PROJECT OFFICE QUALITY ASSURANCE AUDIT REPORT FOR

THE YUCCA MOUNTAIN PROJECT OFFICE AUDIT OF

THE UNITED STATES GEOLOGICAL SURVEY

AUDIT NO. 89-4

CONDUCTED: AUGUST 14 - 23, 1989

Prepared By: 2

Audit Team Leader

Date: 10 8

Approved By:

Dale Hedges, Manager -

Verification Department

Date:

Approved By:

Edwin L. Wilmot, Acting Director Quality Assurance Division

Yucca Mountain Project

Date: 10/12/89

EXECUTIVE SUMMARY

PROJECT OFFICE AUDIT REPORT NO. 89-4

UNITED STATES GEOLOGICAL SURVEY

DENVER, COLORADO

AUGUST 14 - 23, 1989

In the opinion of the Yucca Mountain Project Office (Project Office) audit team, the United States Geological Survey (USGS) currently has a sufficient Quality Assurance (QA) program (QAPP-01, Revision 5) in place to provide adequate controls to permit the initiation of quality related work.

This audit covered the fourteen QA criteria comprising the USGS QA program and their Software QA Plan. In all but one case (Criterion #2), the audit team was able to determine that adequate controls were in place. Because of lack of access to the training files due to restrictions imposed by the Privacy Act, no determination could be made on the adequacy of the controls provided by Criterion #2, "QA Program."

Also, due to the limited amount of quality related work being performed at the time of the audit, the effectiveness of implementation of the USGS QA program cannot be determined at this time.

Five Standard Deficiency Reports (SDRs) were issued as a result of this audit, four to the USGS and one to the Project Office. A total of eight Observations were issued during the course of the audit, seven to the USGS and one to the Project Office. It should be noted that during the course of the audit, the USGS was able to correct eight concerns identified by the auditors.

It was apparent to the audit team that the USGS had put forth a considerable effort in bringing their program into compliance with the requirements of NNWSI/88-9, Revision 2. USGS personnel should be commended for the cooperation extended during the audit and the effort necessary to bring their QA program to this level.

1.0 INTRODUCTION

This report contains the results of a QA audit of the USGS Yucca Mountain Project activities. The audit was conducted at the USGS facilities in Denver, Colorado and Las Vegas, Nevada, August 14-23, 1989. The audit was conducted in accordance with the requirements of QMP-18-01, Revision 3, Audit System for the Waste Management Project Office. The QA program requirements to be verified were taken from the QA Plan, NNWSI/88-9, Revision 2.

2.0 AUDIT SCOPE

The following program elements were audited to assess compliance with NNWSI/88-9, Revision 2, and USGS QAPP-01, Revision 5, although only limited evidence of implementation was available at the time of the audit:

- 1.0 Organization (USGS Matrix Management)
- 2.0 QA Program (subject to Privacy Act restrictions)
- 3.0 Scientific Investigation Design Control
- 4.0 Procurement Process
- 5.0 Instruction, Procedures, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items
- 8.0 Identification and Control of Items, Samples, and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage
- 15.0 Nonconformances
- 16.0 Corrective Actions
- 17.0 Control of QA Records
- 18.0 Audits

The following program elements described in the USGS QAPP were reviewed prior to the audit and found to be not applicable to the activities assigned to the USGS at this time:

- 9.0 Control of Processes and Special Processes
- 10.0 Inspections
- 11.0 Test and Experiment Control
- 14.0 Inspection, Test, and Operating Status

2.0 AUDIT SCOPE (CONTINUED)

The scope of this audit also included a review of the following technical activities:

SCP Section	<u>Title</u>
8.3.1.2.1.2.1	Surface water runoff monitoring
8.3.1.2.1.2.2	Transport of debris by severe runoff
8.3.1.2.3.1.2	Site potentiometric-level evaluation
8.3.1.5.2.1.5	Studies of calcite and opaline silica vein deposits
8.3.1.9.2.1	Mineral and energy assessment of the site, comparison to known mineralized areas, and the potential for undiscovered resources
8.3.1.16.1.1.1	Site flood and debris hazards studies
8.3.1.17.4.1.2	Monitor current seismicity
8.3.1.17.4.3	Study: Quaternary faulting within 100 km of Yucca Mountain, including the Walker Lake
8.3.1.17.4.6	Study: Quaternary faulting within the site area
8.3.1.17.4.7	Study: Subsurface geometry and con- cealed extensions of quaternary faults at Yucca Mountain

3.0 AUDIT TEAM PERSONNEL

Henry H. Caldwell	Audit Team Leader
James Blaylock	Auditor/Audit Manager
Sidney L. Crawford	Auditor
Neil D. Cox	Auditor

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3.0 AUDIT TEAM PERSONNEL (CONTINUED)

James E. Clark Auditor

John C. Friend Auditor

Daniel A. Klimas Auditor

Frederick J. Ruth Auditor

Keith M. Kersch Lead Technical Specialist

David Cummings Technical Specialist

Joy Fiore Technical Specialist

Carolyn Rutland Technical Specialist

Roselund M. C. Klimist Auditor-In-Training

Catherine E. Hampton Auditor-In-Training

Mario R. Diaz Auditor-In-Training

Scott G. Van Camp Observer, DOE/HQ

Carl E. Webber Observer, DOE/HQ

Susan W. Zimmerman Observer, State of Nevada

John Gilray Observer (Lead), Nuclear Regulatory

Commission (NRC)

Charlotte E. Abrams Observer, NRC

Robert Brient Observer, NRC

James T. Conway Observer, NRC

Neil M. Coleman Observer, NRC

Keith McConnel Observer, NRC

Tilak Verma Observer, NRC

4.0 SUMMARY OF AUDIT RESULTS

4.1 STATEMENT OF PROGRAM EFFECTIVENESS

It was determined by the audit team that in all criteria except Criterion #2, adequate controls existed to support the initiation of quality related work. Criterion #2 was considered indeterminate by virtue of the limited access gained by the audit team to information governed by the Privacy Act. In the opinion of the Project Office audit team, the effectiveness of the QA program at the USGS cannot be determined at this time. Until sufficient objective evidence has been generated to demonstrate technical adequacy and program implementation, the effectiveness will remain indeterminate. All of the quality implementing procedures were either found to meet or were amended to meet (during the course of the audit) the requirements of NNWSI/88-9, Revision 2.

4.2 SUMMARY OF TECHNICAL ACTIVITIES

The team of technical specialists focused on the status and adequacy of plans and procedures that were written to meet the requirements of NNWSI/88-9, Revision 2. To date, technical work has been limited to the preparation of study plans and technical procedures. The activities reviewed by the technical team are outlined in the following section.

The technical specialists reviewed the following attributes to evaluate the technical aspects of the activities audited:

- 1. Understanding of Scientific/Quality Assurance Process
- 2. Understanding of Procedural Requirements as They Pertain to Activities
- 3. Procedural Adequacy from a Technical Standpoint

For Attributes 1 and 2 above, the technical team was able to determine that the USGS technical staff and management had an adequate understanding of both the scientific/QA process and the procedural requirements as they pertain to the technical activities.

For Attribute 3, where procedures existed, the USGS investigators had a detailed understanding of these procedures and their application to the appropriate studies.

4.2 SUMMARY OF TECHNICAL ACTIVITIES (CONTINUED)

Based on the interviews conducted for the activities listed above, the technical team was able to determine that the qualifications and experience of the USGS personnel were commensurate with these assigned tasks.

4.3 SUMMARY OF FINDINGS

A total of five Standard Deficiency Reports (SDRs) were generated as a result of this audit. Information copies of these SDRs are included as Enclosure 3. Four SDRs were issued to the USGS and one to the Project Office. Eight Observations were generated, seven to the USGS and one to the Project Office. A synopsis of SDRs and Observations is discussed in Section 6 of this report. This synopsis also includes eight concerns that were corrected during the course of the audit.

5.0 AUDIT MEETINGS

The audit was conducted in Denver, Colorado and Las Vegas, Nevada, which required separate entrance and exit meetings at different locations.

5.1 PRE-AUDIT CONFERENCE

A pre-audit conference was held with the USGS Technical Project Officer (TPO) and his staff at 10:00 a.m. on August 14, 1989. The purpose, scope, and proposed agenda for the audit were presented and the audit team was introduced. A list of attendees for this and subsequent meetings is provided as Enclosure 1.

5.2 PERSONS CONTACTED DURING THE AUDIT

See Enclosure 1.

5.3 POST-AUDIT CONFERENCE

The post-audit conference was held at 2:00 p.m. on August 23, 1989, at the USGS offices in Denver. A synopsis of the preliminary SDRs and Observations identified during the course of the audit was presented to the TPO and his staff. A list of those attending is provided in Enclosure 1.

5.4 AUDIT STATUS MEETINGS

Audit status meetings were held with the USGS TPO and his key staff at 8:30 a.m. each day of the audit. A status of how the audit was progressing and identification of discrepancies were discussed.

5.5 ENTRANCE AND EXIT MEETINGS

An exit meeting was held for the USGS TPO and his full staff on August 18, 1989 in Denver, Colorado to update USGS personnel on the progress of the audit and plans for its completion. An entrance meeting was held for USGS personnel at their Las Vegas, Nevada Office on August 21, 1989.

6.0 SYNOPSIS OF STANDARD DEFICIENCY REPORTS, OBSERVATIONS, AND CONCERNS CORRECTED DURING THE AUDIT

6.1 STANDARD DEFICIENCY REPORTS

- SDR No. 414 ... Contrary to the requirements of AP-1.7Q, the USGS has not been permitted to submit QA records to the Central Records Facility (Las Vegas) per written direction from the Project Office.
- SDR No. 415 ... Contrary to the requirements of USGS/QMP-12.01, Revision 3, seven different instruments were found to be out of calibration and no Nonconformance Reports (NCRs) had been written identifying this condition.
- SDR No. 416 ... There was no objective evidence that calibration QA forms had been checked before being processed and retained as QA records as required by USGS/QMP-17.04, Revision 3.
- SDR No. 417 The documentation of technical reviews performed for the Study Plans reviewed during the audit did not provide evidence of resolution of reviewer's comments or reviewer acknowledgment of comment resolution.
- SDR No. 418 Numerous QA calibration forms were found in the USGS Local Records Center that did not comply with the requirement of USGS/QMP-17.01, Revision 3; examples include:
 - o Corrections made without required date and identification of person(s) making same.
 - o No indication of when record was received by QA, making it impossible to determine if the record was transmitted prior to equipment use.
 - o Serial number calculation date and expiration date missing from record.

6.2 OBSERVATIONS

- 1. USGS/QMP-17.01, Revision 3 and other affected procedures need updating to the current requirements of AP-1.7Q and AP-5.1Q for capture of field data in the LRC (via field notebooks).

 Observation 89-4-01 (USGS).
- The disposition of two USGS Corrective Action Reports (CARs) is in conflict with the requirements of USGS/QMP-15.01, Revision 3. The use of "Hold Tags" and some form of dispositioning for out of calibration equipment is indicated. Observation 89-4-02 (USGS).
- 3. Numerous minor discrepancies related to Quality Assurance Level Assignments (QALAs) were identified during a review of USGS—generated Study Plans. Observation 89-4-03 (USGS).
- 4. The proposed reorganization of USGS/YMP to allocate QA implementation personnel to USGS line organization should be tabled pending an analysis of the independence of quality personnel so assigned. Observation 89-4-04 (USGS).
- 5. The audit team identified that based upon a review of deficiency documents (NCRs and CARs), the USGS TPO and other technical personnel were not actively involved in the disposition and resolution of these documents. Observation 89-4-05 (USGS).
- 6. Changes are required to USGS/QMP-2.02, Revision 3; USGS/QMP-2.07, Revision 3; and USGS/QMP-2.08, Revision 0, to provide necessary clarification on the USGS instructional process used to ensure the qualification and proficiency status of USGS personnel performing quality related work. Observation 89-4-06 (USGS).
- 7. Project Office direction is needed to provide guidance to participants whenever organizational responsibilities change. In the course of this audit, it was discovered that the USGS still had implementing procedures on "active" status for which there is currently no corresponding relevant technical activity. Observation 89-4-07 (Project Office).
- 8. The USGS did not perform a Management Assessment for 1988 (the period ending 2/89). This was identified by USGS audit activity on AFR No. USGS 8903-03. The USGS needs to evaluate its finding and determine the appropriate level of authority needed to waive this annual requirement. Observation 89-4-08 (USGS).

6.3 CONCERNS CORRECTED DURING THE AUDIT

- o While assessing the adequacy of implementation of QMP-5.01, Revision 2 provisions, the auditor found that the USGS had developed a technical review checklist to document the generation and resolution of comments. The checklist served as a record of the issues considered during the technical review. However, the checklist did not include a review item specified in the text of the QMP, which is a QAP requirement. The USGS resolved this condition by adding the review requirement to the review checklist via Mod. 01-Revision 0, dated 8/16/89.
- o During examination of controls applied to scientific notebooks in QMP-5.05, Revision 1, the auditor found that revisions to Scientific Notebook Plans were not required to be approved by the original approvers, which did not comply with the requirement to have changes to approved documents reviewed and approved by the original approvers. Since no revisions to Scientific Notebook Plans had occurred, the USGS was permitted to correct this deficiency via Mod 01-Revision 0, dated 8/23/89, which requires the original approvers' signatures whenever major changes are made.
- o QMP-17.01, Revision 3 requires that all records transmitted to the LRC be authenticated and forwarded to the LRC via a Records Transmittal form. The auditor discovered calibration records in the LRC that were not authenticated and transmitted per the QMP requirements. The records had not been processed; therefore, USGS corrected the condition by gathering the unauthenticated records and resubmitting authenticated documents in accordance with QMP-17.01, Revision 3 requirements.
- O Identification of data is to be accomplished in accordance with USGS QMP-8.03, Revision 1, which provides a Data Authorization form to identify the source of the data (WBS number/SP number), QA level, and reference to the document number, if published as a report. Two Open File Reports had been submitted to the Site Engineering Properties Data Base (SEPDB) on July 28, 1989. The reports were forwarded using a Data Authorization form provided by YMP AP-5.2Q, Revision 0 in lieu of the form in QMP-8.03, Revision 1. As a result, the transmittal did not identify the data source (WBS number). Corrected forms were prepared and forwarded to Sandia National Laboratories during the audit.

6.3 CONCERNS CORRECTED DURING THE AUDIT (CONTINUED)

- o During the review of QMP-15.01, Revision 3, the auditor identified that the interfaces between USGS/Denver, Menlo Park, and Las Vegas offices were not clearly defined as to the handling/processing of NCRs. This condition was corrected during the course of the audit by changing the distribution requirements and requiring that the point of origin or originating organization be identified on the NCR form.
- o The above review of QMP-15.01, Revision 3 also identified that distribution of NCRs to the Project Office did not comply with the requirements of the procedure. The distribution instructions for NCRs sent to the Project Office were amended, thus resolving the concern.
- o The review of QMP-16.01, Revision 0 disclosed that the identification of remedial and corrective actions to prevent recurrence was not addressed. Further, a response due date was not an integral part of the corrective action process. These conditions were corrected by the issuance of Mod 01-Revision 0, dated 8/23/89, to QMP-16.01, Revision 0 during the course of the audit.
- o The auditor also found that USGS had methods for immediate and interim changes for the QAP and technical procedures, but none for QMPs. The USGS corrected the condition via Mod. 01-Revision 0, dated 8/23/89, to QMP-5.03, Revision 3, which authorizes "modifications" to QMPs, and added provisions to QMP-6.01, Revision 4 that establish requirements for modifications and interim change notices.

7.0 RECOMMENDED ACTION

A written response is required for each SDR delineated in Section 6.0. Responses to each SDR are due 20 working days from the date of the SDR transmittal letter. Upon response, acceptance, and satisfactory verification of all remedial and corrective actions, the SDRs will be closed and the USGS notified by letter of closure.

A written response is required for the Observations contained in Enclosure 2 of this report. Responses are due 20 working days from the date of the transmittal letter of this report.

ENCLOSURE 1

UNITED STATES GEOLOGICAL SURVEY 89-4 AUDIT ROSTER

NAME	ORGIZATION	TITLE	PRE- AUDIT	CONTACTED DURING AUDIT	POST AUDIT
Abrams, Charlotte	NRC	Geologist	X	x	
Baldwin, Darrell	USGS	Hydro. Technician	••	X	
Bahorich, Rick	TEMSS	QA Manager		•	x
Barth, Joe	USGS	QA		x	X
Barton, Robert	DOE	Physical Scientist		X	A
Bauer, David	USGS	Hydro. Technician		X	
Beck, David A.	USGS	PI		x	x
Benington, Mary E.	SAIC	QA Specialist	X	X	x
Berquist, Joel R.	USGS	Geologist	••	X	^
Blaylock, James	DOE/YMP	Auditor	X	X	x
Brient, Robert	NRC/CIMIRA	QA Group Leader	X	X	^
Brooks, James R.	USGS	Seismologist Tech.		X	
Brooks, Mark C.	SAIC/GD	SAIC/Geologic Div.	X	X	x
Bruker, Michelle	USGS	NHP QA	X	x	X
Bufe, Chuck	USGS	PI Seismic Met	••	X	X
Buono, Tony	USGS	TPO's NV Rep.	X	x	^
Caldwell, Henry H.	SAIC	Auditor	X	X	x
Casseaux, Wil	USGS	NHP QA Asst.	X	X	X
Chaney, Tom	USGS	Asst. QA Mgr.	X	x	X
Ciesnik, Marek	USGS/NHP	QA Implementation	X	•	X
Clark, Jim	SAIC	Auditor	X	x	X
Coleman, Neil M.	NRC	Hydrologeologist	X	x	^
Conway, Jim	NRC	QA Project Manager	X	x	
Covington, Pam .	SAIC	QA Software Tech.	••	A	X
Cox, Neil D.	SAIC	Auditor	X	x	^
Crawford, Sidney L.	SAIC	Auditor	X	**	X
Diaz, Mario R.	DOE/YMP	Auditor	X	x	
Douglas, Michael F.	USGS	GD QA	X	X	X
Dudley, Jr., William W.		Specialist		X	*
Fehr, Gregory	SAIC	Dep. APM. QA	X	••	
Flint, Alan	USGS	Project Chief	-	x	
Forester, Richard D.	USGS	Research Geologist		X	
Friend, John	SAIC	Auditor	X		
Gibbons, William S.	MACTEC	Mgr. Quality Systems	X	×	
Gillies, Daniel C.	USGS	Assoc. Ch, Hydrol.	X	X	
Gilray, John	NRC	Resident	X	X	X
Glangman, Virginia	USGS	Tech. Publ. Editor	X	X	X

UNITED STATES GEOLOGICAL SURVEY 89-4 AUDIT ROSTER

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NAME	ORG.	TITLE	PRE- AUDIT	CONTACTED DURING AUDIT	POST AUDIT
Hampton, Catherine E.	DOE/YMP	Auditor	x		
Handy, A. H.	USGS	QA Specialist	X	X	X
Hayes, Larry R.	USGS	TPO	X	X	X
Hedges, Dale	SAIC	Mgr. Verif. Dept.	X		
Hoxie, Dwight T.	USGS	SQA Specialist	X	X	X
Jafari, Bahram A.	TSI	Tech Consultant			X
Jorgensen, Donald	USGS	NHP Chief	X	x	X
Keller, Stephen M.	SAIC	Staff Geologist			X
Kersch, Keith M.	SAIC	Lead Tech. Specialist	X	X	X
Klimas, Daniel A.	SAIC	QA Engineer	X	X	
Klimist, Rosalunde M.	CER/DOE	QA Engineer	X	X	X
Langer, William H.	USGS	Hydrologist	X	X	X
Langsteiner, Bruce E.	SAIC/GD	QA Auditor	X		
Lobmeyer, David	USGS	Data Processor		X	
Luckey, Richard R.	USGS	Hydrologist	X	X	X
Mallon, Cheryl	USGS/NHP	Software QA	X	X	X
McConnell, Keith	NRC	Geologist	X	X	
Mendez-Vigo, Tracy	USGS	QA Specialist	X		X
Meyer, David	USGS	Rydrologist		X	
Murray, Mildred	SAIC	Sr. Records Spec.		X	
Mustard, Martha H.	SAIC	QA Specialist	X	X	X
O'Brien, Grady	USGS	Data Processor		X	
Otto, Gary	USGS	Hydrol. Field Tech.		X	
Overturf, Dee	USGS	Electronic Tech.	X	X	
Pabst, Marilyn E.	USGS	WRD	X		
Porter, Darrell	SAIC/GD	Mgr. QA Support	X		X
Raup, Jr., Robert B.	USGS/GD	Geol. Div. Coord.	X	X	X
Reilly, Patricia G. S.	SAIC	Implementation Spec.		X	X
Reynolds, Mitchell W.	USGS/GD/ORG	Ch. Off. of Reg. Geo.	X	X	
Roadway, Linda L.	USGS	Budget Analyst		X	
Rodman, Wayne	USGS/HIF	QA Specialist	X	X	
Roseboom, Gene	USGS	Dir. Office	X	×	X
Ruth, Frederick J.	SAIC	Auditor	X	X	
Rutland, Carolyn	SAIC	Technical Specialist	X		
Salamon, Mary E.	USGS	QA Implementation	X		X
Schleiche, Dave	USGS	Geologist	X		
Schmidt, Jr., Norman E.	USGS/WRD	Ch., Br. of Manpower	X	X	X

UNITED STATES GEOLOGICAL SURVEY 89-4 AUDIT ROSTER

NAME	ORG.	TITLE	PRE- AUDIT	CONTACTED DURING AUDIT	POST AUDIT
Shideler, Gerald L.	USGS/GD	Assoc. Coordinator	x	x	x
Shipley, Susan	USGS/WRD	QA Specialist	X	X	X
Simpson, Michael	SAIC/GD	TPO Support	X	X	X
Sinks, Donna	SAIC/SMF	Spvr. Field Operations		x	-
Spaulding, Ron	USGS	Hydrol. Field Tech.		x	
Stuckless, John	USGS	PI Paleohydro.	X		
Valega, Dan	SAIC/GD	QA Auditor	X	X	X
Van Camp, Scott G.	WESTON/DOE	Sr. Geologist	X	x	
Verma, Tilak (Teek)	NRC	QA Project Manager	X	x	X
Wallendorf, Mark A.	SAIC	SCM Technician		-	X
Warner, Peggy J.	SAIC	Records Manager	X	x	X
Watkins, Richard V.	USGS	Assoc Ch, Br of Mnpwr	X		••
Weber, Carl E.	WESTON	Staff QA Engineer	X	X	X
Whelan, Joseph F.	USGS	Geologist		X	
Whiteside, Ardell M.	SAIC	TPO Spp./QA Audit Spvr.	X	X	X
Williams, Wesley	MACTEC	QA Engineer			X
Williston, Willis	USGS	QA Specialist		x	
Willmon, Joe R.	USGS	QA Manager	X	X	X
Wilmot, Ed	DOE	Act. Dir. QA/YMP			X
Wilson, William E.	USGS	Escort	X	x	X
Woolverton, Jon B.	USGS/NHP	QA Technical Spec.	X	X	X ·
Yang, Al	USGS	Hydrologist		X	
Zeigler, Ben	SAIC/GD	QA Specialist	X	X	
Ziemba, James M.	SAIC	QA Auditor	X	X	x
Zimmerman, Susan	State of NV	QA Manager	X	x	X

ENCLOSURE 2

- ૧	YUCCA TOUNT	AIN PRO TON NO.	JECT OFFICE 089-4-01	N-QA-012 4/89
ion	2Noted During: AUDIT 89-4 (USGS)	³ Identifie	d By: J. E. CLARK	4 Date: AUG. 22, 1989
rganizat	5Organization: USGS	,	s) Contacted: R. NG, G. OTTO, R. LUCKEY	7 Response Due Date is 20 Days from Date of Transmittal
Completed by Originating Organization	BDiscussion: Records of field data are copi forwarded to the cognizant PI. the LRC until the study is comrecords on a more frequent bas data will be clarified in AP-5 need updating to ensure captur files* in PI offices. Procedu numbering pages in field noteb	The not uplete or is is recorded to the control of	tebooks are not submitted at the notebook is filled. Quired by AP-1.7Q; applicated SQMP-17.01 and other affold data in the LRC rather to should include requirements	as records to Capture of tion to field ected procedures than in *hold nts for
	QAE/Lead Auditor	Pate 89	19 Branch Manager	Date 9/20/89
Completed by Respondee	11 Response:			
	12Signature:		Date:	
Jrg.	13 Response Receipt Acceptable Initiator	Date	QA/Lead Auditor	Date
Completed by QA Org.	14Remarks:			·
				Page _1 _ of _2

YMPO OB ERVATION NO. 89-4-01 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)
 requirements.

Page

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*	YUCCA MOUNT 1YMPO OBSERVAT	N-QA-012 4/89				
·	2Noted During: AUDIT 89-4	³ Identifie	ed By: J. FRIEND	4Date:		
ion	(USGS)			AUG. 22, 1989		
nizat	5Organization: USGS		(s) Contacted: J. WILMON,	7 Response Due Date is 20 Days from Date of Transmittal		
Orgai						
Completed by Originating Organization	During the review of CAR-89-02 and CAR-89-04 several pieces of equipment were identified that had not been calibrated or had missed calibration. An addendum to the CAR's stated that no NCR would be generated for these nonconformances. However, this appears to be in conflict with QMP 15.01 since the CAR does not provide for "HOLD" tags on equipment, nor does it provide for the same type of dispositioning for corrective action. The use of CAR for tracking equipment problems should be reevaluated.					
		Date	10 Branch Manager	Date		
	The Colorell 20to	£ 89	Mul for	9/20/89		
Completed by Respondee	11 Response:	·				
	12Signature:		Date:	·		
	13 Response Receipt Acceptable □					
	Initiator	Date	QA/Lead Auditor	Date		
rg.						
Completed by QA Org.	14 Remarks:			Page _1of_1_		

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	YUCCA MÓ		OJECT OFFICE 0. 89-4-03	N-QA-0 4/89	
E O	2Noted During: AUDIT 89-4 (USGS)	³ Identifie	ed By: S. L. CRAWFORD	4Date: AUG. 22, 1989	
rganizati	5Organization: USGS	⁶ Person W. CAUS	(s) Contacted: W. LANGER,	7 Response Due Date is 20 Days from Date of Transmittal	
Completed by Originating Organization	USGS prepared Study Plans (SP) include QA Level Assignment (QALA) sheets as required by YMP Administrative Procedure AP-1.10Q. Although the currently approved QALA sheets in the SPs are to be replaced with new QALAs and are considered obsolete, numerous minor discrepancies were noted during the review of the SPs: 1. Not all QALA pages included (SP 8.3.1.2.2.6, 3 QALAs) 2. QALA included twice in SP (SP 8.3.1.2.2.6, 3346G-01-01) 3A. QALA in Table 3.1-2, but not in Appdx 7.1.2				
O	PQAE/Lead Auditor	Date April 89	10Branch Manager	Date 9 2 89	
Completed by Respondee					
Ö					
<u>ن</u>	¹² Signature:		Date:		
Completed by QA Org.	12 Signature: 13 Response Receipt Acceptable Initiator	□ Date	Date: QA/Lead Auditor	Date	

8 Discussion: (continued)

(SP 8.3.1.2.2.6, 3346G-01-01)

3B. QALA in Table 3.1-2, but not in Appdx 7.1.2

(SP 8.3.1.2.3.1, 3331G-01-07)

- 4A. QALA not in Table 3.X-2, but in Appdx 7.1.2 (SP 8.3.1.2.3.1, 8 QALAs)
- 4B. QALA not in Table 3.X-2, but in Appdx 7.1.2 (SP 8.3.1.2.1.2, 3310G-01-01)
- 5. QALA incorrectly numbered in Table 3.1-3 (SP 8.3.1.2.2.6, 3331G-01-01)
- 6. QALAs not approved by YMP* (SP 8.3.1.2.2.6, 3332G series)
- 7A. Superseded QALAs in Appdx 7.1.2 (SP 8.3.1.2.3.1, 4 QALAs)
- 7B. Superseded QALAs in Appdx 7.1.2 (SP 8.3.1.2.1.2, 7 QALAs)

The lack of a Technical Review of the final version of the Study Plans, identified by SDR NO. 417, is considered to be a contributing factor to the above discrepancies.

* Approved copies of QALA-3332-01-XX were available at USGS, but unsigned copies were attached to SP 8.3.1.2.2.6

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· (*	YUCCA MOUNT YMPO OBSERVAT	N-QA-012 4/89				
	2Noted During: AUDIT 89-4	3 Identifie	d By: D. A. KLIMAS, R. M.	4Date:		
<u>و</u>	(USGS)	C. KLIM	IST	AUG. 18, 1989		
rganizati	5 Organization: USGS 6 Person(s) Contacted: L. HAYES, J. WILLMON 7 Response Due Date is 20 Days from Date of Transmittal					
g	⁸ Discussion:			-		
Originatin	The TPO and QAM depicted the U The depiction differs from the 1.01.	_				
Completed by Originating Organization	The depiction incorporated the assigned to technical program in-line QA to the technical pr	elements	. This approach is intende			
	9QAE/Lead Auditor	Date	10 Branch Manager	Date		
	A Calquell 20 to	739	Athu	9/20/89		
Respondee	11 Response:		U			
Completed by Respondee						
	¹² Signature:		Date:			
	13 Response Receipt Acceptable □					
.ĝ	Initiator	Date	QA/Lead Auditor	Date		
Completed by QA Org.	14Remarks:			Page 1 of 2		
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YMPO OB ARVATION NO. 89-4-04 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

The approach is also configured such that a QA staff under the QAM will provide the verification activities. This will most likely need to be analyzed and/or expanded to ensure: (a) that in-line QA support activities do not become absorbed in the technical processes such that independence is abrogated, (b) that the program is being implemented and actively supported by technical personnel as well as QA personnel, and (c) that the QAM at least quarterly interview those assigned to QA Unit Support to discuss the administrative functionality of their work position.

Page

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*	YUCCA OUNT YMPO OBSERVAT		DJECT OFFICE 089-4-05	N-QA-012 4/89	
Ľ	2Noted During: AUDIT 89-4 (USGS)	³ Identifie	d By: J. FRIEND	4Date: AUG. 22, 1989	
ganizatic	5Organization: USGS	1	s) Contacted: J. WILLMON, ESIDE, J. ZIEMBA	7 Response Due Date is 20 Days from Date of Transmittal	
Completed by Originating Organization	During the review of USGS NCR's and CAR's, a concern was identified in that it is not apparent the TPO, PI's or other technical personnel are adequately involved in the resolution and correction of deficiencies that affect them. Several examples of corrective action documents (eg. CAR 89-13 and NCR 89-23) were issued to the TPO for resolution, however, the documents reflect that the deficiencies were issued and dispositioned by QA, and it appears QA is mainly responsible for correcting the deficiencies. Additionally, during the audit process it was noted that calibration deficiencies were not being identified by QAE/Lead Auditor				
	A Calmel 20	Apt 89	Xione	9/20/89	
Completed by Respondee	11 Response:				
	12Signature:		Date:		
Completed by QA Org.	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date	
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YMPO OBSERVATION NO. 89-4-05 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

technical personnel on a timely basis. In these examples it is apparent that the TPO and other technical personnel were not actively involved in the corrective action process.

The audit team is concerned that the effectiveness of the corrective action system is questionable when the personnel responsible for deficient activities depend solely on QA to resolve those problems in a timely manner.

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	YUCCA OUNT		DJECT OFFICE U 89-4-06	N-QA- 4/89
on O	2Noted During: AUDIT 89-4 (USGS)	3 Identified By: R. M. KLIMIST, D. KLIMAS		4Date: AUG. 18, 1989
ganizati	5Organization: USGS	•	s) Contacted: M. SIMPSON, MON, L. HAYES	7 Response Due Da is 20 Days from D of Transmittal
Completed by Originating Organization	**BDiscussion: The USGS training and indoctrination is being performed to unapproved, unsigned position papers that do not meet or comply with existing, approved USGS QA program documents. Indoctrination is being treated as essentially an informal process that does not require development, review and approval of lesson plans that cover QA Program and detailed USGS QA procedures. As a result, objective evidence is inadequate and forms are being completed as "Training" without approved lesson plans as			
ŏ	QAE/Lead Auditor AAAAQuell & fape	Date	10 Branch Manager	Date 9/20/8°
	11 Response:			
Completed by Respondee			•	
	12Signature:		Date:	
	13 Response Receipt Acceptable Initiator	Date	QA/Lead Auditor	Date
Completed by QA Org.	14 Remarks:		,	
				Page _1 _ of _

YMPO OB _______RVATION NO._89-4-06 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued) required by QMP 2.07.

This condition is being identified as an observation based on USGS presenting modification to QMP's 2.02, 2.07, and 2.08, the governing indoctrination and training procedures.

Page

*	YUCCA MOUNT 1YMPO OBSERVAT	N-QA-012 4/89				
on	2Noted During: AUDIT 89-4 (USGS)	3 Identifie	d By: J. BLAYLOCK	4Date: AUG. 22, 1989		
ganizati	5Organization: PROJECT OFFICE	⁶ Person(s) Contacted: J. WILLMON	7 Response Due Date is 20 Days from Date of Transmittal		
Completed by Originating Organization	a variety of reasons: complet responsibilities by the Project work. In the case of added rethe organization must have a undertaking quality affecting responsibilities, however, the	tional responsibilites of YMP participants continually change reasons: completion of assigned activities, interpretation of ties by the Project Office, and change in an organization's sche case of added responsibility, the course of action is unequization must have approved procedural controls in place prior to quality affecting activities. In the case of changing ies, however, the course of action is not clear. As an example ticipating organizations had NUREG 1318 procedural implementat				
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Completed by Respondee	11 Response:					
	12Signature:		Date:			
	13 Response Receipt Acceptable Initiator	Date	QA/Lead Auditor	Date		
Completed by QA Org.	14 Remarks:			Page _1of_2		

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YMPO OB ARVATION NO. 89-4-07 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

responsibilities in the orginal suite of procedures. However, Project Office guidance letters redefined implementation responsibilities; two organizations were assigned document preparation, review, and approval responsibilities. USGS has current, approved QALAs which will eventually be superseded by new QALAs when NUREG 1318 procedures are implemented. In the interim, USGS maintains their QMP 3.02 for generation of QALAs as an active procedure to support the current documents. The procedure was obsolete. There will be no further implementation of the procedure; likewise, USGS no longer has implementation responsibilities associated wuth NUREG 1318 procedures.

Page

	YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 1YMPO OBSERVATION NO. 89-4-08						
on	2Noted During: AUDIT 89-4 (USGS)	³ Identified By: J. BLAYLOCK		4Date: AUG. 15, 1989			
rganizati	5Organization: USGS	⁶ Person(s) Contacted: J. WILLMON		7 Response Due Date is 20 Days from Date of Transmittal			
Completed by Originating Organization	**BDiscussion: The USGS must annually conduct a Management Assessment of its Quality Assurance Program. This assessment was not conducted for 1988; the deficiency was noted and written as AFR No. USGS 8903-03. In the discussion and recommended action (Block 9 of the USGS form) the auditor identified that the TPO does not have the authority to waive the requirement, but such dispensation must come from the Assistant Director of Engineering Geology. This recommendation is incorrect; waiver of the requirement must come from Yucca Mountain Project Office, not USGS.						
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	12 Signature:		Date:				
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ENCLOSURE 3

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	1 Date August 17, 1	989 2 Severity Lev	vel 01 102 03	Page 1 of 2		
Organization	3 Discovered During Audit 89-4	3a Identified By J. E. Clark		SDR No. 14 Rev0		
	5 Organization YMP	6 Person(s) Contactor Dick Watkins, Peg		7 Response Due Date is 20 Working Days from Date of Transmittal		
Originating QA	a Requirement (Audit Checklist Reference, if Applicable) AP-1.7Q, Sec. 5.7.3, states in part, "Record Transmittal to the CRF: The LRC shall perform the following activities:(7) Package the records and transmit them to the CRF within 10 working days of receipt."					
B I Project Datticipant uses has not been allowed to transmit on record						
Completed by		ion(s): D Remedial D In				
Aprvi.	11 QAE/Lead Auditor/D	ate 12 Division Mana	ک محمدا د	ject Quality Mgr./Date Blankal 8/25/67		
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6	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
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6 Persons contacted (continued)
 Sharon Carter, Don Helton, & Jan Statler
 (Project Office)

- 8 Requirement (continued)
- 9 Deficiency (continued)

records to the CRF. Although USGS records procedure QMP-17.01, Revision 3, was not in full compliance with AP-1.7Q regarding accession numbers on published reports (Section 5.5.1.6) denial of CRF access was applied to all records collected by the USGS LRC.

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	1 Date August 15,	1989 2 Severity Le	vel 01 002 03	Page 1 of 2		
Organization	3 Discovered During Audit 89-4			4 SDR No. 415 Rev. 0		
	5 Organization USGS	6 Person(s) Contac Ben Ziegler	ted	7 Response Due Date is 20 Working Days from Date of Transmittal		
Originating QA	a Requirement (Audit Checklist Reference, if Applicable) YMP-USGS-QAPP-01, Revision 5, measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals.					
ā	9 Deficiency Inspection of the quarterly calibration record of June 30, 1989 and associated NCRs, 7 different instruments were found to have missed the calibration dates and NCRs were not written in a timely manner.					
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8 Requirement (continued)

YMP-USGS-QMF-12.01, Revision 3, all equipment found to be not in compliance is removed from service and documented on a nonconformance report.

10 Recommended Actions (continued)

equipment on time per YMP-USGS-QAPP-01, Revision 5.

2.

Retrain PI's and field personnel on their responsibilities to immediately file an NCR and remove from service equipment overdue for calibration.

INSTRUMENT NAME	ID NUMBER	CALIBRATION DUE DATE
Balance	342457, G-290713	3-1-89
Balance	675991, G-366026	3-1-89
Mercury Therm. on Const. Temp.	TB-1	6-13-89
Oscilloscope	0309545	4-20-89
Oscilloscope	0309759	4-22-89
Digital Multimeter	373582 7	5-27-89
Time Base	R099237	4-16-89

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	1 Date August 17, 1	.989 2 Severity Let	vel 🗆 1 202 🗆 3	Page 1 of 2	
Organization	3 Discovered During Audit 89-4	3a Identified By J. E. Clark		SDR No. 16 Rev. 0	
	s Organization USGS	6 Person(s) Contact Peggy Warner, Mil		7 Response Due Date is 20 Working Days from Date of Transmittat	
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) AI #17-5, USGS-QMP-17.04, Revision 3, Sec. 5.3.4, states in part "Quality Verification: The LRC shall check the records, using the Quality Verification Checklist (Attachment 4), to ascertain acceptability of records prior to				
ă	Openiciency Contrary to the requirement, there was no objective evidence that calibration QA Record Forms had been checked before being processed and retained as a QA record. The filed forms had numerous deficiencies when compared to the				
Completed	1.	ce to establish a method			
Aprvt.	11 QAELBAG Auditor/D		lger/Date 13 Pro	ject Quality Mgr./Date Blankyl 8/28/89	
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	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
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8 Requirement (continued)
 submittal to the CRF.

9 Deficiency (continued)

Quality Verification Checklist; e.g., no transmittal forms and authentication signatures, and no WBS numbers.

- 10 Recommended Actions (continued) have been subjected to checklist review.
 - Train records personnel to revised procedure.
 - Check filed calibration records against Quality Verification Checklist.
 - 4. Determine the extent of noncompliance among the other QA records.

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	1 Date August 16, 1	989 2 Severity Lev	vel 🗆 1 🗆 2 🗷 3	Page 1 of 2		
Organization	3 Discovered Durino	3a Identified By S. L. Crawford		4 SDR No. 417 Rev. 0		
	s Organization USGS	6 Person(s) Contact W. Langer	ed	7 Response Due Date is 20 Working Days from Date of Transmittal		
Originating QA	a Requirement (Audit Checklist Reference, If Applicable) NNWSI/88-9, Section III, Para. 1.3.1, requires "The responsible Participating Organization shall conduct a technical review of the scientific investigation planning document The results of this technical review, and the					
	8.3.1.2.3.1, an	ws conducted by Study I d 8.3.1.16.1.1, although	h stated by the USG			
Completed by	Perform all new results of the	on(s): A Remedial In Intercept Inter	the current QMP-3.03 and reviewer's comm	7. Document the ent resolution.		
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8 Requirement (continued)

resolution of any comments by the reviewer or reviewers shall be documented, and shall become a part of the QA records.**

YMP Procedure AP-1.10Q, Para. 5.1.2, requires "Participating organizations perform technical reviews of Study Plans prepared or revised by them in accordance with their procedures." Paragraph 3.11 defines Technical Reviews, in part, as: "in-depth, critical analyses and evaluations of documents, material, and data." USGS technical reviews are to be performed in accordance with QMP-3.07.

9 Deficiency (continued)

to meet the preparation and review requirements of AP-1.10Q, were performed on draft versions of the Study Plans that did not include sections required by AP-1.10Q. The later Study Plan versions that did comply with AP-1.10Q and were submitted to YMP were not subjected to new technical reviews. This contributed, in part, to the numerous discrepancies noted related to QALAs included in the Study Plans, identified in an Observation generated on this subject. The technical reviews were not performed in accordance with the revision of QMP-3.07 in effect at the time of submittal of the Study Plan.

- The documentation of technical reviews performed for the above listed Study Plans did not provide evidence of resolution of reviewer's comments or reviewer acknowledgement of comment resolution.
- Technical reviews for Study Plan SP 8.3.1.2.1.2 were conducted November 22, 1988 and December 13, 1988 following USGS procedure QMP-3.07, Revision 0; QMP-3.07, Revision 1, was issued effective November 4, 1988 and, if used, would have documented acceptance of reviewer's comments.
- 10 Recommended Action(s) (continued)

documented technical reviews.

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	1 Date August 17, 1	989 2 Severity Lev	vel 🗆 1 🖸 2 🖂 3	Page 1 of 3			
Organization		3a Identified By Mario R. Diaz/ J. E. Clark	1	SDR No. 18 Rev. 0			
	s Organization USGS	6 Person(s) Contactor Peg Warner and Ber		7 Response Due Date is 20 Working Days from Date of Transmittal			
Originating QA	USGS-QMP-12.01, by the PI or de	Checklist Reference, if Ap Revision 3, Para. 5.1. legate for each equipment he form is sent to the	.15, a QA calibration ent requiring calibrat	tion after each			
Completed by	1.	on(s): X Remedial X Invalid					
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8 Requirement (continued)

equipment's use. USGS-QMP-17.01, Revision 3, Para. 5.1.7.2.6, the record shall be recorded with an indelible medium preferably black ink, against a light background. Para. 5.1.8, the correction shall include the date and initials or signature of the record source making the correction.

9 Deficiency (continued)

Records not completed such as:

RECORD ID	
GS.89.Q.000541	

NONCOMPLIANCE

Corrections made without required date and ID of person(s) doing it. Calibration performed 2/28/89, reported on 3/7/89 and received by QA on 3/14/89 which is after equipment's use.

GS.89.Q.000542 Corrections made without required date and ID of person(s) doing it. Calibration performed 2/28/89, reported on 3/7/89 and received by QA on 3/14/89. No indications or documented evidence that equipment was used after receiving QA calibration form.

GS.89.Q.006661 GS.89.Q.006662

Record was not completed by PI/designee, contains corrections made by QA. Calibration performed by 4/6/89, reported on 4/18/89. No indications of when the record was received by QA, therefore, it is not possible to determine if record was transmitted to QA prior to equipment's use.

GS.89.Q.000841

Does not contain calibration date revision of procedure used is not recorded. Required range and accuracy is missing. Calibration was reported on 6/12/89. However, indications of when the record was received by QA do not exist. Therefore, it is not possible to determine if record was transmitted to QA prior to equipment's use.

GS.89.Q.000831

Serial number, calibration date and expiration date are missing. Procedure revision number is missing. Signature is not complete. Documented evidence form was received does not exist. Not possible to determine if record was transmitted to QA prior to equipment's use.

All Remote Seismic Telemetry Station dated 4/25/89 Calibration dates since 1/18/89. However, record written on 4/25/89 and received by QA on 5/1/89 which is after equipment's use. All QA calibration form contain zerox copy of the signature of person completing form.

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9 Deficiency (continued)

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Additionally, QA records provided by USGS Las Vegas Office did not contain information required by the calibration procedure such as technical procedure and revision number used for calibration, name of person performing the calibration, required range and accuracy, etc.

10 Recommended Actions (continued)

with all the requirements of the USGS QA program.

- Determine the impact are quality work done to date on YMP.
- Determine the cause of the condition noted in this SDR and what action will be taken to prevent recurrence.
- A.

 Revise procedures to clearly establish requirements for writing QA calibration forms;
 i.e., time limitation, data required, personnel authorized to authenticate those
 forms, indicate and clarify records originator, verification of equipment's use,
 transmittal to LRC, etc.
- Any NCR condition detected during item (1) above shall be identified, reported, and controlled by the appropriate NCR program.
- Retrain all affected personnel to the current requirements and any changes due to this SDR. Provide documented evidence of this action.