requirements. Assigned response dates did not exceed the 30 days from initiation date. Distribution of the closed CARs was appropriate and a statement of immediate actions was included. The only discernable concern was not related to closed CARs, but with open CARs.

At the time of the audit, USGS had 14 open CARs which ranged in age from nine to 32 months. In examining the CARs, management continually granted extensions to the dispositioner without establishing that progress was being made in working towards closure. USGS generates a monthly "Status of Open Items and Trend Analysis" report that clearly identified that the CARs had been open for long periods of time. This report is distributed to appropriate levels of management. Clearly management needs to aggressively pursue the closure of CARs or have demonstrated progress towards this end if an extension is granted. Some of the older CARs have convoluted into a form that is different from the original deficiency, further complicating closure. Three of the open CARs deal directly with this lack of closure. This condition was documented on CAR YM-93-052, which describes the lack of management controls in the QMP to assure timely closure of CARs.

There was no activity in the area of Stop Work; subsequently, no evaluation for compliance could be performed.

In relation to implementation of QMP-16.03, the USGS prepares a monthly "Status of Open Items and Trend Analysis" report. The reports for January 1993 through May 1993 were reviewed to verify incorporation of relevant data. This report tracks SWOs, NCRs, and audit/surveillance observations. The information is presented in charts and graphs for management review.

Several of the open CARs were initiated through the Trend Analysis. For example, CARs 90-04, 92-02, and 92-07 were initiated through trending analysis to document the untimely, ineffective corrective actions. The report is distributed to all levels of USGS management, including the TPO's management in Reston, Virginia. The trend analysis has been effective in identifying recurring or trending deficiencies.

The USGS has established a trend analysis data base that tracks the necessary information.

Overall, the implementation of QA Program Element 16.0 is satisfactory except for the timely closure of CARs which was considered unsatisfactory as documented in CAR YM-93-052.

17.0 QUALITY ASSURANCE RECORDS

An evaluation was performed to determine if USGS was implementing the applicable requirements of QMPs 17.01 and 17-03. The selected requirements that were evaluated are as follows:

Records Management (QMP 17.01)

- The original of oversized records are to be submitted to the LRC. One-of-a-kind records submitted to the LRC are records no longer in use, records source left the project, or not a project acceptable format.

- QA records must contain or posses specification and identification, authentication, protection after authentication, QA designation, indexing, legibility, microfilm suitability, etc. prior to submission to LRC.

- Records are to be submitted within 10 working days. For QA record(s) which will not become a part of a records package, the records source has either noted that the record copy is being sent to LRC or listed the "QA: QA" individual records on submittal form.

- Copy of first page returned to records source. Component files are established and maintained by LRC for all package segment materials. Table of Contents becomes a part of records package.

- Only authorized personnel allowed access to files. Authorized Access list up to date. Requests for records from persons outside YMP-USGS were processed per approval of Chief, YMPB.

Local Records Center (QMP 17.03)

- Individual records to be submitted to LRC by records source. Receipt by LRC is noted as "received." Records packages to be prepared by records source. Notification received by records source that specific records are being delayed.

- Acceptance of the records package is the date that it meets the requirements of (QVC). Material received that becomes a part of a package is held in component file until package is complete. Records marked confidential are to be kept in a locked cabinet.

- The LRC performs the following activities for records generated by the USGS: copied all accepted records, generated specific transmittal form, and transmitted completed records to Central Records Facility (CRF).

- Upon completion of the research, the list of Cited Reference Ascension Numbers is sent to appropriate division for inclusion in final printed open-file publication. Photocopy or purchase copy of all Cited References for each publication sent to CRF.

- Hard copy of records to be placed in binders, folders, or envelopes and stored in lockable file cabinets. Have provisions been established for the storage of photographs, magnetic material, etc? Duplicates of original records retained in LRC. One-of-a-kind records to be stored in fireproof containers.

- Large quantities of one-of-a-kind records to be stored in a YMP-USGS approved commercial facility. Temporary storage of records in a UL one-hour fire-rated cabinet. Temporary storage not to exceed two years.

The results of the evaluation of QMP-17.01 in the area of control of QA records was considered to be satisfactory. The only oversized records that could be evaluated were maps. The maps have been transmitted to the CRF and are maintained for reference only. Likewise, the one-of-a-kind records available for evaluation was in the form of magnetic media. The magnetic media does not have Project Acceptable Format and will probably remain until either transferred to optical disk or the format becomes Project Acceptable.

Several records packages were reviewed to verify records sources have properly completed all steps and that the records contain the required information prior to submittal to the LRC. Based on the sample selected, all applicable attributes were found to have been satisfied. Also, timely submittal of records was also checked. USGS initiated NCR 93-28 based on the 10 working day requirement. The NCR was voided on May 28, 1993 as not being substantiated. Based on the NCR package reviewed, implementation of the 10 working day requirement was satisfactory.

Records sources were submitting "QA: QA" records to the LRC or using the Submittal Form. For records packages, a Table of Contents was being completed and was a part of the package submitted. The LRC was acknowledging receipts.

The LRC maintains records package segments for records sources. On a monthly basis, records sources are given a printout of segments on file in the LRC.

The records facility maintains an access list. The lists were conspicuously posted within the LRC. Records marked "confidential" were either in a UL rated safe or a lockable cabinet.

The results of the review of QMP-17.03 was satisfactory. Incoming records underwent a "QA Verification" check to assure all attributes were satisfied prior to further processing. The records were then copied and dual stored. There were no examples of any records/records packages being returned to the records source since the last audit. Upon acceptance, the receipt acknowledgment was sent to the source. All records were transmitted to the CRF within the 30 working day period. Confidential records were segregated and handled in accordance with QMP-17.01.

PIs are responsible for submitting reference material to the CRF. Cited references were being collected and processed in accordance with the above requirements. All hardcopy records were being stored in binders, folders, or envelopes and stored in fully enclosed, lockable file cabinets while in the LRC. Duplicate hard copy records are retained until received and acknowledged by the CRF. These records are being indefinitely stored at Security Archives. Security Archives is on the approved vendors list as the commercial facility that meets security and fireproof storage requirements.

Overall, the implementation of QA Program Element 17.0 was considered satisfactory.

18.0 AUDITS/SURVEILLANCE

An evaluation was performed to determine if USGS was implementing the applicable requirements of QMPs 18.01 and 18.02. The selected requirements that were evaluated are as follows:

Audits (QMP-18.01)

- Audit schedules are to be prepared by the QA Manager and will include internal and external audits. Audit schedules are evaluated quarterly.
- Internal audits shall audit each QA program element annually. External audits of vendors to be performed triennially.
- Audit plans shall be developed. Audit numbers shall be documented in log. Objective evidence is to be documented on checklists.
- Deficiencies are to be documented on Finding Reports or Observations, as appropriate.
- An audit report is to be prepared and signed by ATL and approved by QA Manager, must be issued within 30 days.
- Upon completion of verifications to AFRs and acceptance of observations, ATL prepared formal closeout letter.

Surveillances (QMP-18.02)

- An annual schedule of surveillance is to be prepared by QA Manager and updated quarterly. Distribution of schedule to include YMP QA.
- QA designates personnel to perform surveillance. A surveillance log is maintained and reflects unique identification number.

- A surveillance plan is to be prepared which reflects basic elements and documents to be utilized. A checklist is to be used for surveillance.

- Results of interviews and evidence to be documented on checklist. Surveillance report to be prepared with statement of effectiveness and issued within 30 calendar days after surveillance.

- Copies of surveillance report to be distributed.

General

- Copies of audit and surveillance records to be sent to LRC.

During the course of the evaluation of implementation of the above requirements, objective evidence in the form of audit and surveillance plans, audit and surveillance reports, AFRs, NCRs, and associated correspondence was reviewed and evaluated for compliance and effectiveness in achieving the desired results.

The results of the evaluation identified three conditions adverse to quality and one recommendation. The first condition adverse to quality related to the incidence of the a triennial audit of a supplier. This condition was corrected during the audit and is noted as Item 4 in Section 5.5.2 of this report. The next condition adverse to quality related to a surveillance report which failed to address overall effectiveness. This condition was corrected during the audit and is noted as Item 5 in Section 5.5.2 of this report. The third condition adverse to quality identified that the Surveillance Schedule did not reflect an annual schedule through fiscal year 1993 and that there was two instances on the schedule where "TBD" was used in place of a specific date. This condition was corrected during the audit and is noted as Item 6 in Section 5.5.2 of this report.

During the course of the audit, two areas for improvement were noted in the effectiveness of the evaluations performed during the external audits of calibration suppliers. Details of these areas for improvement in the QA program are noted in Section 6.0 of this report.

With the exception of external audits, which is considered weak, overall implementation of QA Program Element 18.0 is considered satisfactory.

ATTACHMENT 3

OBJECTIVE EVIDENCE

QA PROGRAM ELEMENT 1.0, ORGANIZATION

Procedures:

Compliance with the following procedures was reviewed:

YMP-USGS-QMP-1.01, Revision 4, "Organization Procedure"

Objective Evidence Reviewed:

YMP-USGS-QMP-1.01, Revision 4, "Organization Procedure"

Quality Assurance Support Organization Chart 92c-06 5-6.93; VG-111-12

Letter, T. Chaney (USGS) to R. Spence (YMQAD), Subject: USGS Transition Plan to QARD DOE/RW-0333P, dated 2/4/93

Chart: Active agreements as of 6/7/93. Nine pages listing Memorandums of Understanding (MOUs)/Memorandums of Agreement (MOAs)

Memorandum, Chief, YMPB (USGS) to YMPB QA Personnel, Subject: YMP USGS Organization, dated 1/27/92

Memorandum, Chief, YMPB (USGS) to Distribution (USGS Managers), Subject: YMPB USGS Summary Account Managers (equivalent to PIs), dated 3/26/93

Memorandum, TPO (USGS) to Chief HIP, Chief GSP, QA Manager, Associate Chief, Chief YMPB, and Nevada Operations Officer, Subject: YMP Cost/Schedule Status Report for May 1993, dated 6/10/93

YMP USGS QAPP -01, Revision 5 and YMP USGS QA Program implementing procedure QMP-1.01, Revision 4

Memorandum, Chief YMPB (USGS) to Distribution, Subject: MOA between Geologic Division and the Water Resources Division for Borehole Geophysical Surveys at Yucca Mountain, dated 3/26/93

Letter, L. Hayes, TPO (YMP USGS) to C. Gertz, Subject: USGS YMP Monthly Summary for May 1993, dated 6/9/93

Planning Document for USGS Guidance for Planning, June 11, 1993, "Fiscal Year 1994 Planning Process, YMP Project Control Branch"

Memorandum, JoAnne LaMonica HIP to Distribution, Subject: Publications - Status of Scientific Reports and Abstracts for HIP, dated 11/5/91

Memorandum of Agreement between Geologic Division and the Water Resources for Lead Isotopic Study of Surface and Subsurface Carbonate and Silicate Systems at Yucca Mountain (SCP No. 8.3.1.5.2.1 Quaternary Regional Hydrology)

Memorandum, TPO YMP USGS Larry Hayes to Distribution, Subject: Delegation of Authority and Responsibility for Acting Chief, YMPB, Lou Ducret, dated 7/28/91

QA PROGRAM ELEMENT 2.0, QUALITY ASSURANCE PROGRAM

Procedures:

Compliance with the following procedures was reviewed:

YMP-USGS-QMP-2.01, Revision 2, Modification 4, "Management Assessment of the YMP-USGS"

YMP-USGS-QMP-2.02, Revision 5, Modifications 1 and 2, "USGS Personnel Qualification"

YMP-USGS-QMP-2.05, Revision 3, "Qualification of Audit and Surveillance Personnel"

YMP-USGS-QMP-2.07, Revision 1, Modification 5, "YMP-USGS Instruction"

YMP-USGS-QMP-2.08, Revision 1, Modifications 2 and 3, "Non-Federal Contractor Personnel"

Objective Evidence Reviewed:

Reports:

YMP-USGS Management Assessment Report for FY 1991
YMP-USGS Management Assessment Report (Draft) for FY 1992

Letter:

V. R. Schneider to C. P. Gertz, dated 8-18-92

Resumes:

Resumes for the following USGS personnel were reviewed:

K. Causseaux	M. Chornack
R. Craig	A. Flint
E. Gutentag	D. Hoxie
M. Mustard	W. Rodman
J. Stuckless	I. Yang

Resumes for the following SAIC personnel were reviewed:

N. Karras	T. Mendez-Vigo
P. Rodriguez	M. Watt
A. Whiteside	J. Ziemba

Position Descriptions:

Position Descriptions (Forms OF-8, U. S. Office of Personnel Management) and attachments for the following USGS personnel and positions:

K. Causseaux, Supervisory Hydrologist, Signed: 11-19-85
M. Chornack, Supervisory Hydrologist, Signed: 2-12-92
R. Craig, Supervisory Hydrologist, Signed: 6-24-91
A. Flint, Hydrologist, Signed: 12-20-89
E. Gutentag, Hydrologist, Signed: 11-26-86
D. Hoxie, Hydrologist, Signed: 3-18-93
M. Mustard, Hydrologist, Signed: 4-5-91
W. Rodman, Quality Assurance Specialist, Signed: 5-25-89
J. Stuckless, Geologist, Signed: 7-11-89
I. Yang, Hydrologist, Signed: 9-27-89

Position Descriptions for the following SAIC personnel:

N. Karras, Program Development Coordinator, Approved: 9-11-92

T. Mendez-Vigo, Lead Quality Assurance Implementation Specialist, Approved: 9-11-92

P. Rodriguez, Quality Assurance Auditor, Approved: 9-11-92

M. Watt, YMP-USGS Records Coordinator, Approved: 5-20-91

A. Whiteside, Quality Assurance Implementation Advisor, Approved: 9-11-92

J. Ziemba, Quality Assurance Audit Supervisor, Approved: 5-16-91

Memorandums:

Memorandums attesting to qualifications of the following USGS personnel:

K. Causseaux, Dated 5-16-91
R. Craig, Dated 8-31-91
E. Gutentag, Dated 4-18-91
M. Mustard, Dated 8-16-91
J. Stuckless, Dated 4-29-91
M. Chornack, Dated 7-21-92
A. Flint, Dated 4-18-91
D. Hoxie, Dated 8-13-92
W. Rodman, Dated 3-21-91
I. Yang, Dated 4-16-91

Memorandums attesting to qualifications of the following SAIC personnel:

N. Karras, Dated 9-11-92
P. Rodriguez, Dated 9-11-92
A. Whiteside, Dated 9-11-92
T. Mendez-Vigo, Dated 9-11-92
M. Watt, Dated 10-3-91
J. Ziemba, Dated 5-16-91

USGS Memorandum to the Training Coordinator from the TPO, Dated June 15, 1993

Geological Survey Memorandum to the Training Coordinator from Alan Flint, Principal Investigator, Dated June 15, 1993

YMP-USGS Indoctrination Assignment forms for the following employees:

V. Cacaro, Dated 3-26-93
W. Guertal, Dated 4-27-92
P. Rodriguez, Dated 7-23-92
R. Drake, Dated 2-1-93
N. Karras, Dated 4-15-91

YMP-USGS Technical Procedure Instruction Assignment forms for the following employees:

M. Chornack, Dated 9-4-92, 2-8-93, 3-27-93, 6-8-93, 6-10-93
A. Flint, Dated 9-30-91, 11-26-91, 4-23-92, 7-1-92, 8-27-92
I. Yang, Dated 5-27-92, 8-13-92, 3-29-93, 5-6-93, 5-17-93

YMP-USGS Record of Instruction forms for orientation of the following employees:

V. Cacaro, Dated 4-7-93
W. Guertal, Dated 6-19-92
R. Drake, Dated 2-9-93
P. Rodriguez, Dated 7-22-92

YMP-USGS Record of Instruction form for Orientation Part I, Dated 6-16-93

Orientation Session:

YMP-USGS Orientation Session, Part I, presented by Karen Burgess-Kohn on 6-16-93

Records Package:

No. 93-QA-016 YMP-USGS 92c-06 YMP-USGS Orientation Parts I, II, III, and IV

Waiver Letter for Orientation of J. Nelson and J. Haney, by R. Spengler, Dated May 4, 1993

Audit Team Qualification Records:

USGS QA Lead Auditor Qualification Records were reviewed for the following personnel:

D. Valega, Original Certification Dated: 9-5-90
A. Whiteside, Original Certification Dated: 4-28-87
J. Ziemba, Original Certification Dated: 11-17-89

USGS Auditor Qualification Records were reviewed for the following personnel:

P. Rodriguez, Original Certification Dated: 8-17-92
D. Dahl, Original Certification Dated: 2-18-93
D. Cummings, Original Certification Dated: 8-17-92
H. Essaid, Original Certification Dated: 3-8-93

QA PROGRAM ELEMENT 4.0, PROCUREMENT DOCUMENT CONTROL

Procedures:

USGS QAPP, Revision 5
USGS QMP-4.01, Revision 4, "Procurement Document Control"

Objective Evidence:

P.O. 150669, dated 08/04/92, Colorado State Department of Agriculture
P.O. 162338-93, dated 06/01/93, Intertyme Metrology
P.O. 162193-93, dated 05/19/93, VICI Metronics

QA PROGRAM ELEMENT 5.0, PLANS, PROCEDURES, INSTRUCTIONS, AND DRAWINGS

Procedure:

YMP-USGS-QMP-5.01, Revision 4, "Preparation of Technical Procedures"
YMP-USGS-QMP-5.03, Revision 7, "Development and Maintenance of Quality Management Procedures"
YMP-USGS-QMP-5.04, Revision 4, "Preparation and Control of the YMP-USGS Quality Assurance Program Plan"
YMP-USGS-QAPP, Revision 5

Record Packages:

LRC No. 92.QA.103

NWM-USGS-GP-50, Revision 0, "Identification of Geomorphic Features of Possible Tectonic Origin using Conventional and Low Sun-angle Vertical Aerial Photographs"

NWM-USGS-GPP-20, Revision 3, "Measurement of Subsurface Temperatures"

NWM-USGS-GCP-30, Revision 0, "Carbon Dioxide Measurement with EGM-1 and WMA-2 Portable IRGA"

NWM-USGS-HP-192, Revision 2

NWM-USGS-GP-43, Revision 0, "Geodetic Trilateration and Global Positioning System (GPS) Surveys"

USGS QA Program, Requirement Matrix Report, 6/17/93

QMP-2.07, Revision 1, Modification 5, "YMP-USGS Instructions"

QMP-5.01, Revision 4, Modification 4, "Preparation of Technical Procedures"

QMP-1.01, Revision 4, Modification 2, "Organization Procedure"

QMP-4.01, Revision 4, Modification 1, "Procurement Document Control"

Objective Evidence Reviewed:

YMP-USGS-QMP-5.03, Revision 7, "Development and Maintenance of Quality Management Procedures"

Memorandum, QA Manager YMP to Chief YMPB, Subject: Updated DOE/YMP QAP List used by YMP USGS. Concurrence Signature: L. Hayes (GS.92.A.004012)

YMP-USGS-QMP-5.04, Revision 4, "Quality Assurance Program Plan"

YMP-USGS-QAPP, Revision 5

QA PROGRAM ELEMENT 6.0, DOCUMENT CONTROL

Procedure:

YMP-USGS-QMP-6.01, Revision 5, "Document Control"

Record Packages:

Transmittal of Procedures
GPP-20, Revision 3
HP 256, Revision 0, Modification (M) 1

Scientific Notebooks:

LRC Nos. 3.003522
3.003523
3.003524
3.003525

DTM - Recession Rescission of 3.06R

DTM - Trans of: QMP-2.01, Revision 2, M3
QMP-3.03, Revision 3, M2
QMP-3.-4, Revision 4
QMP-15.01, Revision 4, M4
QMP-16.01, Revision 3, M2

LRC Nos. 3.00734 3.00735 3.00736 3.00737
3.00738 3.00739 3.00740 3.00741
3.00742

USGS Audit Report USGS 92-04

Record Package Transmittal No. GS QA.404

ACS G1232846-1.50
ACS G12328412-120

LRC Nos. 3.002617
3.002618
3.002619
3.002620

YMP-USGS Controlled Document
Configuration Report Package
Transmittal No. GS-QA-379 of YMP-USGS-Records

QA PROGRAM ELEMENT 12.0, CONTROL OF MEASURING AND TEST EQUIPMENT

Procedures:

YMP-USGS-QMP-12.01, Revision 5, Modifications 1, 2 and 3, "Instrument Calibration"

NWM-USGS-HP-257, Revision 0, "Method to Measure Shut-In Pressure in Unsaturated Zone Boreholes"

NWM-USGS-GCP-28, Revision 0, "Uranium Isotope Geochemistry"

NWM-USGS-HP-167, Revision 0, "Precipitation Measurement Using a Belfort Weighing Rain Gage"

NWM-USGS-GCP-03, Revision 2, "Labeling, Identification, and Control of Samples for Geochemistry and Isotope Geology"

NWM-USGS-HP-190T, Revision 0, "Scientific Notebook Plan"

Objective Evidence Reviewed:

USGS Calibration Record for Calibration Status = Active, Pending, Dated June 16, 1993

USGS NCR No. USGS-NCR-93-05

Memorandums regarding quarterly calibration listings addressed to the following PIs from Wayne Rodman:

M. P. Chornack	I. C. Yang
Z. E. Peterman	A. L. Flint

YMP-USGS-Notification of Calibration Status forms for the following equipment:

Differential Pressure Transducer, Serial No. 254563, Dated 10-17-91
Mass Spectrometer, Serial No. G-372674, Dated 5-13-93
Weighing Raingage, Serial No. 3013, Dated 9-17-92
Analytical Balance, Serial No. 2709742, Dated 6-2-93
Electronic Balance, Serial No. 3312097, Dated 4-6-93

Calibration Stickers attached to the following equipment:

Mass Spectrometer, Serial No. G-372674
Analytical Balances, Serial Nos. 2709742 and 3404218
Electronic Balance, Serial No. 3312097

Vendor Certificates of Calibration for the Following Instruments:

Pressure Tranducer, Serial No. 154563, by NASA, Dated 10-17-91
Analytical Balances, Serial Nos. 2709742 and 3404218, Dated 6-2-93
Electronic Balance, Serial No. 3312097, Dated 4-8-93

YMP-USGS Approved Suppliers List, Page 18, Revision 1 and Page 32, Revision 1

Calibration Records for the following calibrations performed by USGS:

Weighing Raingage, Serial No. 3013, 9-23-90
Mass Spectrometer, Serial No. G-372674

Annual Supplier Evaluation YMP-USGS-93-E02

QA PROGRAM ELEMENT 13.0, HANDLING, SHIPPING AND STORAGE

Procedures:

YMP-USGS-QMP-12.01, Revision 5, Modifications 1, 2 and 3, "Instrument Calibration"

NWM-USGS-HP-62, Revision 6, "Method for Measuring Sub-Surface Moisture Content Using a Neutron Moisture Meter"

Objective Evidence Reviewed:

Storage Practices for Analytical Balances, Serial Nos. 2709742 and 3404218

QA PROGRAM ELEMENT 16.0, CORRECTIVE ACTION

Procedures:

USGS QMP-16.01, Revision 3, "Corrective Action"
USGS QMP-16.02, Revision 0, "Control of Stop Work Orders"
USGS QMP-16.03, Revision 2, "Trend Analysis"

Objective Evidence Reviewed:

CAR Log

CARs: 90-04, 91-06, 91-07, 91-09, 91-10, 91-11, 92-10, 92-02, 92-03, 92-05, 92-06, 92-07, 92-08, 92-09, 92-10, 92-11.

Status of Open Items and Trend Analysis reports for Jan 1993 through May 1993

QA PROGRAM ELEMENT 17.0, QUALITY ASSURANCE RECORDS

Procedures:

USGS QMP-17.01, Revision 5, "Records Management"
USGS QMP-17.03, Revision 0, "YMP-USGS Local Records Center"

Objective Evidence Reviewed:

Authorized Access List dated 05/07/93

Record/Records Packages

NNA 910628.0052	NNA 921211.0043
NNA 920618.0055	NNA 92093.0005-0015
GS 921283114220.014	GS 93.A000141
GS 93.A001312	GS 93.A002420
GS 93.A002471	GS 93.A003062

QA PROGRAM ELEMENT 18.0, AUDITS

Procedures:

QMP-18.01, Revision 6, M2, "Audits"
QMP-18.02, Revision 2, M1, "Surveillances"

Objective Evidence Reviewed:

FY 1993 Internal/External Audit and Surveillance Schedules for January 93 Quarter and April 1993 Quarter.

Internal Audit Reports, Audit Plans, and associated checklists for USGS Audits 92-10, 93-02, and 93-06.

External Audit Reports, Audit Plans, and associated checklists for USGS Audits 93-01, 93-03, 93-04, and 93-05.

Surveillance Reports, Surveillance Plans, and associated checklists for USGS Surveillances 93-S03, 93-S04, and 93-S05.

Audit and Surveillance Log

NCR-93-24
AFR 9210-02
AFR 9210-03

ATTACHMENT 4

INFORMATION COPIES

OF

CORRECTIVE ACTION REQUESTS

ORIGINAL
THIS IS A RED STAMP

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

8 CAR NO.: YM-93-052
DATE: 06/25/93
SHEET: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document
QAPP, Revision 5, Section 16.0

2 Related Report No.
Audit YMP-93-010

3 Responsible Organization
USGS

4 Discussed With
T. Chaney/L. Hayes

5 Requirement:
Section 16.0 states in part: "This system shall insure that significant conditions that are adverse or potentially adverse to quality, are identified promptly and corrected as soon as practical."

6 Adverse Condition:
YMP-USGS-QMP-16.01, Revision 3 does not have sufficient management controls for timely closure of CARs. As an example of procedural ineffectiveness, three of eighteen open corrective actions deal with late evaluation, late responses, or failure to implement timely corrective action (CARs 90-04, 92-02, and 92-07). These three CARs range from 14 months to 32 months old.

9 Does a significant condition adverse to quality exist? Yes___ No X
If Yes, Circle One: A B C

10 Does a stop work condition exist?
Yes___ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

11 Response Due Date:
20 Working Days from Issuance

12 Required Actions: ☒ Remedial ☐ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

13 Recommended Actions:
Establish stringent guidelines in granting extension requests. Establish plans for closing older CARs.

7 Initiator James Blaylock — Date 06/24/93	14 Issuance Approved by: QADD — Date 07-01-93
15 Response Accepted QAR — Date	16 Response Accepted QADD — Date
17 Amended Response Accepted QAR — Date	18 Amended Response Accepted QADD — Date
19 Corrective Actions Verified QAR — Date	20 Closure Approved by: QADD — Date

REV. 08/91

ORIGINAL
THIS IS A RED STAMP

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

8 CAR NO.: YM-93-053
DATE: 6/25/93
SHEET: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document	2 Related Report No.
QAPP, Revision 5, QMP-4.01, Revision 4	

3 Responsible Organization	4 Discussed With
USGS	J. Ziemra/A. Lykins/P. Rodriguz

5 Requirement:

QAPP, Revision 5, Subsection 4.3.3 states in part: "Procurement documents shall require that the suppliers have a documented QA program that implements either part or all of the requirements of this document."

QMP-4.01, Revision 4, Section 5.0, Paragraph 5.1 states in part: "The requester shall initiate a procurement action by the completion and submittal of a Requisition Request.... The following topics shall be considered and included as appropriate: o Scope of Work, o Technical Requirements, ... o Requirements...."

6 Adverse Condition:

Contrary to the above, P.O. 150669, dated 8/4/92 to "Colorado State Department of Agriculture," P.O. 162338-93, dated 6/1/93 to "Intertyme Metrology," and P.O. 162193-93, dated 5/19/93 to "VICI Metronics," do not include applicable QA program requirements such as: QA Element 2 (Personnel Qualifications), QA Element 5 (Procedures to Perform Calibrations), QA Element 12 (Calibration), and QA Element 17 (Control Records).

9 Does a significant condition adverse to quality exist?	10 Does a stop work condition exist?	11 Response Due Date:
Yes___ No X_	Yes___ No X_; If Yes - Attach copy of SWO	20 Working Days from Issuance
If Yes, Circle One: A B C	If Yes, Circle One: A B C D	

12 Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

13 Recommended Actions:

Review existing contracts and modify accordingly. Take the necessary action to evaluate the extent of the deficiency. Take action to preclude recurrence as the root cause. Revise QMP-4.01 to assure correct understanding and interpretation of application of QA requirements.

7 Initiator	14 Issuance Approved by:
R. L. Mauldin Date 06/24/93	QADD for Date 07-01-93
15 Response Accepted	16 Response Accepted
QAR Date	QADD Date
17 Amended Response Accepted	18 Amended Response Accepted
QAR Date	QADD Date
19 Corrective Actions Verified	20 Closure Approved by:
QAR Date	QADD Date

REV. 08/91