



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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M E M O R A N D U M

DATE: November 15, 1989

FOR: John J. Linehan, Director, Repository Licensing Project
Directorate, Division of High-Level Waste Management,
M/S 4-H-3

FROM: John W. Gilray, Sr. *John W. Gilray* OR - YMP

SUBJECT: YMP Site Report for the month of October, 1989

The following report pertains to the QA, waste package and surface facility activities associated with the Yucca Mountain Project for the month of October, 1989.

I. GENERAL

A major effort has been expended by the YMPD and participants in realigning YMP work task activities and priorities due to significant budget cuts. This is expected to affect manpower levels especially at F&S and H&N.

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II. QUALITY ASSURANCE

A. Qualification of H&N Personnel

As a result of an H&N QA surveillance of personnel qualifications, Congressman Jim Bilbray and the Secretary of Energy James Watkins have been informed by a H&N Quality Assurance Engineer Don Brown that discrepancies and conflict exists between the documented qualifications of H&N personnel and the minimum qualification requirements for their respective position. Subsequent to this surveillance DOE/YMP has instructed H&N and other participants not to disclose the training, qualification and resume records of employees to audit and surveillance personnel due to the Privacy Act. As a consequence it would be very difficult to verify acceptable corrective actions of this issue without access to pertinent qualification records. Mr. Brown alleges that he is being urged to close out the corrective actions without sufficient evidence that the findings have been resolved. Mr. Brown was temporarily assigned to the Test Site October 30, 1989, to assist in the update of QA procedures relating to the weapons program. According to Congressman Bilbray, Mr. Brown claims this action was taken to get him out of the way. I understand Mr. Brown has finished this assignment to the extent that he is now stationed at the H&N Las Vegas office working on YMP QA activities. H&N is actively investigating and following up on these findings to resolve and close them out. This documentation should be available to the YMPD and NRC the week of November 20, 1989. Jim Blaylock of the YMPD has recently conducted an investigation of this issue and determined that while some discrepancies do exist between position description requirements and resumes there is no question in regards to the competency and qualification of personnel in question. Mr. Blaylock had access to the resumes and qualification records due to his management position within the YMPD. The H&N TPO has certified in writing attesting to the qualifications of each technical employee working on the YMP.

GAO has been requested by Congressman Bilbray to investigate this matter. The main problem in resolving this issue is attributed to the Privacy Act which limits the accessibility of qualification records to the H&N QA organization. The legal staff of YMPD is working with DOE Headquarters preparing the necessary government notices to allow access to qualification records. Available back-up documentation pertaining to this subject has been transmitted by this office to Bill Belke of NRC. We will continue to keep Bill up-to-date and informed on this subject.

B. QA Qualification Listing of Items and Activities

YMP has decided to do away with the three quality level system and adopt a classification system for identifying only those items and activities which fall under the control of the QA program. A new procedure is under development and should be released by the YMP by mid-December.

C. Actions Underway to Improve the YMP QA Program

As of November 13, 1989, the YMP has assigned a dedicated technical staff from YMPD, SAIC and MACTEC to review all YMP existing administrative and management plans and procedures including the YMP QA Program 88-9 Rev. 2 and to revise these documents as necessary to meet current requirements and to be more effective in carrying out these requirements. This effort will involve (1) qualifying each staff member to preestablished criteria, (2) identifying the hierarchy of requirements and documents, (3) reviewing and revising procedures to assure that requirements are correctly identified and that they can be effectively carried out, (4) establishing a Plans and Procedures Division to prepare and revise procedures rather than relying on each department for the preparation of procedures (5) developing and implementing an improved training program and (6) resolving approximately 150 deficiency reports keyed to procedures and take

corrective actions where necessary.

As a result of this effort it is expected that certain revisions to the YMP-88-9 Rev 2 QA Program will be forthcoming. The YMPD expects this overall task to take approximately three months and be ready for a formal audit sometime in March of 1990.

D. USGS

The YMPD has, through their letter of October 19, 1989 to L. Hayes of USGS (Enclosure 1), rescinded the stop work order on certain activities at USGS. Prior to starting work, USGS is required to conduct internal readiness reviews/surveillances of the activities to assure the necessary QA controls are in place. The YMPD will conduct surveillances of selected start-up work activities to determine effectiveness of program implementation and will conduct a formal audit of USGS implementing activities tentatively scheduled for May of 1990.

The YMP USGS QA Manager Joe Willmon has been reassigned to other responsibilities. Tom Chaney will be acting QA Manager until this position can be filled by a senior qualified QA individual.

E. Software QA Programs

The status of the YMPD review and approval of software QA Programs are as follows:

USGS: Program approved
F&S: Conditionally approved
LLNL: Detailed review completed, resolution of comments
underway
SNL: Preliminary review completed, rewrite underway
H&N: Preliminary review underway
LANL: Preliminary review completed, rewrite underway
Project Office/SAIC: Detailed review underway

In an informal discussion with the Center it was confirmed that they have an expert in the area of software programs. This individual has reviewed the NRC guidance for software programs and had some preliminary concerns with this document. The NRC staff may want to consider using this individual in the review of our guidance document and the YMP software programs and provide comments as to the strength and weakness of the software controls.

F. Miscellaneous

- ◆ The YMP QA organization is planning to move their office to the sixth floor of the Valley Bank Building within a couple of months so they can be more effective in interacting with the SAIC QA organization which is on the same floor.
- ◆ The YMPD has decided to require SAIC to be a participant in the YMP which will require them to develop their own QA Program Plan. As a participant SAIC will be allowed to develop their own implementing procedures without YMP in the approval cycle. MACTEC will continue to work under the controls of the YMP plans and procedures including the YMP QA Program 88-9 Rev 2. Within the SAIC QA audit section three lead auditors have left the SAIC to work for other companies not involved with the Yucca Mountain Project and two other lead auditors have been transferred to SAIC departments outside the audit section. There are some serious morale problems within the SAIC QA organization that have contributed to some of these events.
- ◆ Don Horton, the recently appointed Director of Quality Assurance Division, is actively taking management responsibility of the YMP QA program. His contribution to the program looks promising.

- ◆ A YMP surveillance was conducted at LLNL regarding procedural controls, document controls, procurement controls, purchased material controls, and record controls. All controls were found acceptable except for one finding pertaining to two minor procedural deficiencies. The surveillance report is in preparation.

- ◆ Through inquiries with the YMPO it was learned that DOE Hqts. has responsibilities for the development of the Licensing Support System (LSS) including the QA controls to be applied. It was inferred that very little 10 CFR 50, Appendix B controls were being applied to the development of the LSS. The NRC office may want to look into the overall end-use and development of this system to determine if sufficient QA controls are being applied.

III. WASTE PACKAGE

I attended the October 26 NRC/DOE technical exchange meeting on Waste Package Container Material Selection, Testing and Modeling which was informative and beneficial. Of particular interest are the following:

- ◆ LLNL has developed a procedure 033-NNWSI-P3-1 for controlling the collection, storage and distribution of J-13 well water samples taken from J-13 well located east of Yucca Mountain. I have obtained and reviewed a copy of this procedure (Enclosure 2) and find that it contains meaningful and reasonable controls. Since the Center is also taking water samples from J-13 well it would seem appropriate that they also follow equivalent controls. Therefore consideration should be given to the merits of requesting the Center to review the procedure and determine the extent it can comply with the controls.

- ♦ Since the Center, NIST and Cortest of Columbus are performing research studies, some of which appear to be for confirming tests and data performed by LLNL, the NRC QA staff may want to determine the extent 10 CFR 50 Appendix B controls are being applied to these activities in order that the result of the studies can be supported in the licensing phase.

- ♦ A representative from LLNL stated that under the current QA Program controls it would take 40 months to obtain vadose water from the Yucca Mountain area. There was a clear impression from this discussion that the QA controls were significantly impacting on the testing and studies at LLNL. However, it was not clear as to what specific QA controls were causing this impact. This office intends to follow-up on this concern by having further discussions with the technical and QA staff of LLNL in order to identify and understand what controls are causing such an impact, and the reasons why.

Due to budget constraints the YMPO is considering closing G-Tunnel which would seriously impact on the G-Tunnel tests that support the waste package investigations.

LLNL has reinstated the policy of preparing monthly technical reports. This office has received and reviewed the LLNL July monthly status report dated October 27, 1989 (enclosure 3). Status reports for August, September and October are in preparation and will be available in late November. In the future each status report will be issued on the 21st day of the month following the month for which the technical work is being reported.

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OCT 16 1989

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STATUS OF ACTIONS TO RESCIND THE STOP WORK ORDER ON SELECTED U.S. GEOLOGICAL SURVEY (USGS) ACTIVITIES

References: (1) Letter, Gertz to Hayes, 7/26/88
(2) Letter, Gertz to Hayes, 5/22/89
(3) YMP QA Audit 89-4, 8/4-23/89

The purpose of this letter is to provide the status of the actions necessary to rescind the stop work order on selected USGS activities and to return control of affected technical activities to the Technical Project Officer (TPO).

Reference 1 required the USGS to stop work on specified activities effective July 26, 1988. Conditions for rescinding the stop work order were detailed in the referenced letter.

Reference 2 outlined an approach to control USGS activities to be in compliance with NNWSI/88-9, Revision 2. The referenced letter provided further detail on the steps necessary to rescind the stop work order.

Reference 3 provides the results of the Yucca Mountain Project Office (Project Office) audit of the USGS Quality Assurance (QA) program. The audit team determined the USGS QA program was adequate to control quality affecting work.

Status of Actions Necessary to Rescind the Stop Work Order Placed on the USGS by the Project Office (Reference 1)

The actions necessary to rescind the stop work order (Reference 2) are listed below, along with their status.

1. The USGS will perform an evaluation to determine the differences between the QA requirements that are presently in place and implemented on the 12 USGS monitoring programs and the QA requirements that need to be implemented for compliance with NNWSI/88-9, Revision 2, and the USGS Quality Assurance Program Plan (QAPP), Revision 5.

ENCLOSURE 1

Status

The USGS has performed the required evaluation and issued Corrective Action Reports (CARs) USGS-CAR-89-02 through 89-12 on May 23, 1989. The CARs detail the differences between the QA requirements of NNWSI/88-9, Revision 2 and the QA requirements in place and implemented on the twelve USGS monitoring activities. The CARs identify USGS Nonconformance Reports (NCRs), Audit Finding Reports, and Project Office Standard Deficiency Reports (SDRs) related to each activity. The potential impact to data and the proposed corrective measures are identified. The CARs are being processed per procedure YMP-USGS-QMP-16.01. Corrective actions are not complete.

2. The USGS will document actions to be taken to assure compliance with NNWSI/88-9, Revision 2.
 - a. Issue a CAR for each monitoring task subject to Project Office review and acceptance.
 - b. Issue NCRs, if necessary, to resolve specific discrepancies.
 - c. Reference NCRs; related externally identified SDRs; etc. for linkage and tracking for each CAR.

Status

The actions taken by the USGS to address Item 1 have also addressed Item 2. A detailed CAR has been issued and is being tracked by procedure for each monitoring task. All related NCRs and SDRs are listed on the CAR to ensure their closure before closing the CARs. For those areas in which SDRs have not been closed, adequate management controls have been instituted; e.g., software and training. The Project Office will review the results of this process in the USGS-conducted readiness reviews/surveillances required for restart of work activities.

3. As part of the corrective action, the USGS will perform an analysis of the deficiencies identified in Items 1, 2b, and 2c to determine any technical impact on the adequacy and validity of the data collected to date. Documented justification of impacts will be part of the USGS CAR.

Status

The USGS has performed the required analysis and determined that no technical impact exists. Any impact identified during the readiness reviews/surveillances will be resolved and documented at that time.

4. Any data determined to have a technical impact according to Step 3 will have to be processed through the methods outlined in NUREG-1298/ Administrative Procedure (AP)-5.9Q prior to issuance for Project use.

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Status

No technical impact has been identified as a result of the conditions that led to imposing the stop work order at the USGS. Any data to be used to support the license application that was not collected under an acceptable QA program will undergo evaluation in accordance with AP-5.9Q to determine its acceptability for use in the licensing process. During the evaluation, the QA control under which the data was collected will be scrutinized to establish impacts beyond the conditions identified by the stop work order that may impact the suitability of the information. This process is necessary for any data collected prior to the Project Office qualification audit of 1989. No further action is required of the USGS before rescission of the stop work order.

5. The USGS CARs will be completed through the identification of the corrective actions and a schedule for completing the actions prior to the audit scheduled for May 1989.
1990.

Status

The USGS CARs were completed as required prior to the Project Office audit, which was conducted August 12-23, 1989.

In addition to these above five specific actions required of the USGS, recommended methods to control restart were also addressed in Reference 2. The status of actions related to those recommendations is as follows:

1. Full compliance with NNWSI/88-9, Revision 2, and the USGS QAPP, Revision 5.
2. Approved study plans/Site Investigation Plan.
3. QA level assignments and grading in accordance with the new Project Office APQs.

Status

The USGS is addressing all three recommendations in the CAR process. The results will be reviewed as part of the readiness reviews/surveillances.

Comments and Recommendations Associated with Activities Subject to the USGS Stop Work Order

1. The Project Office QA Department will perform a full scope, in-depth audit evaluation of the USGS QAPP and procedure implementation and effectiveness.

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2. The USGS CAR process should involve the Project Office/Scientific Applications International Corporation (SAIC) QA Department "up front" to review (formally or informally) the adequacy and comprehensiveness of the CARs to control and document work activities pending the future full scope, in-depth audit evaluation of the USGS QAPP.
3. The stop work order will be rescinded when an audit in Step 1 confirms procedure implementation and effectiveness across all areas of QAPP application and participating USGS offices, personnel, and subcontractors.

Status

The Project Office has conducted an audit (Reference 3) and determined that the USGS has an adequate QA program in place to start quality-related work. The effectiveness of the USGS implementation of its QA program will be determined by the Project Office surveillances and audits and observations of the USGS-conducted internal surveillances.

The Project Office has reviewed the adequacy and comprehensiveness of the USGS CARs and found the documents and the process to correct identified deficiencies to be adequate.

The Project Office will participate in the USGS readiness reviews/surveillances or conduct Project Office surveillances of start-up activities to ensure effectiveness of the USGS QA program implementation.

Conclusions

The Project Office hereby rescinds the stop work order for the activities identified in Reference 1 and returns management control for these activities to the USGS TPO. The USGS must conduct internal readiness reviews/surveillances of the activities prior to allowing the principal investigators to resume the tasks. The Project Office shall be given the opportunity to participate in the readiness reviews/surveillances for these activities. The Project Office will schedule surveillances of selected start-up work activities to ensure effectiveness of the USGS QA program implementation.

If you have any questions regarding this matter, please call James Blaylock of my staff at 794-7913, or V. Dale Hedges of Science Applications International Corporation at 794-7239.



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YMP-ELW-292

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OCT 16 1989

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JUL 26 1988

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WASTE MANAGEMENT PROJECT OFFICE (WMPO) STOP WORK ORDER FOR THE U.S. GEOLOGICAL SURVEY (USGS) NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT SUPPORT

During the course of WMPO Quality Assurance (QA) Audit 88-04 of USGS, the audit team reviewed sufficient objective evidence and generated numerous Standard Deficiency Reports to conclude the following based on the sample taken:

1. The QA program currently in place is not being properly implemented in all areas.
2. In specific areas the effectiveness of the QA program is questionable.

As a result of these findings, the following actions are ordered:

1. A stop work order is hereby placed on the analysis, interpretation, publication, and dissemination of data and information generated from the following activities:
 - a. 8.3.1.2.3.1.2, Site Potentiometric Level Evaluation
 - b. 8.3.1.5.2.1.5, Studies of Calcite and Opaline Silica Vein Deposits
 - c. 8.3.1.17.4.1.2, Current Seismicity
 - d. 8.3.1.2.1.2.1, Surface Water Runoff Monitoring
 - e. 8.3.1.2.1.2.2, Transport of Debris by Severe Runoff

All other tasks, including data collected for the preceding monitoring activities, will continue. The sole exception to this provision is the Calcite and Opaline Silica Vein Deposits study, for which sample collection is not authorized.

This stop work order will remain in effect until a readiness review, in which the U.S. Department of Energy is a direct participant, determines that the affected activities have been brought into full compliance with the provisions of the USGS NNWSI Project QA program.

RECORD COPY

BACKUP INFORMATION

JUL 26 1988

Larry R. Hayes

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2. Further, an in-depth investigation shall be undertaken to determine the extent to which the identified deficiencies in the QA program noted above apply to the balances of the QA Level I and II monitoring activities being conducted by the USGS. This investigation shall commence by the submittal of a course of action plan(s) to the NNWSI Project Manager no later than 20 working days from the stop work notification letter date. This plan shall include the timetables, milestones, manpower requirements, and criteria necessary to both detail the extent of the deficiencies and outline the measures necessary to correct them.

Effective immediately, this stop work order is placed on the preceding USGS activities and subject to the conditions outlined above.

The activities affected by this stop work order are crucial to the successful completion of the site characterization at Yucca Mountain. WMPO is confident that USGS can and will develop the required course of action plan(s) and implement corrective actions expeditiously.

If you have any questions regarding this matter, please call me at FTS 544-7920 or James Blaylock at FTS 544-7913.



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WMPO:JB-3061

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"QA"

MAY 22 1989

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RESOLUTION OF JULY 22, 1988, STOP WORK ORDER ON SELECTED U.S. GEOLOGICAL SURVEY (USGS) ACTIVITIES MEETING OF MARCH 21, 1989

The following is a summary of the stop work order resolution process of selected USGS activities.

Persons Attending

James Blaylock, Project Quality Manager, Project Office
 Catherine Hampton, Quality Specialist, Project Office
 Larry Hayes, Technical Project Officer, USGS, Las Vegas, NV
 J. R. Willmon, QA Manager, USGS, Las Vegas, NV
 Tom Chaney, QA Assistant Manager, USGS, Las Vegas, NV
 Darrell Porter, USGS QA Consultant, SAIC, Golden, CO
 Stephen Metta, QA Manager, SAIC, Las Vegas, NV
 Henry Caldwell, QA Audits Manager, SAIC, Las Vegas, NV
 Sidney Crawford, QA Engineer, SAIC, Las Vegas, NV
 Sidney Ailes, Quality Outreach, SAIC, Las Vegas, NV
 Scott Sittner, Quality Outreach, SAIC, Las Vegas, NV

Background

In 1986, Yucca Mountain Project Office (Project Office) Audit 86-21, conducted March 11-14, 1986, identified 22 audit findings and 5 observations. As a result, a stop work order was issued April 28, 1986, noting five conditions for lifting. Audit 87-6/7, conducted August 10-21, 1987, identified four SDRs and six observations. The report recommended the stop work order not be lifted at that time. The stop work order was lifted December 10, 1987, based on approval of all USGS Scientific Investigation Plans (SIPs) and Quality Assurance Level Assignment Sheets by the Project Office. Audits 88-3 (Menlo Park, CA) and 88-4 (Denver, CO and Nevada Test Site), conducted April 26-28, 1988, and June 9-24, 1988, respectively, identified 9 SDRs and 8 observations for Menlo Park, and 20 SDRs and 16 observations for Denver. A stop work order was issued July 26, 1988, restricting five listed activities and noting two conditions for lifting the stop work order.

Currently, there are roughly 32 "ongoing activities," including approximately 12 "monitoring only" tasks (5 under the present stop work order) and 20 "interrupted" tasks. The net impact of the stop work order is to preclude the interpretation and reporting of data being collected in the five specific task areas identified by the stop work order. The remaining activities are "de facto" (stopped pending approval of study plans and work packages under the Yucca Mountain Project QA Plan, Nevada Nuclear Waste Storage Investigations (NWSI)/88-9, Revision 2).

Discussion

The meeting participants discussed an approach to control USGS activities in compliance with NWSI/88-9, Revision 2.

1. Identify a new method to rescind the stop work order on the five monitoring activities due to new constraining action within the project.
2. Establish measures to control all USGS activities.
3. Establish measures to validate previous USGS data.
4. Verify effective USGS Quality Assurance Program Plan (QAPP) implementation.

The specific methodology recommended during the meeting to rescind the stop work order on the five monitoring activities and control the remaining ongoing monitoring activities includes:

1. The USGS will perform an evaluation to determine the differences between the QA requirements that are presently in place and implemented on the 12 USGS monitoring programs and the QA requirements that need to be implemented for compliance with NWSI/88-9, Revision 2, and the USGS QAPP, Revision 5.
2. The USGS will document actions to be taken to assure compliance with NWSI/88-9, Revision 2.
 - a. Issue a Corrective Action Request (CAR) for each monitoring task, subject to Project Office review and acceptance.
 - b. Issue Nonconformance Reports (NCRs), if necessary, to resolve specific discrepancies.
 - c. Reference NCRs, related externally identified SDRs, etc. for linkage and tracking for each CAR.

MAY 22 1989

Note: SDR closeout will require independent verification of corrective actions; SDRs will not be automatically closed by USGS CAR closure.

3. As part of the corrective action, the USGS will perform an analysis of the deficiencies identified in 1, 2b, and 2c above to determine any technical impact on the adequacy and validity of the data collected to date. Documented justification of impacts or lack of impacts will be part of the USGS CAR.
4. Any data for which it is determined that there was a technical impact in step 3 will have to be processed through the methods outlined in NUREG-1298/ Administrative Procedure (AP)-5.9Q prior to issuance for project use.
5. The USGS CARs will be completed through the identification of corrective actions and a schedule for completing the actions prior to the audit in May 1989.

The specific methods recommended to control any restart of ongoing or interrupted activities or the start of new activities include:

1. Full compliance with NWSI/88-9, Revision 2, and the USGS QAPP, Revision 5.
2. Approved study plans/SIPs.
3. QA level assignments and grading in accordance with the new Project Office AFQs.

Comments and Recommendations associated with Activities subject to USGS Stop Work Order

1. The Project Office QA Department will perform a full scope, in-depth audit evaluation of the USGS QAPP and procedure implementation and effectiveness.
2. The USGS CAR process should involve the Project Office/SAIC QA Department "up front" to review (formally or informally) the adequacy and comprehensiveness of the CARs to control and document work activities pending the future full scope, in-depth audit evaluation of the USGS QAPP.
3. The stop work order will be rescinded when an audit in step 1 above confirms procedure implementation and effectiveness across all areas of QAPP application and participating USGS offices, personnel, and subcontractors.

MAY 22 1989

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If you have any questions regarding this matter, please call James Blaylock of my staff at 794-7913.



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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

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Henry H. Caldwell
Audit Team Leader

Date: 10 Oct 89

Approved By: *Dale Hedges*
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Date: 10-10-89

Approved By: *James Blamford*
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Yucca Mountain Project

Date: 10/12/89

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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 NWISI/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:

<u>SCP Section</u>	<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 concealed 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

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).
2. 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

<u>NAME</u>	<u>ORGIZATION</u>	<u>TITLE</u>	<u>PRE- AUDIT</u>	<u>CONTACTED</u>	
				<u>DURING AUDIT</u>	<u>POST- AUDIT</u>
Abrams, Charlotte	NRC	Geologist	X	X	
Baldwin, Darrell	USGS	Hydro. Technician		X	
Bahorich, Rick	T&MSS	QA Manager			X
Barth, Joe	USGS	QA		X	X
Barton, Robert	DOE	Physical Scientist		X	
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/CNWRRA	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	Hydrogeologist	X	X	
Conway, Jim	NRC	QA Project Manager	X	X	
Covington, Pam	SAIC	QA Software Tech.			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.	USGS	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	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

<u>NAME</u>	<u>ORG.</u>	<u>TITLE</u>	<u>PRE- AUDIT</u>	<u>CONTACTED DURING AUDIT</u>	<u>POST AUDIT</u>
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	Hydrologist		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	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

<u>NAME</u>	<u>ORG.</u>	<u>TITLE</u>	<u>PRE- AUDIT</u>	<u>CONTACTED DURING AUDIT</u>	<u>POST AUDIT</u>
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
Wilnot, 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

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-01

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: J. E. CLARK	4 Date: AUG. 22, 1989
	5 Organization: USGS	6 Person(s) Contacted: R. SPAULDING, G. OTTO, R. LUCKEY	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: Records of field data are copied from notebooks on a quarterly basis and forwarded to the cognizant PI. The notebooks are not submitted as records to the LRC until the study is complete or the notebook is filled. Capture of records on a more frequent basis is required by AP-1.7Q; application to field data will be clarified in AP-5.1Q. USGS QMP-17.01 and other affected procedures need updating to ensure capture of field data in the LRC rather than in "hold files" in PI offices. Procedure update should include requirements for numbering pages in field notebooks to comply with records transmittal		
Completed by Respondee	9 QAE/Lead Auditor Date <i>[Signature]</i> 22/08/89		10 Branch Manager Date <i>[Signature]</i> 9/20/89
	11 Response:		
	12 Signature: Date:		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator Date	QA/Lead Auditor Date	
14 Remarks:			

8 Discussion: (continued)
requirements.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-02

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: J. FRIEND	4 Date: AUG. 22, 1989
	5 Organization: USGS	6 Person(s) Contacted: J. WILMON, A. WHITESIDE, J. ZIEMBA	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: 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.		
	9 QAE/Lead Auditor <i>[Signature]</i>	Date 20 Sept 89	10 Branch Manager <i>[Signature]</i>
			Date 9/20/89
Completed by Respondee	11 Response:		
	12 Signature: _____ Date: _____		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator _____	Date _____	QA/Lead Auditor _____
	14 Remarks:		

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-03

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: S. L. CRAWFORD	4 Date: AUG. 22, 1989
	5 Organization: USGS	6 Person(s) Contacted: W. LANGER, W. CAUSSEAU	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: 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		
Completed by Respondee	9 QA/Lead Auditor <i>AA Adwell</i> 20 Oct 89		10 Branch Manager <i>J. Brown</i> 8/20/89
	11 Response:		
	12 Signature: _____ Date: _____		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____	
14 Remarks:			Page <u>1</u> of <u>2</u>

8 Discussion: (continued)

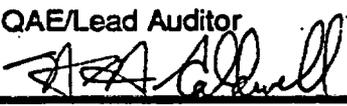
- (SP 8.3.1.2.2.6, 3346G-01-01)
- 3B. QALA in Table 3.1-2, but not in Appdx 7.1.2
(SP 8.3.1.2.3.1, 3331G-01-07)
- 4A. QALA not in Table 3.X-2, but in Appdx 7.1.2
(SP 8.3.1.2.3.1, 8 QALAs)
- 4B. QALA not in Table 3.X-2, but in Appdx 7.1.2
(SP 8.3.1.2.1.2, 3310G-01-01)
- 5. QALA incorrectly numbered in 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

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-04

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: D. A. KLIMAS, R. M. C. KLIMIST	4 Date: AUG. 18, 1989				
	5 Organization: USGS	6 Person(s) Contacted: L. HAYES, J. WILLMON	7 Response Due Date is 20 Days from Date of Transmittal				
	8 Discussion: The TPO and QAM depicted the USGS organizational interfaces for the audit team. The depiction differs from the current representations in QAPP Section 1 and QMP 1.01. The depiction incorporated the recently established QA Support Units being assigned to technical program elements. This approach is intended to provide in-line QA to the technical processes.						
Completed by Respondee	9 QAE/Lead Auditor 	Date 2/20/89	10 Branch Manager 				
	11 Response:						
12 Signature: _____ Date: _____							
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>	<table style="width:100%; border: none;"> <tr> <td style="width: 30%; border: none;">Initiator</td> <td style="width: 20%; border: none;">Date</td> <td style="width: 30%; border: none;">QA/Lead Auditor</td> <td style="width: 20%; border: none;">Date</td> </tr> </table>		Initiator	Date	QA/Lead Auditor	Date
	Initiator	Date	QA/Lead Auditor	Date			
14 Remarks:							

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.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-05

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: J. FRIEND	4 Date: AUG. 22, 1989	
	5 Organization: USGS	6 Person(s) Contacted: J. WILLMON, A. WHITESIDE, J. ZIEMBA	7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: 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			
	9 QAE/Lead Auditor <i>[Signature]</i>	Date 20/8/89	10 Branch Manager <i>[Signature]</i>	Date 9/20/89
Completed by Respondee	11 Response:			
	12 Signature: _____ Date: _____			
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>			
	Initiator	Date	QA/Lead Auditor	Date
14 Remarks:				Page <u>1</u> of <u>2</u>

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.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-06

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: R. M. KLIMIST, D. KLIMAS	4 Date: AUG. 18, 1989
	5 Organization: USGS	6 Person(s) Contacted: M. SIMPSON, J. WILLMON, L. HAYES	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: 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		
	9 QAE/Lead Auditor <i>[Signature]</i>	Date <i>20 Sept 89</i>	10 Branch Manager <i>[Signature]</i>
	Date <i>9/20/89</i>		
Completed by Respondee	11 Response:		
	12 Signature: _____ Date: _____		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator _____	Date _____	QA/Lead Auditor _____
	14 Remarks:		
	Page <u>1</u> of <u>2</u>		

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.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-4-07

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT 89-4 (USGS)	3 Identified By: J. BLAYLOCK	4 Date: AUG. 22, 1989	
	5 Organization: PROJECT OFFICE	6 Person(s) Contacted: J. WILLMON	7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: The organizational responsibilities of YMP participants continually change due to a variety of reasons: completion of assigned activities, interpretation of responsibilities by the Project Office, and change in an organization's scope of work. In the case of added responsibility, the course of action is unequivocal - the organization must have approved procedural controls in place prior to undertaking quality affecting activities. In the case of changing responsibilities, however, the course of action is not clear. As an example, most YMP participating organizations had NUREG 1318 procedural implementation			
Completed by Respondee	9 QAE/Lead Auditor Date 20 Sept 89		10 Branch Manager Date 9/20/89	
	11 Response:			
12 Signature: Date:				
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>			
	Initiator Date	QA/Lead Auditor Date		
14 Remarks:				
Page <u>1</u> of <u>2</u>				

8 Discussion: (continued)

responsibilities in the original 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 with NUREG 1318 procedures.

ENCLOSURE 3

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization

1 Date August 17, 1989	2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Page 1 of 2
3 Discovered During Audit 89-4	3a Identified By J. E. Clark	4 SDR No. 414 Rev. 0
5 Organization YMP	6 Person(s) Contacted Dick Watkins, Peggy Warner (USGS);	7 Response Due Date is 20 Working Days from Date of Transmittal
8 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."		
9 Deficiency Project participant USGS has not been allowed to transmit QA records to the CRF to satisfy the above requirement. The Project Office, via letter YMP: DLH-4757, dtd. July 17, 1989, withheld approval for USGS transmittal of QA		
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective		

Aprvl.

11 QAE/Lead Auditor/Date <i>J. E. Clark 8/22/89</i>	12 Division Manager/Date <i>Dale Hedges 8-28-89</i>	13 Project Quality Mgr./Date <i>Jane Blyford 8/25/89</i>
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Completed by Organization in Block 5

14 Remedial/Investigative Action(s)	15 Effective Date _____
16 Cause of the Condition & Corrective Action to Prevent Recurrence	17 Effective Date _____
18 Signature/Date	

Comp. by Org. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks			
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/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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Completed by Originating QA Organization

Apr. 5

Completed by Organization in Block 5

Comp. by Orig. QA Org.

1 Date August 15, 1989 2 Severity Level 1 2 3 Page 1 of 2

3 Discovered During Audit 89-4 3a Identified By N. D. Cox and M. R. Diaz 4 SDR No. 415 Rev. 0

5 Organization USGS 6 Person(s) Contacted Ben Ziegler 7 Response Due Date is 20 Working Days from Date of Transmittal

8 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.

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.

10 Recommended Action(s): Remedial Investigative Corrective
1. Retrain PI's and field personnel on their responsibilities for calibrating

11 QAE/Lead Auditor/Date 12 Division Manager/Date 13 Project Quality Mgr./Date
JA Adwell 8/28/89 *W. Helge 8-28-89* *James Blaylock 8/28/89*

14 Remedial/Investigative Action(s) 15 Effective Date _____

16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____

18 Signature/Date

19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
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20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
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21 Remarks

22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date
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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	3735827	5-27-89
Time Base	R099237	4-16-89

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Completed by Originating QA Organization

1 Date August 17, 1989	2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Page 1 of 2
3 Discovered During Audit 89-4	3a Identified By J. E. Clark	4 SDR No. 416 Rev. 0
5 Organization USGS	6 Person(s) Contacted Peggy Warner, Mildred Murray	7 Response Due Date is 20 Working Days from Date of Transmittal
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		
9 Deficiency 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		
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input type="checkbox"/> Corrective 1. Revise procedure to establish a method for identifying those records which		

Apv.

11 QAE/Lead Auditor/Date <i>R. A. [Signature] 8/28/89</i>	12 Division Manager/Date <i>R. [Signature] 8-28-89</i>	13 Project Quality Mgr./Date <i>James Blaylock 8/28/89</i>
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Completed by Organization in Block 5

14 Remedial/Investigative Action(s)	15 Effective Date _____
16 Cause of the Condition & Corrective Action to Prevent Recurrence	17 Effective Date _____
18 Signature/Date	

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks			

22

22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/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.

2.

Train records personnel to revised procedure.

3.

Check filed calibration records against Quality Verification Checklist.

4.

Determine the extent of noncompliance among the other QA records.

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Completed by Originating QA Organization	1 Date August 16, 1989		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 89-4		3a Identified By S. L. Crawford		4 SDR No. 417 Rev. 0	
	5 Organization USGS		6 Person(s) Contacted W. Langer		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 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					
Completed by Organization in Block 5	9 Deficiency 1. Technical reviews conducted by Study Plans SP 8.3.1.2.1.2, 8.3.1.2.2.6, 8.3.1.2.3.1, and 8.3.1.16.1.1, although stated by the USGS submittal letters					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective Perform all new technical review per the current QMP-3.07. Document the results of the evaluations, reviews, and reviewer's comment resolution. Assure that future Study Plans submitted to YMP are supported by properly.					
	11 QAE/Lead Auditor/Date <i>S. L. Crawford</i> 8/28/89		12 Division Manager/Date <i>N. L. Hedges</i> 8-28-89		13 Project Quality Mgr./Date <i>James Blaylock</i> 8/28/89	
Comp. by Org. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date _____					
18 Signature/Date						
19 Response Accepted		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
21 Remarks						
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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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.

2.

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.

3.

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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Completed by Originating QA Organization	1 Date August 17, 1989		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 3	
	3 Discovered During Audit 89-4		3a Identified By Mario R. Diaz/ J. E. Clark		4 SDR No. 418 Rev. 0	
	5 Organization USGS		6 Person(s) Contacted Peg Warner and Ben Zeigler		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) USGS-QMP-12.01, Revision 3, Para. 5.1.15, a QA calibration form is completed by the PI or delegate for each equipment requiring calibration after each calibration. The form is sent to the YMP-USGS QA office prior to an					
9 Deficiency Contrary to the above numerous QA calibration forms were found in the Local Records Center that did not comply with the following requirements:						
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Review all QA calibration forms located at LRC to ensure that they do comply						
Completed by Organization in Block 5	11 QAE/Lead Auditor/Date <i>A. A. Bell 2/24/89</i>		12 Division Manager/Date <i>Robert G. F-26-89</i>		13 Project Quality Mgr./Date <i>James Blaylock 5/28/89</i>	
	14 Remedial/Investigative Action(s)				15 Effective Date _____	
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____	
	18 Signature/Date					
Comp. by Orig. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
	21 Remarks					
	22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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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	NONCOMPLIANCE
GS.89.Q.000541	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 xerox copy of the signature of person completing form.

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9 Deficiency (continued)

"A"

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.

2.
Determine the impact are quality work done to date on YMP.
3.
Determine the cause of the condition noted in this SDR and what action will be taken to prevent recurrence.
4.
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.
5.
Any NCR condition detected during item (1) above shall be identified, reported, and controlled by the appropriate NCR program.
6.
Retrain all affected personnel to the current requirements and any changes due to this SDR. Provide documented evidence of this action.