

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 NUMBER YMP-93-01  
OCTOBER 19 THROUGH 23, 1992

Prepared by: Kenneth T. McFall Date: 11/12/92  
Kenneth T. McFall  
Audit Team Leader  
Yucca Mountain Project Office Quality  
Assurance Division

Approved by: D. G. Horton Date: 11/19/92  
Donald G. Horton  
Director  
Office of Quality Assurance

## **1.0 EXECUTIVE SUMMARY**

As a result of Quality Assurance (QA) Audit YMP-93-01, the audit team determined that the U.S. Geological Survey (USGS) is satisfactorily implementing an effective QA program in accordance with the USGS Quality Assurance Program Plan (QAPP) and implementing procedures. QA Program elements evaluated during this audit are listed in Section 2.0 of this report.

The audit team identified seven deficiencies during the course of the audit. Of those, three were corrected prior to the postaudit meeting. Therefore, four of the deficiencies resulted in the issuance of Corrective Action Requests (CARs). CAR YM-93-012 concerned the failure to write a Nonconformance Report (NCR) after the use of a non-approved vendor. CAR YM-93-013 concerned a vendor that was used, though the vendor had been removed from the Approved Vendors List (AVL). CAR YM-93-014 concerned the lack of carry-through of requirements from the USGS QAPP to software implementing procedures. CAR YM-93-015 concerned the transmittal of data without documented evidence of an Internal Memorandum of Understanding (IMOU) or a Technical Data Information Form (TDF).

## **2.0 SCOPE**

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

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

### **QA PROGRAM ELEMENTS/REQUIREMENTS**

- 4.0 Procurement Document Control**
- 7.0 Control of Purchased Items and Services**
- 8.0 Identification and Control of Items, Samples, and Data**
- 15.0 Control of Nonconforming Items**
- 19.0 Computer Software**
- 20.0 Scientific Investigations\***

The following QA Program elements/requirements were not reviewed during the audit because USGS had either no responsibilities or no activities in these areas.

- 10.0 Inspection**
- 11.0 Test Control**
- 14.0 Inspection, Test, and Operating Status**

\*For the purposes of this audit, QA Program Element 3.0 was combined with QA Program Element 20.0.

**TECHNICAL AREAS**

In addition to the above mentioned QA Program elements, the scope of the technical areas included activities related to the following:

**Site Characterization**

<b><u>Plan (SCP) No.</u></b>	<b><u>Title</u></b>
8.3.1.2.2.7.1	Gaseous-Phase Chemical Investigation
8.3.1.2.2.7.2	Aqueous-Phase Chemical Investigation
8.3.1.4.2.1.1	Surface and Subsurface Stratigraphic Studies of the Host Rock and Surrounding Units
8.3.1.4.2.2.1	Geologic Mapping of Zonal Features in the Paintbrush Tuff
8.3.1.14.2	Studies to Provide Soil and Rock Properties of Potential Locations of Surface and Subsurface Access Facilities
8.3.1.2.3.1.2	Site Potentiometric-Level Evaluation
8.3.1.2.3.1.3	Analysis of Single and Multiple-Well Hydrologic Stress

**3.0 AUDIT TEAM AND OBSERVERS**

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

<b><u>Individual</u></b>	<b><u>QA Program Element/Requirement or Technical Area</u></b>
Kenneth T. McFall, Audit Team Leader (ATL), Yucca Mountain Quality Assurance Division (YMQAD)	
Robert E. Harpster, Lead Technical Specialist, YMQAD	3/20 (Combined)
James Blaylock, Auditor, YMQAD	8, 15
Thomas J. Higgins, Auditor, YMQAD	19
Richard L. Maudlin, Auditor, YMQAD	3/20 (Combined)
Cynthia H. Prater, Auditor, YMQAD	4, 7
Thomas W. Bjerstedt, Technical Specialist, U.S. Department of Energy (DOE)	SCP 8.3.1.4.2.1.1 SCP 8.3.1.4.2.2.1 SCP 8.3.1.14.2

<u>Individual</u>	<u>QA Program Element/Requirement or Technical Area</u>
(Continuation)	
Keith M. Kersch, Technical Specialist, Science Applications International Corporation (SAIC)	SCP 8.3.1.2.2.7.1 SCP 8.3.1.2.2.7.2 SCP 8.3.1.2.3.1.2 SCP 8.3.1.2.3.1.3
William Belke, Observer, U.S. Nuclear Regulatory Commission (NRC)	
John Buckley, Observer, NRC	
Robert Brient, Observer, NRC	
Kenneth Kalman, Observer, NRC	
John Trapp, Observer, NRC	
Susan Zimmerman, Observer, State of Nevada	
Donald G. Horton, Observer, Director, OQA DOE	

#### **4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED**

The preaudit meeting was held at the USGS offices in Denver, Colorado, on October 19, 1992. A daily debriefing and coordination meeting was held with USGS management and staff, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the USGS offices in Denver, Colorado on October 23, 1992. 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**

The audit team concluded that, in general, the USGS QA Program was being fully implemented to the extent of the activities examined and for this reason was determined to be satisfactory. In addition, seven recommendations are presented to the auditee for consideration.

##### **5.2 Stop Work or Immediate Corrective Actions or Additional Actions**

There were no Stop Work Orders nor related documents issued.

### **5.3 QA Program Audit Activities**

Details of the USGS 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**

Details of the technical activities examined during this audit are provided in Attachment 2.

### **5.5 Summary of Deficiencies**

The audit team identified seven deficiencies during the audit; three 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-92-012**

Contrary to the requirements in Quality Management Procedure (QMP)-7.01, Revision 4, there was no QA office working vendors list, and no NCR issued 60 days after the QA Manager agreed to allow the use of a vendor not on the AVL.

##### **CAR YM-93-013**

Contrary to the requirements of QMP-7.01, Revision 4, a vendor provided services after being removed from the AVL.

##### **CAR YM-93-014**

Contrary to the requirements in the USGS QAPP, Section 6.1.2, requirements from QAPP, Interim Change Notice (ICN) No. 8 were not incorporated into QMP-3.03, Revision 3, titled Software Quality Assurance (SQA).

CAR YM-93-015

Contrary to the requirements in Administrative Procedures (APs)-5.19Q and 5.1Q, acquired data was transmitted to Los Alamos National Laboratory (LANL) without documented evidence of a processed IMOU or a TDIF, nor was the data entered into the Participant Data Archive (PDA).

**5.5.2 Deficiencies Corrected During the Audit**

Deficiencies which are considered 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. Contrary to the requirements of the USGS QAPP, Revision 3, Paragraph 5.1, ICN No. 8, which calls for quantitative and qualitative acceptance criteria, Appendix H of the USGS QAPP and QMP-3.03, Revision 3, failed to provide acceptance criteria for the proper choice of quality controls to take into account the nature, complexity, importance, and intended application of software. This potential deficiency was corrected by the USGS providing the needed, properly approved acceptance criteria and incorporating it into the applicable documents prior to the close of the audit.
2. Contrary to the requirements of QMP-5.01, Revision 4, Modification 3, Paragraph 5.4, three technical procedures were reviewed without documented evidence that technical and QA reviews were performed. The documentation attesting to the technical reviews was supplied prior to the conclusion of the audit.
3. Contrary to the requirements of AP-1.10Q, Revision 5, USGS technical procedure GP-38T, Revision 0, "Scientific Notebook Plan," is being implemented under two SCP activities but is not cited in the list of procedures to be implemented by either study or activity. Modifications to the two SCP activities were made to include technical procedure GP-38T, Revision 0, on the list of procedures to be implemented.

**5.5.3 Follow-up of Previously Identified CARs**

Follow-up was made to previously identified deficiency documents (in this case the deficiency document was a Standard Deficiency Report [SDR]). SDR No. 18 was examined to determine if the completion of corrective

action was satisfactorily progressing toward the due date of November 23, 1992. It was determined that completion of corrective action would be difficult but achievable by the prescribed date.

## 6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by USGS management:

1. Calibration of equipment in USGS procedures generally references the manufacturer's specifications. QMP-12.01, Revision 5, Paragraph 5.1.5, implies that the Principal Investigator (PI) specifies calibration requirements based on required accuracy, intended use, and manufacturer's recommendations. Cases were observed in which the required accuracy was much less precise than the manufacturer's specifications. It is recommended that the USGS describe a method by which PIs can define alternate specifications, with justification, for calibration of equipment.
2. Technical procedure GP-01 makes reference to a field notebook as a scientific notebook. However, in discussion, it was identified that the field notebook is not a scientific notebook and as such need not comply with QMP-05.05. It is recommended that technical procedure GP-01 be revised to exclude field notebooks from the category of scientific notebook.
3. Technical procedure GP-01 specifies the requirements for corrections made to entries in the field notebook. Specifically, the requirement states that corrections "should" be initialed and dated. It is recommended that this requirement be revised to state that corrections "shall" be initialed and dated which is consistent with records correction requirements as noted in a subsequent section of technical procedure GP-01.
4. It is recommended that the YMP-USGS review all procurement record packages now being processed for obliterations, legibility and blank lines, and correct them before they are sent to the Local Records Center (LRC). In addition, several of the procurement record packages already processed through the Central Records Facility (CRF) contained the above mentioned deficiencies and it is recommended that those conditions also be corrected and the packages amended. This condition was identified in CAR YM-93-004, written on the Yucca Mountain Site Characterization Project Office (YMPO). The corrective action taken by YMPO will resolve this situation for all participants.

5. It is recommended that the USGS consider identifying an external seminar or educational course in the area of software testing, and verification and validation that is compatible with the USGS program, and establish a policy to enroll all Software Configuration Control committee members in the course.
6. It is recommended that the USGS consider establishing an in-house course to teach the technical aspects of software testing, and verification and validation. All software technical contacts should be required to attend.
7. Lack of controlled access to the storage room for soil samples is a concern. It is recommended that USGS management take action to resolve this issue with the U.S. Bureau of Reclamation (USBR) to provide controlled access to this storage facility.

## **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

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Appel, D. H.	USGS/Chief-HIP	X	X	
Belke, W.	NRC/Observer	X		X
Berger, N.	USGS/Budget Analyst		X	
Bjerstedt, T. W.	DOE/Technical Specialist	X		X
Blaylock, J.	YMQAD/Auditor	X		X
Boucher, M. S.	USGS/FEC/QA Specialist	X	X	X
Boulton, A.	SAIC/QA IMP Specialist	X	X	X
Bram, C. A.	SAIC/Geologist		X	
Brient, R.	NRC/Observer	X		
Buckley, J.	NRC/Observer	X		X
Burgess-Kohn, K. L.	SAIC/Training Coordinator	X		X
Campbell, D. A.	USBR/TPO	X		
Causseaux, K. W.	USGS/Sr. QA Specialist	X	X	X
Chaney, T. H.	USGS/QA Manager	X	X	X
Chomack, M. P.	USGS/UZ Chief	X		X
Ciesnik, M.	USGS/QA Specialist			X
Dickerson, R. P.	SAIC/Geologist		X	X
Dollar, M.	USBR/Chief, Q-Mgmt. Office			X
Ducret, G. L.	USGS/Asso. Branch Chief	X		X
Frans, S.	USGS/FEC/QA Assistant	X		
George, D. F.	USBR/Dep. QA Manager	X		X
Gockel, D. J.	USGS/SQA Specialist	X	X	
Handy, A. H.	USGS/QA Specialist	X	X	X
Harper, B.	USBR/Civil Eng. Tech.		X	
Harpster, R. E.	YMQAD/Lead Tech. Spec.	X		X
Hayes, L. R.	USGS/TPO	X		
Henderson, J.	USGS/Adminis. Officer		X	
Hennessy, P.	USGS/Secretary	X		
Hersh, B. Y.	SAIC/DC Specialist		X	
Higgins, T. J.	YMQAD/Auditor	X		X
Hovenden, C. E.	USBR/Asst. QA Manager	X		X
Hunter, W. C.	USGS/Geologist	X	X	X
Kalman, K.	NRC/Observer	X		X
Karas, N.	SAIC/Prog. Dev. Coord.			X
Kerans, B. K.	USGS/Computer Specialist		X	
Kersch, K. M.	YMQAD/Tech. Specialist	X		X
Kinney, J. L.	USBR/QA Manager	X	X	X

**ATTACHMENT 1**

**Personnel Contacted During the Audit**  
**(Continuation)**

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Krulik, J. A.	USBR/Geotech. Prog. Mgr.	X		X
Larsen, K. A.	SAIC/Data Mgmt. Spec.		X	X
Luckey, R. R.	USGS/SZ Section Chief	X	X	X
Lykins, A. E.	USGS/QA Specialist	X	X	X
Marshall, B. D.	USGS/Geologist		X	
Maudlin, R. L.	YMQAD/Auditor	X		X
McFall, K. T.	YMQAD/ATL	X		X
McKeown, M.	USBR/Geologist	X	X	X
McKinley, P. W.	USGS/Data Mgmt. Coord.		X	X
Mendez-Vigo, T. M.	SAIC/QA Specialist			X
Murray, M. T.	SAIC/YMP-USGS-LRC Sup.	X	X	X
Mustard, M. H.	USGS/Hydrologist	X	X	X
O'Brien, G. M.	USGS/Hydrologist		X	
Ortiz, H.	SAIC/Training Asst.	X		X
Pabst, M.	USGS/QA Specialist	X	X	X
Parks, B.	USGS/Hydrologist	X		X
Peterman, Z. E.	USGS/Chief Iso./Geo. Group		X	
Peters, C.	USGS/Hydrologist		X	
Porter, D. D.	SAIC/Dep. Prog. Manager	X		
Prater, C. H.	YMQAD/Auditor	X		X
Reilly, P. G.	SAIC/QA Specialist	X	X	X
Rodman, W.	USGS/QA Specialist	X		X
Rodriguez, P. V.	SAIC/QA Specialist			X
Route, D. W.	USBR/QA Implementor	X		X
Scavusso, R.	USBR/Civil Eng. Soils Test.		X	
Spengler R. W.	USGS/Chief Rock Charac.		X	X
Strauss, T.	USBR/Head Rock Tech.		X	
Stuckless, J. S.	USGS/Chief GSP	X		
Trapp, J.	NRC/Tech. Observer	X		
Tucci, P.	USGS/Hydrologist		X	X
Umari, M. J.	USGS/Hydrologist		X	
Valega, D.	SAIC/QA Auditor		X	X
Wallendorf, M. A.	SAIC/Software CM Coord.	X	X	X
Watson, J.	USGS/QA Specialist			X
Whiteside, A.	SAIC/QA IMP. Advisor	X	X	X

**ATTACHMENT 1**

**Personnel Contacted During the Audit**  
**(Continuation)**

<b><u>Name</u></b>	<b><u>Organization/Title</u></b>	<b><u>Preaudit Meeting</u></b>	<b><u>Contacted During Audit</u></b>	<b><u>Postaudit Meeting</u></b>
Whitfield, M. S.	USGS/Hydrologist		X	
Yang, A.	USGS/Project Chief		X	
Zimmerman, S. W.	State of Nevada/QA Mgr.			X

CM = Configuration Management  
DC = Document Control  
FEC = Foothills Engineering Consultants  
GSP = Geologic Studies Program  
HIP = Hydrologic Investigations Program  
IMP = Implementation  
SZ = Saturated Zone  
TPO = Technical Project Officer  
UZ = Unsaturated Zone  
YMP = Yucca Mountain Site Characterization Project

## ATTACHMENT 2

### Audit Details

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

#### 4.0 PROCUREMENT DOCUMENT CONTROL

The evaluation of this QA Program element was based on the examination of objective evidence to determine compliance with selected requirements taken from implementing procedures QMP-4.01, Revision 3, and QMP-4.02, Revision 3. The selected requirements are listed below.

- Requisition requests were used to initiate all USGS procurement.
- Requestors for QA Level I and II procurement considered specific provisions.
- Requisition requests were signed by the requestor and approved by the chief of the organizational unit.
- Delegation of signature authority for reviews and approvals of requisition requests were in writing.
- The Contracting Officer (CO) prepared the final procurement document ensuring that all requirements specified in the requisition requests were included.
- The QA Manager verified that all requirements on the requisition request had been included on the final procurement document, and that the supplier had been qualified.
- The Project Administrative Officer retained copies of each final procurement document, it's requisition, and the requisition request.
- Procurement records were submitted to the LRC and included the appropriate documents.
- Personnel preparing management agreements considered, as a minimum, specific identified topics.
- QA reviewed the management agreement and performed an evaluation of the supplier of services and standards in accordance with QMP-7.01.

- Management agreements were approved by the appropriate management level and the YMP-USGS originator or office, the Chief, Yucca Mountain Project Branch (YMPB), and the YMP-USGS QA Manager.
- Revised agreements required the same review and approval, except for insignificant changes.
- QA records packages for management agreements consisted of the appropriate documentation.

Based on the examination of the above requirements, implementation of this QA Program element is considered satisfactory.

#### 7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

The evaluation of this QA Program element was based on the examination of objective evidence to determine compliance with selected requirements taken from implementing procedure QMP-7.01, Revision 4. The selected requirements are listed below.

- Suppliers were evaluated by QA prior to the purchase of an item or service. The method was an evaluation of the supplier's QA program by audit, surveillance or history. The method was so designated on the AVL.
- The AVL includes the required information.
- Vendors not on the AVL are used only if irrecoverable loss of data would result.
- Proposal evaluations were completed by the requestor prior to contract award and documented on the proposal evaluation form.
- Completed proposal evaluation forms and pertinent procurement documents were reviewed and approved by QA.
- An annual requalification of the vendors on the AVL was accomplished by USGS.
- The CO accepted the item.
- The QA Manager evaluated the QA requirements in the procurement document for compliance and performed acceptance via the appropriate method.
- Commercial-grade and made-to-order items requiring calibration met the requirements of QMP-12.01.

- Alternate commercial-grade items included a verification from the vendor that the alternate meets the requirements.
- Post-installation testing was used for acceptance. The post-installation test equipment requirements and acceptance documentation were incorporated into the procurement document by USGS.
- USGS designated the method of accepting services on the requisition form.
- Commercial-grade items were identified on the procurement document by vendor's catalog number or other manufacturer's published product description.
- Items that required calibration were accepted after approval of conformance certificate and successful calibration.
- Associated records including the AVL were submitted to the YMP-USGS LRC.

During the audit of QA Program Element 15.0, "Control of Nonconforming Items," an NCR was reviewed which resulted in a vendor being removed from the AVL. During review of this NCR, it was concluded that the vendor had performed calibration on several USGS instruments after a letter dated April 21, 1992, from the YMP-USGS QA Manager, had been issued informing them of their status. OCRWM CAR YM-92-013 was issued concerning this incident. During a discussion with a member of the YMP-USGS staff concerning this situation, it was ascertained that the same vendor had been used for instrument calibration in August, 1992, to prevent an irrecoverable loss of data. This is allowed per QMP-7.01, Revision 4, Modification 2, Paragraph 5.1.4 as long as "...the vendor is added to the...working vendors list...A Nonconformance Report shall be written if the vendor is not qualified on the Approved Vendors List within 60 calendar days of the QA Office verbal approval..." As of the date of the audit, the vendor had not been approved. Additionally, it was determined that the QA Office did not have a current "working vendors list" to which to add the vendor if the approval for use was granted by the YMP-USGS QA Manager. In response to this condition, OCRWM CAR YM-92-012 was issued.

One recommendation resulted from the examination of this QA Program element, and concerns the quality of the procurement records submitted to the LRC. Details of the recommendation are provided in Section 6.0, Item 4 of this report.

Based on the examination of the above requirements, with the exception of the areas identified in the CARs, this QA Program element is considered to be satisfactorily implemented.

### 8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

This QA Program element was evaluated based on objective evidence to determine compliance with implementing procedures QMP-8.01, Revision 2, and QMP-8.03, Revision 4. The selected requirements are as listed below.

- Samples shall be uniquely identified and traceable to documentation associated with the samples.
- PIs shall establish a system for the control, handling, and transport of samples from collection to disposition.
- PIs shall store samples under conditions appropriate to their intended use.
- Sample curation shall be consistent with Sample Management Facility (SMF) procedures.
- Candidate data for the Technical Data Base shall be submitted on a TDIF form with appropriate backup information.
- The candidate data is reviewed by the Branch Data Management Coordinator and QA Manager prior to being transmitted to the TPO for authorization of transmittal of the TDIF.
- Approved data will be transmitted in accordance with QMP-8.03 and available to DOE upon approval of its release by the USGS Director.
- Changes or corrections to the Technical Data Base shall be accomplished in accordance with QMP-8.03.

As a result of the examination of the above procedures, one recommendation concerning calibration is made and included in Section 6.0, Item 1 of this report.

Based on the examination of two procedures, 10 TDIF packages and three samples and associated documentation, implementation of this QA Program element is satisfactory.

#### 15.0 CONTROL OF NONCONFORMING ITEMS

This QA Program element was evaluated based on objective evidence to determine compliance with QMP-15.01, Revision 4. The selected requirements are listed below:

- Personnel initiate an NCR upon detection of such a condition. Part 1 of the form, Hold Tags, and significance are implemented, as appropriate.
- An NCR Log is maintained by the QA office, actions are monitored using the Log as a guide, and repetitive or recurring NCRs identified.
- Nonconforming items are identified and segregated, Hold Tags applied, and work stopped, as appropriate. The QA office is responsible for the removal of Hold Tags.

- NCRs are to be dispositioned within 30 calendar days or less by qualified personnel. NCRs can be voided with justification and QA Manager's concurrence. The voided NCR is then reviewed and approved by the cognizant personnel and QA Manager.
- Corrective actions are implemented by personnel identified on the NCR. Any changes other than those classified as minor must undergo the same review and approval as the original NCR.
- The QA Manager verifies completed disposition of actions and closes the NCR. If verification is unacceptable, the NCR is closed and a new NCR initiated. Closed NCRs are distributed as described in the procedure.

Based on the examination of the procedure and a sample of 12 NCR packages, implementation of this QA Program element is satisfactory.

#### 19.0 COMPUTER SOFTWARE

The evaluation of this QA Program element was accomplished through interviews with each of the members of the software Configuration Control Committee (CCC), comparison of the implementing procedure against the requirements document, and examination of objective evidence obtained from the LRC. The documents, from which the requirements were taken, are the "Software Quality Assurance Plan" and its implementing procedures which are YMP-USGS-USGS QAPP-01, Revision 3, ICN No. 8 and QMP-3.03, Revision 3, Modification 1.

A statement of the selected requirements taken from the implementing procedure are listed below:

- Prior to productive use in a quality-affecting activity, software products must be classified and released.
- The required software documents for all software products classified as Critical and Non-Critical shall be completed, reviewed, and released before the productive use of the software product in quality-affecting activities.
- The QA controls placed on software products shall depend on the software classification as Critical and Non-Critical.
- The Verification and Validation of software shall include inspection, analysis, demonstration, review, and/or test, and shall be performed relative to a specific hardware configuration.
- Software verification activities for the Requirements Phase shall consist of verifying that all requirements can be tested.

- Software verification activities for the Design Phase shall consist of confirming that the requirements are reflected in the design.
- The controls selected for Critical and Non-Critical software shall be documented on the Software Control Form (SCF) and approved by the CCC. These controls shall include change control.
- Beyond the SCF, the minimum amount of additional documentation typically required for Critical and Non-Critical software is the Software Requirements Specification, Software Design Description, Software Validation Report, Software User Documentation, Software Release Request, and a paper and magnetic copy of the software code when this is possible. For externally supplied software, the preceding may not be available and should be explained on the SCF.
- The Software Lifecycle Documents shall contain the required information and level of detail as specified in the relevant subsections.
- Each software product and lifecycle document shall have a unique configuration identifier that links and distinguishes each. Revisions shall be denoted by a suffix to the configuration identifier.
- Data produced by software for subsequent use in a quality-affecting activity shall be uniquely linked to the software product and version that produced it through the configuration identifier.
- The Software CM Coordinator shall maintain a Configuration Status Accounting Log that contains the status of all received software documentation, documented software users, documented software problems, the status and a brief description of software changes.
- The CCC shall review each SCF and approve software classification, controls, documentation requirements, and proposed changes. Review of proposed changes shall include an evaluation of the impact on classification, controls, and documentation requirements.
- Review comments of software document reviews shall be recorded on a Software Document Review form. Comments shall be resolved as necessary.
- Membership of the CCC shall include the Software QA specialist or designee, the Software CM Specialist or designee, a representative for the USGS-GSP, and a representative for the USGS-HIP.
- Records generated through the implementation of the procedure (QMP-3.03) shall be submitted to the USGS LRC.

- The procedure specifies the responsibilities of the Software QA Specialist, the Software CM System Coordinator, and the CCC.

During the examination of objective evidence, two conditions adverse to quality were noted. The first condition was the lack of qualitative or quantitative criteria by which successful implementation of QMP-3.03 could be determined. No negative consequences from the failure to provide such criteria were found. This condition was resolved during the audit and is discussed in this report in Section 5.5.2, Item 1. The second adverse condition is related to the failure to carry down certain requirements from Appendix H into the implementing procedure (QMP-3.03). This condition resulted in the issuance of CAR YM-93-014.

Two recommendations for the consideration of USGS management resulted from the evaluation of QA Program Element 19.0. These are found in Section 6.0 of this report as Items 5 and 6.

The following objective evidence was examined and compared: the Configuration Status Accounting Log in both electronic and hardcopy forms; the meeting minutes of three regularly scheduled CCC meetings; 37 records that make up the record packages of seven software products which contained the existing lifecycle documentation for those products; USGS Corrective Action Report USGS-91-09 and its supporting record package which deals with the identification and subsequent corrective actions taken to address an adverse trend related to the effectiveness of training related to software QA. In addition, all four members of the CCC were interviewed in-depth to determine their individual capabilities to meet their responsibilities for SQA. The knowledgeability of these individuals is vital to the effectiveness of the USGS SQA Program since this committee reviews and has approval authority over the software lifecycle and its documentation, and over proposed changes to documentation and codes.

Based on the examination of the objective evidence above and listed in Attachment 3, the interviews with the CCC and, in spite of the two conditions adverse to quality discussed in the paragraphs above, the implementation of QA Program Element 19.0 is determined to be satisfactory.

## 20.0 SCIENTIFIC INVESTIGATIONS

An evaluation was conducted of the requirements identified in USGS implementing procedures YMP-USGS-QMP-3.04, QMP-3.07, QMP-3.10, QMP-3.13, QMP-3.15, QMP-5.05, and adopted YMP AP-1.10Q and AP-5.1Q. It should be noted that there were two areas (QMP-3.11, Peer Reviews and AP-5.9Q, Qualification of Existing Data) where no activity was reported since the last audit. Areas reviewed related to activities being performed for the following SCP numbers:

SCP 8.3.1.2.2.7.1    SCP 8.3.1.2.2.7.2    SCP 8.3.1.4.2.1.1    SCP 8.3.1.4.2.2.1  
SCP 8.3.1.14.2    SCP 8.3.1.2.3.1.2    SCP 8.3.1.2.3.1.3

Selected elements of the referenced procedures that were evaluated include:

- **Technical review of USGS publications shall be performed and documented on YMP-USGS Review/Comment Resolution Forms.**
- **Reviews shall be performed by qualified reviewers and the reviews shall be documented on YMP USGS Review/Comment Resolution Forms.**
- **Major comments shall be responded to and if rejected by the preparer, justification of the rejection shall be documented.**
- **Verification of scientific investigations shall be performed by personnel independent of the scientific investigations.**
- **Verification plans shall be prepared and the results of the verifications shall be documented in a Verification Activity Completion Report.**
- **Design input will be made by written communications from the Exploratory Studies Test Manager to the USGS Exploratory Studies Facility (ESF) Coordinator.**
- **Details of QA grading activities or tier subparts shall be documented on an Activity Controls Specification report.**
- **Chief, YMPB, shall establish a QA Grading Acceptance Committee (GAC).**
- **The Activity Controls Specifications Report shall be performed by the GAC members.**
- **Scientific notebooks shall be sufficient to the extent that another qualified scientist can retrace or repeat an experiment.**
- **Scientific notebooks system documentation shall include (1) initial entry, (2) in-process entries, and (3) final entries.**
- **Scientific Notebook Plans and scientific notebooks require a technical review. Reviews are to be documented in accordance with QMP-3.07.**
- **Scientific Notebook Plans are required to have QA review and to be documented in accordance with QMP-3.07.**
- **Study Plans should conform to the level of detail specified in the DOE/NRC Agreement.**
- **Draft Study Plans are to be internally reviewed by the participant.**

- All mandatory comments are to be resolved and the revised Study Plan submitted to the Director, Regulatory and Site Evaluation Division.
- Data Package Segments are to be submitted attached to a TDIF to the PDA within 45 days of data accession completion.
- Data packages and associated TDIFs are to be submitted to the CRF within 45 days of the end of the quarter in which the data was placed in the participants PDA.

In addition to the above, the audit team reviewed compliance to limited aspects of AP-5.19Q, Interface Control. This procedure was not originally included within the scope of this audit; however, in the review of transmittal of acquired technical data, the audit team reviewed an IMOU related to the request of this data by Los Alamos National Laboratory (LANL). The results of this investigation revealed that USGS had transmitted acquired technical data to LANL in the absence of: (1) a processed IMOU, and (2) a TDIF which reflected transmittal of the data to the PDA. CAR YM-93-015 was issued as a result of this condition.

The results of the review of Study Plans, Review/Comment Resolution Forms, Scientific Investigation Plans/Notebooks, Technical Procedures, TDIFs and other objective evidence as referenced in Attachment 3 of this report indicate that implementation of QMP and AP requirements is satisfactory. There was one instance of noncompliance identified which related to the lack of documented evidence of technical and QA review of three USBR technical procedures. These reviews were completed prior to the close of the audit and details of the action are noted in Section 5.5.2 of this report. Also, two recommendations were made in regards to requirements specified in technical procedure GP-01. Details of these recommendations are referenced in Section 6.0, Items 2 and 3 of this report.

Overall, implementation of the USGS QA procedures for this QA Program element were considered to be satisfactory.

### TECHNICAL ACTIVITIES

#### Activities 8.3.1.2.2.7.1 and 8.3.1.2.2.7.2

In Activities 8.3.1.2.2.7.1 and 8.3.1.2.2.7.2, the audit team interviewed the PI, Dr. Al Yang of the USGS and Charles Peters, with input from Rick Whitfield and others.

One subject that was discussed concerned gas sampling in borehole UZ-1. The PI told the auditors that gas sampling has been conducted in this hole since 1984. During the first five years, samples were taken twice each year; after that, once each year. When asked if he thought the samples were representative of gas within the rock, the PI presented a report in preparation that showed the sulfur hexafluoride (SF<sub>6</sub>) content of these samples as a function of time. Recent samples had leveled off to a very low SF<sub>6</sub> content, indicating that residual contamination of recent samples with drilling air was low.

Since borehole UZ-1 was drilled before there was a QA program, the PI was asked if he thought there would be problems with qualifying the data from borehole UZ-1, specifically, how did he know that the samples he had taken were actually from the interval claimed. The data that he presented showed that isotope indicators of age were monotonic with depth, which confirms that the sampling locations are in the right order. He said that the knowledge of the exact depths are not as important as the sequence.

Some recently prepared reports were examined and it was noted that one of the authors was an outside contractor, named J. D. Higgins. His training and qualification records were examined as well as records packages for several reports and the review package for the preparation of the Study Plan and found to be adequate.

The audit team is concerned with the quality of data that is placed into the project data bases. The PI indicated that he was not responsible for submission of data to these data bases (Reference Information Base and Site and Engineering Properties Data Base), that responsibility lies with the Technical Data Manager, Pat McKinley. Pat indicated that he submits reports to the data base administrators, who then decide what part of the report to place in the data base. Usually, this involves the selection of a critical table or figure from the report, and entering it into the data base. The problem with this practice is that the report may contain limitations or conditions to be placed on the data and these conditions are not included in the data base. It does not appear that there is enough guidance from YMPO to indicate how data is to be entered or how these data bases are to be used.

#### Activity 8.3.1.2.3.1.2

In Activity 8.3.1.2.3.1.2, the audit team interviewed the PI, Pat Tucci and the hydrologist, Grady O'Brian, with input from the Section Chief, Dick Luckey and others. This activity has been examined several times in the past few years, so there was not a lot of new technical activity to discuss. It is significant that there were several large earthquakes on the west coast within the past year. A report was published on one of the earthquakes and another is in preparation. A report on accuracies of the water level measurements is still in preparation.

The pressure transducers appear to be lasting longer than has been the case in the past. The audit team looked at the regression calculation results for several transducers. Nearly all of the regression results had a correlation coefficient ( $r^2$ ) of 100.0%. These regression calculations use a linear model to relate water level to transducer output. In spite of the excellent correlations it appeared that some of the data could be better fit by using a quadratic rather than a linear equation. The improvement in the regression would be very small, however.

#### Activity 8.3.1.2.3.1.3

In Activity 8.3.1.2.3.1.3, the audit team interviewed the PI, M. J. Umari and discussed the analysis of existing data and planned pressure transient tests (principally in the C-hole complex). The PI told the audit team of an observed pressure response in the annulus between the casing in

some of the wells in response to barometric pressure fluctuations. They are planning to instrument one of the wells and record these pressure fluctuations. The scientific notebook plan was examined and the analysis of these data was discussed. These analyses should yield values of vertical air permeability in the first 300 meters below the surface at the C-hole complex.

#### Activity 8.3.1.4.2.2.1

The focus of the Technical Specialist's evaluation was the technical content, scope, planning, and implementation of Activity 1 of SCP Study Plan 8.3.1.4.2.2 (Characterization of the Structural Features in the Site Area). Activity 1 is Geologic Mapping of Zonal Features in the Paintbrush Tuff. The scope of work entails mapping of bedrock geology and other zonal features, e.g., color, texture, and mineralogy, to identify the presence and offset of faults in volcanic rocks exposed at the surface. The primary mapping scale for the geologic maps to be produced is 1:12,000, and larger scale mapping of the Ghost Dance Fault was being undertaken. Study Plan 8.3.1.4.2.2 was approved by DOE and forwarded to the NRC on February 9, 1989. The NRC accepted the Study Plan on March 27, 1989. The NRC expressed some minor technical concerns which were responded to in a letter from DOE dated May 22, 1989.

This evaluation is based upon interviews with the PI, Richard Spengler and members of his USGS and SAIC technical team, and examination of, 1) technical procedures intended for the scope of work in the activity, 2) information in scientific notebooks representing work in progress, and 3) the technical qualifications of the USGS staff that perform this work.

#### Geologic Mapping:

Evaluation of this work largely depends on good scoping and planning for conduct of routine geologic mapping activities with insight for how the data is to be used. These aspects were examined as opposed to an approach that would be suited to verification of a data gathering program largely dependent on various instrumentations.

There were no publications containing new work that were completed during the period between this audit and a previous USGS audit in 1990 (90-03-2) during which this study Plan was examined. Work currently in preparation for release in a USGS open file report, large scale mapping of the Ghost Dance Fault at 1:240 scale, was examined. The process used for preparation of this first in a series of maps of the Ghost Dance Fault is in a prototype stage. It is prototype in the sense of the application of quality assurance for reproducibility and relocation of zonal features in the field, rather than the mapping scale itself.

The subject draft open file report is in the final stages of being written and covers 61 panels measuring 200' x 200'. It also contains three plates at a mapping scale of 1:600 to locate these panels with respect to about 150 total panels to be mapped at 1:240. This degree of accuracy and precision is quite adequate to allow reproducibility in the field. Draft input for the subject open file report was examined and found to have been prepared in anticipation of inquiries as to completeness and reproducibility of the mapping. In this case a grid system was tied into the

Nevada state coordinate system, each corner of each 200' x 200' panel was staked in the field, marked on the field map, and tied into the 1:600 and 1:240 scale mapping. Mapping of zonal features at 1:240 scale was reported to allow relocation of any specific mapped feature in the field within a radius of three feet.

A field notebook and geologic samples from continuing geologic mapping in the northeast quadrant of Study Plan Figure 2.2-1 at 1:12,000 scale was examined. The PI reported that the field work for the 1:12,000 scale mapping that covers the four quadrants of Study Plan Figure 2.2-1 was 75% complete. The field notebook was the same examined and commented upon for the surface volcanostratigraphic studies (Activity 8.3.1.4.2.1.1). The notebook entries for each field station are features-oriented which would appear to be adequate for the purpose of producing a geologic map. The field samples were temporarily archived in the USGS staff member's (Robert Dickerson's) office prior to identification of specific samples for petrographic analysis. A bar code is attached to the geologic sample in the field, and a duplicate bar code is affixed to the field notebook at the field station where the sample was acquired. The appropriate form indicating that a sample has been procured is filed with SMF staff, and the sample is carried back to Denver, Colorado via personal baggage. In the office, a duplicate nomenclature is written in ink onto the sample for purposes of internal USGS sample management and tracking. A sample was randomly selected from the collection of samples available and traced through the subject notebook to the field map upon which the field station was plotted. Verification was made that the bar code in the notebook and that attached to the sample showed the same code numbers beneath the bar code. The USGS internal tracking number is duplicative and does not interfere with traceability of the sample, rather, it provides one more cross-check to the field station where it was procured.

Jointly with the programmatic auditor, a verification was made against the data required to be recorded in field notebooks for field mapping, per USGS GP-01, Revision 0. The entries in the field notebook and the requirements of the technical procedure were found to be in order, and show that the procedure was effectively being implemented. Data entries were in pencil, and some undated line-throughs of words and passages were present. Mapping in the field is done on 1:12,000 scale orthophotographs, reproduced on paper. A density of anywhere from 100-200 field stations are contained on each 1:12,000 orthophoto. On the orthophotos, the field stations, geologic contacts, and faults are directly plotted. Aerial photographs in the strictest sense are not used. An inquiry as to handling of the field map determined that the mapper would transcribe the data from the field map onto an office compilation copy immediately upon return from the field, indicating that the field map was not a singular and unique record.

The position description, education, work experience, and professional qualifications for Robert Dickerson (SAIC) were examined and found to be adequate for the scope of work in the activity (conduct of 1:12,000 scale field mapping). The same information was examined for C. Art Braun (SAIC) for geologic mapping of zonal features on the Ghost Dance Fault at 1:240 scale, and found to be adequate.

**Conclusions:**

The scope, direction, technical planning, and implementation of the work in this SCP activity is being conducted in a highly competent manner by qualified geologists. It will fulfill the needs of the DOE's site characterization program. No technical recommendations are offered.

**Activity 8.3.1.4.2.1.1**

The technical specialists's evaluation focused on the technical content, scope, planning, and implementation of Activity 1 of SCP Study Plan 8.3.1.4.2.1 (Characterization of Vertical and Lateral Distribution of Stratigraphic Units in the Site Area). Activity 1 is Surface and Subsurface Stratigraphic Studies of the Host Rock and Surrounding Units. The activity directs the collection of surface and downhole data for eventual construction of a 3-dimensional geologic model of the site area. The configuration and data requirements for this model, which was envisioned to be a 3-D computer graphic, is not defined in the Study Plan. When asked what communication had taken place between the PI and performance modelers, it was stated that the zonal features mapping of the Ghost Dance Fault at 1:240 scale was an activity (8.3.1.4.2.2.1) with impetus from unsaturated zone infiltration modelers who stated the need to receive detailed mapping from stratigraphic studies/zonal features as early as possible during site characterization. The stratigraphic data base to be developed from the data gathered and compiled in this activity was discussed. Study Plan 8.3.14.2.1 was approved by DOE and forwarded to the NRC on June 22, 1992.

This evaluation is based upon interviews with the PI, Richard Spengler (USGS), and examination of, 1) technical procedures intended for the scope of work in the activity, 2) information in scientific notebooks representing work in progress, and 3) the technical qualifications of the USGS staff that perform this work.

**Borehole Logging:**

Evaluation of the work under this activity largely depends on good scoping and planning for the conduct of routine geologic mapping activities with insight for how the data is to be used. These aspects were examined as opposed to an approach that would be suited to verification of a data gathering program largely dependent on various instrumentations.

There were no publications containing new work, either completed or in progress, that were available for review. Only work in progress from scientific notebooks was available for examination. At the end of October 1992, approximately 800 feet of core from borehole UZ-16 await examination at the SMF by the PI and staff.

In the face of competing demands for core samples, and the need to log the core prior to significant quantities being sent to other PIs, the PI for this activity explained that core is logged in three phases. These phases are, 1) examination of the entire length of a particular core segment spanning some arbitrary stratigraphic interval, any unusual features are noted, 2)

subdivision of lithostratigraphic units, genetic units (i.e. cooling units), devitrified zones, extent of welding, phenocryst percent and other megascopic characteristics, and 3) detailed logging of Phase 2 characteristics in combination with petrographic characteristics of representative samples. Requests for samples are entertained by the YMPO Sample Overview Committee only after Phase 1 has been completed. Based on the lack of objective evidence, it is indeterminate how this system will work in practice.

Because a core log representing work in progress from borehole UZ-16 was not available, the USGS open file report with the description of core from well G-4 was discussed. It was stated that the many different graphic presentations in the report were data-specific to particular parameters of interest. It is clear that a large data base with the lithologic parameters identified in the Study Plan will be amassed as work proceeds. How this large data set could be optimally used by others on the site characterization program was a point of inquiry. USGS intends to develop the format and content of strip logs using technical procedure GP-38T. No objective evidence was available to show implementation of this procedure for producing a core log.

The stratigraphic data base that is part of this activity is intended to be the initial step in defining the 3-D computer model of geologic characteristics. It was established that megascopic and petrographic data from core logging was intended for presentation on a computer graphic, apparently in a strip log format. Selection of the graphic package to be used, however, was still in a scoping stage, as was the exact geologic data to be included on the graphic. The PI critiqued a core log from borehole NRG-1 prepared by staff at the SMF that was presented for discussion. The PI expressed some differences that could be expected from the core logs prepared by USGS staff for this activity. For example, drill rates that are reported on SMF logs are not believed to yield especially valuable information, drill rates being more indicative of the driller rather than lithology.

The qualifications of David Buesch, a recent USGS staff member retained to examine core at the SMF for this activity, were examined and found to be very adequate for the scope of work for this activity.

#### Surface Geologic Observations:

It was established that much of the data developed for this activity from surface mapping and observations was closely related to, and complementary with, the zonal features mapping of Activity 1 of Study Plan 8.3.1.4.2.2. The same information recorded at field stations during zonal features mapping is available to the volcanostratigraphic activity, and in fact the same PI conducts the work in both activities. The field notebook developed using USGS technical procedure GP-01, Revision 0, for the zonal features mapping activity was examined for application to Activity 8.3.1.4.2.1.1. It was noted that information recorded from field stations is highly features-oriented. There did not appear to be consistency in the type of data recorded from station to station that could be used to systematically compile a 2-dimensional representation of surface geologic observations. Geologic samples that may be applicable to this activity were examined under Activity 1 of Study Plan 8.3.1.4.2.2.

**Conclusions:**

The scope, direction, technical planning, and implementation of the work in SCP Activity 8.3.1.4.2.1.1 is being conducted in a highly competent manner by qualified geologists. With further planning for end usage of the data and foresight as to other down-stream usages, it will fulfill the needs of the DOE's site characterization program.

Based on the interviews conducted and the objective evidence examined, the technical specialist is not now convinced that adequate attention is being paid to computer graphic formats for presentation of borehole and/or core log data that would have utility for other users, and that could be consistently plotted on a single strip log for purposes of comparison. Based on discussions, the technical specialist is not convinced that the PI believes that there is a need to optimize this information for use by others (for example, the natural resource Study Plan 8.3.1.9.2.1), as well as internal USGS users within the PI's sphere of SCP studies. The availability of new core from borehole UZ-16 means that core logging activity can begin on qualified core, and it seems timely for decisions like this to be made.

**Activity 8.3.1.14.2**

The technical specialist's evaluation focused on the technical content, scope, planning, and implementation of SCP investigation 8.3.1.14.2 (Studies to Provide Soil and Rock Properties of Potential Locations of Surface and Subsurface Access Facilities). Studies 1 and 2 were looked at, specifically; Exploration Program Study and Preliminary and Detailed Exploration Activity. These studies call for a preliminary field reconnaissance of the general area of the prospective ESF North Portal (Site 3 in Study Plan Figure C-1). Based on the reconnaissance, a sample program was to be devised to acquire soil and rock geotechnical parameters for phased Title II Design of ESF surface facilities and the launch chamber for a tunnel boring machine.

Study Plan 8.3.1.14.2 was approved by DOE and forwarded to the NRC on October 16, 1991. The NRC accepted the Study Plan on January 23, 1992. Some technical concerns in this acceptance letter were responded to in a letter from DOE dated August 31, 1992. The State of Nevada provided comments on the Study Plan on April 1, 1992, which were responded to in a letter from DOE dated August 21, 1992.

This evaluation is based upon interviews with the PI, Mark McKeown, USBR, and examination of, 1) geologic samples and storage facilities at the USBR facility in Denver, Colorado, 2) a technical data package that constitutes the basis of a deliverable to DOE summarizing soil and rock testing data (a site reconnaissance report), and 3) the technical qualifications of the USBR staff that perform this work.

A minor revision to Study Plan 8.3.1.4.2.2 was carried out regarding Activity 4 to permit initial surface reconnaissance and mapping at the North Portal location while Study Plan 8.3.1.14.2 was still undergoing final DOE approvals and an acceptance review by the NRC.

In response to an inquiry about whether or not the PI worked alone in the field during preparation of soil pit wall maps, it was explained that a USBR assistant, Steve Beason, was also present during mapping. Trench/pit wall maps were prepared in a collaborative effort, and the wall maps were signed by both. Pit walls are photographed before backfill, and their locations are recorded from survey registration stakes on each end of the pit.

The soil samples taken from pits constitute some 5,000 lbs. of material from 33 test pits constructed for this Study Plan (two pits constructed for the Midway Valley study were also accessed). USBR staff member, Robert Scavusso, explained the soil test program. Samples are stored for the indefinite future at the USBR facility at the Denver Federal Center, but it is expected that these samples would eventually be returned to the SMF. The room contained only YMPO samples in large, well marked sacks stored on shelves. Due to renovations in the building, this room had no door handle, door latch, or lock. Consequently, there was no restriction on access to the room. There is controlled access to the building itself after work hours and on weekends when all people entering the Federal Center need identification badges. USBR staff was not able to state when the room would be furnished with a door handle, latch, and lock.

The soils in Midway Valley are non-cohesive. Each sample is about 70 lbs. and is stored in large sacks containing different size fractions of mechanically sieved materials. The characteristics of any specific sample is reconstructed using weight percent of the size fractions. A Gilson mechanical sieve was used to sift soil samples, and is located in the same room where Yucca Mountain samples are stored. A few small cobbles, pebbles, and sand were observed on the floor around the machine. Upon inquiry, it was indicated that the dedicated trays used for sieving Yucca Mountain samples were not nested in the machine. It was also pointed out that USBR used the sieve for other test programs. The first soil test results for 12 samples were included in a submittal to the YMPO technical data base, which was reviewed. Direct density tests were performed in the field, and gradation (cumulative frequency) analyses, specific gravity, and relative gravity tests were conducted in the laboratory by USBR staff. These staff members have about 10 years each of soil testing experience at USBR.

USBR staff member Thomas Strauss discussed the rock testing program for borehole NRG-1 core. The sample preparation saw, direct shear test, uniaxial, and triaxial test equipment was visited. All instruments had calibration instructions and records located in the same room, usually right next to the machine. A copy of the applicable technical procedure was also in these 3-hole notebooks. Where American Society for Testing and Materials procedures were being used directly, there was no indication that the operator was assured of using the latest revision to the procedure, or whether any special adaptations for YMP work was to be done. It was stated upon inquiry that this situation was the subject of ongoing remediation in USGS Corrective Action Report 92-07 issued by the USGS with respect to documented resolutions proposed by the USGS Corrective Action Report Board.

The calibration records were checked for the direct shear test machine, for which calibration was shown to have been performed within the year. It was stated that calibration records periodically are submitted to the LRC, but it was not stated how often this took place. The direct shear test technician, Bonnie Harper, had more than 10 years of rock characteristics testing experience with USBR. Other technicians who performed sample preparation work, or performed test on the core, each had from 2-6 years of experience with USBR in the rock preparation or testing laboratory.

Samples of core from borehole NRG-1 were stored in a locked room that has restricted access at all times. Boxes containing the core were stored on open shelves. The core recovery for borehole NRG-1 approached the 80% threshold. Any less than this and the test planning package called for the PI to be notified before drilling continued. A short interval of the hole was drilled with a different drill bit to attempt increased core recovery. No USGS/USBR core log was available for borehole NRG-1 to corroborate the interval where the bit change took place with the SMF core log of borehole NRG-1 (i.e. the SMF log of borehole NRG-1 did not indicate where downhole a bit change had taken place). USBR indicated it was working with the SMF staff to make modifications to the SMF core logging procedure so that desired information could be included. It was not clear whether or not USGS/USBR intended any other log to be prepared of the core, other than the SMF strip log. A procedure appropriate to preparing a core log is not indicated in the Study Plan. It was pointed out that fracture mapping of the core was being carried out by USGS staff using technical procedure GP-12, under the fracture network mapping activity of Study Plan 8.3.1.4.2.2.

The position description, education, work experience, and professional qualifications of USBR staff member Thomas Strauss were examined and found to be adequate for the scope of work conducted by him (geotechnical rock/core testing).

#### Conclusions:

The scope, direction, technical planning, and implementation of the work in SCP Activity 8.3.1.14.2 is being conducted in a highly competent manner by qualified geologists and civil engineers. The work will adequately fulfill the needs of the DOE's site characterization program for siting and design of the ESF surface and subsurface facilities.

Based on the interviews conducted and the objective evidence examined, the technical specialist is not convinced that a full explanation for the rationale and choice for test strategy and test pit location, density, etc., is to be included in the site reconnaissance report (apparently intended to be a USBR Technical Memorandum) indicated in Study Plan Figure C-1. It is uncertain if this report is poised to discuss how the scope and direction of the site investigation proceeded in light of what was determined in early stages of the study. This study was designed to proceed in light of, and would be dependent on, what early data showed. For example, the Study Plan is written

with the flexibility to use technical procedures found to be most appropriate from a menu of potentially applicable procedures. Interviews with the PI did not suggest that such a discussion is intended to be provided, or that such would be anticipated by DOE.

The lack of controlled access to the storage room for soil samples is a concern. USGS management should take action to resolve this issue with USBR to provide controlled access to this storage facility.

Based on interviews with USGS staff and the combined evidence examined during the course of the audit, it has been determined that the USGS is technically implementing an effective program.

**ATTACHMENT 3**

**List of Objective Evidence Reviewed During the Audit**

**QA Program Element 4.0, "Procurement Document Control"**

Procedures:

Compliance with the following procedures was reviewed:

YMP-USGS-QAPP, Revision 5, Section 4, "Procurement Document Control"  
YMP-USGS-QMP-4.01, Revision 3, Modifications 1-4, "Procurement Document Control"  
YMP-USGS-QMP-4.02, Revision 3, "Control of Management Agreements"  
YMP-USGS-QMP-7-01, Revision 4, Modifications 1-3, "Control of Purchased Items and Services"  
YMP-USGS-QMP-17-01, Revision 5, Modification 1, "YMP-USGS Records Management"

Objective Evidence Reviewed:

Procurement Record Packages for Purchase Orders (POs):

150632-92 150036-92 150669-92 150035-92 154366-92  
150033-92 154383-92 150092-92 154349-92 150019-92

Management Agreement between HIP, YMPB and Western Region of the National Research Program, Water Resources Division, USGS (No. 19)

Management Agreement between HIP, YMPB and USGS and the Western Region of the National Resources Program, Water Resources Division (No. 15)

**QA Program Element 7.0, "Control of Purchased Items and Services"**

Procedures:

YMP-USGS-QAPP, Revision 5, Section 7, "Control of Purchased Items and Services"  
YMP-USGS-QMP-4.01, Revision 3, Modification 1-4, "Procurement Document Control"  
YMP-USGS-QMP-4.02, Revision 3, "Control of Management Agreements"  
YMP-USGS-QMP-7-01, Revision 4, Modifications 1-3, "Control of Purchased Items and Services"  
YMP-USGS-QMP-12-01, Revision 5, Modifications 1 and 2, "Instrument Calibration"  
YMP-USGS-QMP-17-01, Revision 5, Modification 1, "YMP-USGS Records Management"

**Objective Evidence Reviewed:**

**Vendors examined:**

Certified Balance Services  
Colorado Department of Agriculture  
Druck, Inc.  
Eppley Laboratories, Inc.  
IFR Systems  
Radiation and Energy Balance Systems  
Storage Technology Corporation  
Sverdrup Technology Corporation  
USGS Branch of Geochemistry Laboratory  
USGS National Water Quality Laboratory

**Procurement Record Packages for POs:**

150632-92	150036-92	150669-92	140035-92	154366-92
150033-92	154383-92	150092-92	154349-92	150019-92

**QA Program Element 8.0, "Identification and Control of Items, Samples, and Data**

**Procedures:**

YMP-USGS-QMP-8.01, Revision 2, "Identification and Control of Samples"  
YMP-USGS-QMP-8.03, Revision 4, "Control and Transmittal of Technical Information to the  
Project Technical Data Base"

**Objective Evidence Reviewed:**

**Geologic Samples:**

RPD-13	RPD-12	RDD-10	Field Map	Field Notebook
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**Technical Data Information Packages:**

Package dated 9/16/91, GS 910908312132.002  
Package dated 9/16/91, GS 910908312132.001  
Package dated 8/13/91, GS 910808314211.010  
Package dated 7/9/91, GS 910708314211.011  
Package dated 10/8/92, GS 921008314212.011  
Package dated 9/17/92, GS 9209083122332.001  
Package dated 9/17/92, GS 920908312132.004

Package dated 9/23/92, GS 920908314225.002  
Data Transfer Package, GS 9208083112312.017  
Data Transfer Package, GS 920908312332.001  
Field sheets, photographs, and computer file listing with the above.

QA Program Element 15.0, "Control of Nonconforming Items"

Procedure:

YMP-USGS-QMP-15.01, Revision 4, "Control of Nonconforming Items"

Objective Evidence Reviewed:

Records:

Closed NCRs:

NCR Nos. 92-20, 92-21, 92-22, 92-25, and 92-28

Open NCRs:

NCR Nos. 92-23, 92-24, 92-27, 92-31, 92-33, 92-38, and 92-39

Fiscal Year 1992 NCR Log

CAR No. YM-92-005 (related to NCR No. 92-31)

QA Program Element 19.0, "Computer Software"

Procedures:

YMP-USGS-QAPP-01, Revision 3, ICN No. 8, Appendix H, YMP-USGS Software Quality Assurance Plan"

YMP-USGS-QMP-3.03, Revision 3, Modification No. 1, "Software Quality Assurance"

Objective Evidence Reviewed:

Configuration Control Committee Member Interviews:

Wallendorf, M. A., Software Configuration Management Coordinator  
Gockel, D. J., Software Quality Assurance Specialist  
Kerans, B. K., Hydrologic Investigations Program Representative  
Marshall, B. D., Geologic Studies Program Representative

Configuration Control Committee Meeting Minutes

Meeting No. 92-07, GS.92.A.022430

Meeting No. 92-09, GS.92.A.003744

Meeting No. 92-11, GS.92.A.006024

Configuration Status Log

Visual inspection and exercise of the electronic form of the Log as it is most easily accessed using the video monitor.

Hardcopy printout of the entire software product inventory, dated 10/19/92.

Hardcopy printout (dated 10/21/92) of that portion of the software product inventory which involves the implementation of procedure YMP-USGS-QMP-3.03, Revision 3, Modification 1.

Hardcopy printout of the Log of seven software products. The printout detailed the required lifecycle documentation and status of each document for that software product. Record packages were obtained from the LRC for the seven software products and were compared against the Log. The seven software products (are those listed below) which were subjected to detailed examination for lifecycle documentation requirements.

Software Product: THMCAL/1.007      CID = NHP0045.02

CID/Lifecycle Document      Record Mgmt. System Accession No.

NHP0045.02/A01.00/CIR      GS.91.A.002349

NHP0045.02/B01.00/SRS      GS.91.A.002459

NHP0045.02/C01.00/SDD      GS.92.A.002460

NHP0045.02/U01.00/SUD      GS.92.A.002461

Software Product: X-ACQ/1.0      CID = GSP0005.01

GSP0005.00/R01.00/SIR      GS.92.A.001484

GSP0005.00/Q01.00/SCF      GS.92.A.001774

GSP0005.00/B01.00/SRS      GS.92.A.001788

GSP0005.00/C01.00/SDD      GS.92.A.001789

GSP0005.00/SO1.00/HC      GS.92.A.001790

GSP0005.00/U01.00/SUD      GS.92.A.001792

GSP0005.00/W01.00/SRR      GS.92.A.001793

GSP0005.00/Y01.00/SVR      GS.92.A.001794

Software Product: PHREEQE/19904

CID = HIP0023.01

HIP0023.01/R01.00/SIR  
HIP0023.01/Q01.00/SCF  
HIP0023.01/B01.00/SRS  
HIP0023.01/Z01.00/ASD

GS.92.A.005769  
GS.92.A.005768  
GS.92.A.006352  
WATER RESOURCES INVESTIGATIVE  
REPORT #80-96

Software Product: MINITAB/7.2

CID = HIP0021.01

HIP0021.01/R01.00/SIR  
HIP0021.01/Q01.00/SCF  
HIP0021.01/U01.00/SUD  
HIP0021.01/W01.00/SRR  
HIP0021.01/Y01.00/SVR

GS.92.A.001798  
GS.92.A.001797  
GS.92.A.002440  
GS.92.A.002441  
GS.92.A.002442

Software Product: SEISMIC/1.000

CID = GDD0004.01

GDD0004.01/A01.00/CIRF  
GDD0004.01/B01.00/SRS  
GDD0004.01/C01.00/SDD  
GDD0004.01/U01.00/SUD  
GDD0004.01/T01.00/MM  
GDD0004.01/I01.00/SVR  
GDD0004.01/K01.00/SRP  
GDD0004.01/LO1.00/SRR

GS.89.A.001457  
GS.89.A.001981  
GS.89.A.001982  
GS.90.A.000140  
In Records Management System (RMS) safe  
GS.90.A.001124  
GS.91.A.000899  
GS.91.A.000900

Software Product: UTH.FOR/2.00

CID = GDD0020.02

GDD0020.02/R01.00/SIR  
GDD0020.02/Q01.00/SCF  
GDD0020.02/Y01.00/SVR  
GDD0020.02/T01.00/MM  
GDD0020.02/S01.00/HC

GS.92.A.002753  
GS.92.A.002752  
GS.92.A.002478  
In RMS safe  
GS.92.A.002469

Software Product: BANK.FOR/2.00

CID = GDD0021.02

GDD0021.02/R01.00 SIR  
GDD0021.02/Q01.00 SCF

GS.92.A.002754  
GS.92.A.002776

Supporting Documentation of USGS-CAR-91-09, dated 8/05/91:

GS.91.A.002466, Memorandum and Attachments, dated 7/22/91  
Quality Assurance Manager, YMP-USGS to TPO, YMP-USGS  
"Status of Open Items and Trend Analysis Report for June, 1991"

GS.92.A.001498, Memorandum and Attachments, dated 1/31/92  
Quality Assurance Manager, YMP-USGS to R. R. Luckey, Hydrologic Investigations  
Program, YMP-USGS, and to Chief Yucca Mountain Project Branch, YMP-USGS  
"Closure of Nonconformance Report USGS-NCR-91-12"

GS.92.A.001070, Record Package for USGS Audit Finding Report  
No. USGS-9101-02, dated 1/09/91

GS.92.A.002665, Record Package for USGS Audit Finding Report  
No. USGS-9101-02, dated 4/09/91

QA Program Elements 3.0/20.0, "Scientific Investigations"

Procedures:

- YMP-USGS-QMP-3.04, Revision 3, Modification 2, "Technical Review, Approval, and Distribution of YMP-USGS Publications"
- YMP-USGS-QMP-3.07, Revision 3, Modifications 1 and 2, "YMP-USGS Review Procedures"
- YMP-USGS-QMP-3.10, Revision 2, Modification 1, "Verifications to Scientific Investigations"
- YMP-USGS-QMP-3.11, Revision 1, Modification 1, "Peer Review"
- YMP-USGS-QMP-3.13, Revision 1, Modification 1, "Design Input"
- YMP-USGS-QMP-3.15, Revision 0, "Application of Graded Quality Assurance"
- YMP-USGS-QMP-5.05, Revision 2, "Scientific Notebook System"
- YMPO-AP-1.10Q, Revision 5, ICN No. 1, "Preparation, Review, Approval and Revision of Study Plans"
- YMPO-AP-5.1Q, Revision 2, ICN No. 1, "Control and Transfer of Technical Data on the Yucca Mountain Site Characterization Project"
- YMPO-AP-5.9Q, Revision 2, "Qualification of Existing Data"
- YMPO-AP-5.19Q, Revision 2, ICN No. 1, "Interface Control"

**Objective Evidence Reviewed:**

TDIF, WBS 1.2.3.2.6.2.1, dated 9/3/92 (USBR)  
Request for Design Input Letter, Raytheon Services Nevada to USGS, dated 8/28/92,  
Letter No.  
RSN-YMP-607  
Study Plan, Revision 0, "Studies to Provide Soils and Rock Properties of Locations  
of Surface and Subsurface Access Facilities," WBS 8.3.1.14.2  
Technical Procedure GP-01, Revision 2, "Geologic Mapping"  
Technical Procedure YMP-USGS-EGP-5005-86, Revision 2, "Determining Unified Soil  
Classification (Visual Method)"  
Technical Procedure YMP-USGS-EGP-7000-89, Revision 2, "Performing Disturbed Soil  
Sampling in Test Pits, Trenches, Accessible Borings, and Tunnels"  
Technical Procedure YMP-USGS-EGP-7221-89, Revision 2, "Determining Unit Weight  
of Soils In-Place by the Water Replacement Method in a Test Pit"

**Review/Comment Resolution Forms:**

YMP-USGS-EGP-5005-89, Revision 2, Technical 10/22/92, QA 10/23/92  
YMP-USGS-EGP-7000-89, Revision 2, Technical 10/22/92, QA 10/23/92  
YMP-USGS-EGP-7221-89, Revision 2, Technical 10/22/92, QA 10/23/92

Memorandum, Transition of YMP-USBR Technical Procedures to YMP-USGS Technical  
Procedures, dated 10/6/92, WBS 1.2.11.3.1  
USGS Audit Finding Report 9205-02, dated 8/30/92  
Technical and Quality Assurance Review Comments Sheets, dated 7/13/92 and 7/25/92,  
for review of Technical Procedure GP-01, Revision 2

**IMOU:**

330010, WBS 1.2.3.4.1.1 330017, WBS 1.2.3.3.1.2.2 WBS 1.2.3.3.1.3.2

**Publications/Published Reports/Technical Review Letters:**

"Porewater Extraction from Unsaturated Tuff by Triaxial and One Dimensional  
Compression Methods, Nevada Test Site WRIR WBS 1.2.3.3.1.2.1.0 Milestone"

Technical Review Letter dated 7/9/92 (Nelson Reviewer)

Published Report, "Preliminary Study of the Chemistry of Pore Water Extracted from Tuff  
by One Dimensional Compression" (WBS 1.3.3.1.2.1.0) (Peters, Higgins, Burger, Yang)

**TPO/QA Review/Comment Resolution Sheets for the review of 1991 Pore-Water  
Extraction From Unsaturated Tuffs Using One Dimensional Compression**

**Report, "Earthquake Induced Water-Level Fluctuations at Yucca Mountain, NV" by G. M.  
O'Brian (WBS 1.2.3.1.3.1)**

**Technical Review package for report on "Earthquake Induced Water-Level fluctuations at  
Yucca Mountain, NV"**

**Review Comments for Study Plan 8.2.1.2.2.7**

**Study Plan review package for Study Plan 8.3.1.2.2.7, Revision 0**

**Study Plan review package for Study Plan 8.3.1.2.3.1, Revision 0**

**TDIFs:**

**TDIF for WBS 1.2.3.3.1.3.1**

**TDIF for WBS 1.2.3.3.1.2.10**

**Training Records for J. D. Higgins**

**Scientific Notebook Plan No. HWM-USGS-HP-237T, Revision 0**

**Scientific Notebook SN-0019 (HP 220T, Revision 0)**

**Scientific Notebook Package for Scientific Notebook SN-0030**

**Review of Technical Procedure review package for HP-60, Revision 2**

**Review of Technical Procedure review package for HP-196, Revision 1**

**Memorandum to Acting QA Manager, YMP from Acting Chief NHP, YMP: Subject-Request to  
waive verification activity for a change of Principal Investigator for the saturated zone fractured  
Rock Hydrology Project.**

**Grading Reports in Progress;**

**YMP USGS Activity Control Specification Report. (Report No. YMP-USGS-ACS-G1233131.1,  
Revision 0)**

**YMP USGS Activity Control Specification Report. (Report No. YMP-USGS-ACS-G1233127.1,  
Revision 0)**

YMP USGS Activity Control Specification Report. (Report No. YMP-USGS-ACS-G1233127.3, Revision 0)

YMP USGS Activity Control Specification Report. (Report No. YMP-USGS-ACS-G1233127.2, Revision 0)

### TECHNICAL ACTIVITIES

#### Activity 8.3.1.2.2.7.1 and .2

Report and Record Package for: "Pore-Water Extraction from Unsaturated Tuffs Using One-Dimensional Compression," by Mower, Higgins, and Yang. This work was done under prototype WBS No. 1.2.3.3.1.2.10, but is related to and relevant to this study.

Report and Record Package for: "Flow and Transport Through Unsaturated Rock - Data from Two Test Holes, Yucca Mountain, Nevada," by Yang

Report and Record Package for: "A Preliminary Study of the Chemistry of Pore Water Extracted from Tuff by One-Dimensional Compression," by Peters, Yang, Higgins, and Burger. Prototype WBS work.

Scientific Notebook Record Package: "Method for Sealing Unsaturated Zone Borehole Core Samples to Preserve Moisture Content"

Review and Submittal Package for: Study Plan No. 8.3.1.2.2.7

Qualification and Training Records for J. D. Higgins, an outside contractor from Colorado School of Mines

#### Activity 8.3.1.2.3.1.2 and .3

Report and Record Package for: "Earthquake-Induced Water-Level Fluctuations at Yucca Mountain, Nevada - April 1992." Activity 2

Transducer regression results for several transducer calibrations. Nearly all had correlation coefficients  $r^2=100.0\%$  calibrations. Activity 2

Notebook Plan NWM-USGS-HP-220T, Revision 0: "Air Flow Monitoring in Deep Saturation Zone Boreholes and in Partially Cased Boreholes, " dated 2/26/92. Activity 3

Examined analysis technique for Notebook Plan NWM-USGS-HP-220T, Revision 0, published in Water Resources Research by Weeks, October 15, 1979: "Barometric Fluctuations in Wells Tapping Deep Unconfined Aquifers." Activity 3

Activity 8.3.1.4.2.2.1

DOE, (1991), Study Plan 8.3.1.4.2.2 (Characterization of the Structural Features in the Site Area), Activity 1 (Geologic Mapping of Zonal Features in the Paintbrush Tuff), Revision 1.

Work in Progress completed under aegis of USGS technical procedure GP-38T (Scientific Notebook Plan), Revision 0.

Work in Progress completed under aegis of USGS technical procedure GP-01

Position Description, education, work history and professional qualifications for SAIC staff member Robert Dickerson and C. Art Braun.

Technical Specialists' checklist and responses for USGS Audit 90-03-2 pertaining to Study Plan 8.3.1.4.2.2.

USGS Quality Assurance Requirements Assignment Record for SCP Activity 8.3.1.4.2.2.1, for WBS 1.2.3.2.2.1.2, Revision 0, USGS approved 2/14/90.

Activity 8.3.1.4.2.1.1

DOE, (1992), Study Plan 8.3.1.4.2.1 (Characterization of the Vertical and Lateral Distribution of Stratigraphic Units in the Site Area), Activity 1 (Surface and Subsurface Stratigraphic Studies of the Host Rock and Surrounding Units), Revision 0.

Work in Progress completed under aegis of USGS technical procedure GP-38T (Scientific Notebook Plan), Revision 0.

Work in Progress completed under aegis of USGS technical procedure GP-01, (Geologic Mapping), Revision 0.

Position Description, education, work history and professional qualifications for USGS staff member David Buesch.

USGS Quality Assurance Grading Report for SCP Study Plan 8.3.1.4.2.1 (exclusive of Activity 6), Report Number G1232211, Revision 1, USGS approved 10/30/91.

Spengler, R.W. and M.P. Chornack, 1984, Stratigraphic and Structural Characteristics of Volcanic Rocks in Core Hole USW G-4, Yucca Mountain, Nye County, Nevada: USGS Open File Report 80-929.

Activity 8.3.1.14.2

DOE, (1991), Study Plan 8.3.1.14.2 (Studies to Provide Soil and Rock Properties of Potential Locations of Surface and Subsurface Access Facilities), Studies 1 and 2, Exploration Program Study and Preliminary and Detailed Exploration Program: U.S. Bureau of Reclamation/U.S. Geological Survey, Revision 0.

Position description, education, work history and professional qualifications for USBR staff member Thomas Strauss.

USGS Quality Assurance Grading Report for SCP Study Plan 8.3.1.14.2, Report Number G1232621, Revision 0, USGS approved 12/2/91.

DOE (1992), Soil and Rock Properties North Portal Drill Hole and Surface Facility Test Pits, YMPO Job Package 92-2, February 1992.

DOE (1992), Soil and Rock Properties of Potential Locations of Surface and Subsurface Access Facilities, YMPO Test Planning Package 92-01, Revision 0, February 1992.

DOE (1992), Soil and Rock Properties of Potential Locations of Surface and Subsurface Access Facilities, YMPO Test Planning Package, 92-01, Revision 1, September 1992.

Letter, McKeown to Dobson, dated 6/26/91. Requesting minor revision to Study Plan 8.3.1.4.2.2, Activity 4, to accommodate preliminary reconnaissance and surface excavation geologic mapping for Study Plan 8.3.1.14.2.

Letter, DOE to the NRC, dated 8/31/92, addressing technical concerns on Study Plan 8.3.1.14.2.

Letter, DOE to the State of Nevada, dated 8/21/92, addressing comments on Study Plan 8.3.1.14.2

**ATTACHMENT 4**

**INFORMATION COPIES  
OF  
CORRECTIVE ACTION REQUESTS**

**ORIGINAL**  
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<b>OFFICE OF CIVILIAN          RADIOACTIVE WASTE MANAGEMENT          U.S. DEPARTMENT OF ENERGY          WASHINGTON, D.C.</b>		8 CAR NO.: <u>YM-93-012</u> DATE: <u>10-23-92</u> SHEET: <u>1</u> OF <u>1</u> <div style="text-align: right;">QA</div>
<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document YMP-USGS-QMP-7.01 Rev. 4		2 Related Report No. YMP-93-01
3 Responsible Organization USGS	4 Discussed With W. Causseaux	
5 Requirement: QMP 7.01, R4-M2 Para. 5.1.4 allows project personnel to use vendors not on the approved vendors list subject to conditions. These conditions include: <ol style="list-style-type: none"> <li>1. Addition to the QA office working vendors list by the QA Manager, and</li> <li>2. A Nonconformance Report shall be written if the vendor is not qualified for the Approved Vendors List within 60 calendar days of addition to the working vendors list.</li> </ol>		
6 Adverse Condition: Contrary to the above <ol style="list-style-type: none"> <li>1. There is no QA office working vendors list, and</li> <li>2. A Nonconformance Report has not been issued after the QA Manager agreed by memo to allow the use of a vendor on July 23, 1992, and the vendors has not been added to the Approved Vendors List.</li> </ol>		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; 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: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination		
13 Recommended Actions:		
7 Initiator J. Blaylock and C. Prater	14 Issuance Approved by: QADD <u>R.C. Spruce</u> Date <u>11/3/92</u>	
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 _____	

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<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document YMP-USGS-QMP-7.01 Rev. 4		2 Related Report No. YMP-93-01
3 Responsible Organization USGS	4 Discussed With W. Causseaux	
5 Requirement: QMP-7.01 R4, R2 Paragraph 5.1.3 states in part "An approved vendors list will be initiated, maintained, updated, and distributed by the QA Office. The list shall include... "a detailed description of the service or item..."  QMP-12-01, R5 Paragraph 5.22 require calibration service be provided by vendors on the Approved Vendors List in accordance with QMP-7.01.		
6 Adverse Condition: Contrary to the above  LI-COR provided calibration services on April 29, 1992, after being removed from the Approved Vendor List on April 21, 1992.		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; 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: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination		
13 Recommended Actions:		
7 Initiator J. Blaylock and C. Prater	14 Issuance Approved by: <i>[Signature]</i> QADD <i>[Signature]</i> Date <u>11/3/92</u>	
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 _____	

**Original**  
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<b>OFFICE OF CIVILIAN          RADIOACTIVE WASTE MANAGEMENT          U.S. DEPARTMENT OF ENERGY          WASHINGTON, D.C.</b>	8 CAR NO.: <u>YM-93-014</u> DATE: <u>10/23/92</u> SHEET: <u>1</u> OF <u>2</u> QA
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**CORRECTIVE ACTION REQUEST**

1 Controlling Document Quality Assurance Program Plan, YMP-USGS-QAPP-01, R5, ICN-8	2 Related Report No. YMP-93-01
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3 Responsible Organization USGS	4 Discussed With D. Gockel & M. Wallendorf
------------------------------------	---

5 Requirement:  
 The USGS QAPP, Section 6.1.2, "Implementation of Document Control", states in part:  
 "Implementation of Document control shall provide for ....:  
 \* Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance....." (This is the third bullet as it appears in ICN-1 to the QAPP.)

6 Adverse Condition:  
 Contrary to this requirement, the reviews of both ICN-8 to the USGS QAPP, (YMP-USGS-QAPP-01, Revision 5) that made significant changes to Appendix E of the QAPP, and of Change M-1 to procedure YMP-USGS-QMP-3.03, Revision 3, failed to detect that some of the requirements established in ICN-8 were not carried down into procedure "QMP-3.03" that implements Appendix E. Both ICN-8 and M-1 were effective on March 12, 1992.  
 The identified, omitted requirements can be found in Appendix E (ICN-8), sections:  
 \* 4.1 "Requirements Phase", items d and e  
 \* 4.2 "Design Phase", items b and c  
 \* 4.3.2 "Method of Software Validation", second paragraph.  
 An explicit statement of the omitted requirements is provided on page 2.

9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; 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:  
 1. Modify "QMP-3.03" to include all Appendix E requirements.  
 2. Review all Software Lifecycle Documents subject to the current Appendix E requirements to identify those failing to meet all requirements. Revise these lifecycle documents to bring them into compliance with Appendix E, ICN-8, including the conduct of additional testing if this is necessary for compliance. Continued.

7 Initiator T. J. Higgins / <i>[Signature]</i> Date <u>10/27/92</u>	14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>11/3/92</u>
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15 Response Accepted QAR Date	16 Response Accepted QADD Date
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17 Amended Response Accepted QAR Date	18 Amended Response Accepted QADD Date
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19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date
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OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

8 CAR NO.: YM-93-014  
DATE: 10/23/92  
SHEET: 2 OF 2  
QA

**CORRECTIVE ACTION REQUEST (Continuation Page)**

6 Adverse Condition (continued)

Omitted requirements from Appendix E (ICN-8):

\* 4.1 REQUIREMENTS PHASE

A specification of software requirements shall be provided .....  
This specification shall address the following:

- d. attributes - non-time-related issues of software operations such as portability, correctness, security, maintainability, etc.; and
- e. external interfaces - interactions with hardware, other software, and other participants.

\* 4.2 DESIGN PHASE

In this phase the overall structure, ..... This description shall address the following:

- b. A technical description of the software with respect to control flow, data flow, control logic, and data structure; and
- c. The allowable and tolerable ranges for inputs and outputs.

\* 4.3.2 METHOD OF SOFTWARE VALIDATION

2nd paragraph: When testing is the selected method of software validation, test cases shall be developed and executed with inputs and conditions sufficient to invoke all elements of the code that represent implementation of the software requirements. These tests shall also identify boundary conditions, and provide a suitable benchmark.

13 Recommended Action(s) (continued)

- 3. Determine the reason that two related documents (Appendix E, ICN-8 and QMP-3.03, R3-M1), with identical effective dates, were reviewed and issued without identification and correction of the noted discrepancies. Propose suitable corrective action to prevent recurrence if such action is necessary.

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<b>OFFICE OF CIVILIAN          RADIOACTIVE WASTE MANAGEMENT          U.S. DEPARTMENT OF ENERGY          WASHINGTON, D.C.</b>		CAR NO.: <u>DP-93-015</u> DATE: <u>10-22-92</u> SHEET: <u>1</u> OF <u>2</u> QA
<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document AP 5.19Q, R2 AP5.1Q, R2		2 Related Report No. YMP-93-01
3 Responsible Organization USGS		4 Discussed With Ardell Whiteside, R. Spangler
5 Requirement: <p>AP 5.19Q, Step 8b, stated in part: "Data Supplier-If IMOU and/or PIRN have no impact on controlled documents and are acceptable, sign and return original signature document... to the processor."</p> <p>AP 5.19Q, Step 11, states in part: "Data Supplier-Compile and send data to the requester (send and control data per AP-5.1Q....)"</p> <p>AP 5.1Q, Step 2, states in part: "YMP Participant- Submit the DPS to the appropriate participant data archive... Include a TDIF...."</p> <p>AP 5.1Q, Section 3.12 states in part: "The TDIF... is used to provide input to the ATDT System. The form is included with DPSs and Data Transmittal Packages."</p>		
6 Adverse Condition: Contrary to the above: <p>(A) Acquired Data has been transmitted to LANL without documented evidence of processed IMOU.</p> <p>(B) Acquired Data has been transmitted to LANL without evidence of a TDIF being prepared and Data entered into the Participant Data Archive.</p> <p>Example: 6-10-91 "Potential Sr-Isotope Stratigraphy High-Silica Rhyolite."          10-12-92 "Isotope Stratigraphy in the Topopah Springs High-Silica Rhyolite"</p>		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; 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: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination		
13 Recommended Actions: <p>(A) Process IMOU and get number assigned prior to transmittal of Data</p> <p>(B) Transmit Acquired Data to PDA with TDIF</p> <p>(C) Evaluate status of all IMOUS between USGS and other participants. Assure all have been processed and have been assigned a number per AP 5.19Q</p>		
7 Initiator R. L. Maudlin <i>R. L. Maudlin</i> Date <u>10-22-92</u>		14 Issuance Approved by: QADD <i>AC Spangler</i> Date <u>11/3/92</u>
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

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

10-22-92  
CAR NO.: DD-93-015  
DATE: 10-22-92  
SHEET: 2 OF 2  
QA

**CORRECTIVE ACTION REQUEST (Continuation Page)**

13 Recommended Action(s) (continued)

- (D) Evaluate all Data Transmitted to date and determine:
  - (1) is there a valid DMOU for transmittal of this data
  - (2) has data been transmitted to FDA via TDIF prior to being sent to participant
- (E) Determine cause of condition and what action would be taken to preclude recurrence