

U. S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT NO. 89-5  
FOR THE YUCCA MOUNTAIN PROJECT OFFICE  
AUDIT NO. 89-4 OF U. S. GEOLOGICAL SURVEY

Keith McConnell for 12/14/89  
Charlotte Abrams  
Geosciences & Systems Performance Branch  
Division of High-Level Waste Management

Tilak R. Verma 12/11/89  
Tilak Verma  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste  
Management

Keith McConnell 12/14/89  
Keith McConnell  
Geosciences & Systems Performance Branch  
Division of High-Level Waste Management

James Conway for 12/14/89  
John Gilray  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste  
Management

Neil Coleman 12/14/89  
Neil Coleman  
Geosciences & Systems Performance Branch  
Division of High-Level Waste Management

James Conway 12/14/89  
James Conway  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste  
Management

for Tilak R. Verma 12/13/89  
Robert Brient (By Telecon)  
Center for Nuclear Waste Regulatory  
Analysis

Reviewed and Approved by: James E. Kennedy 12/14/89  
James E. Kennedy  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management

## SUMMARY

The Nuclear Regulatory Commission (NRC) staff concludes that, overall, the U. S. Department of Energy (DOE)/Yucca Mountain Project Office (YMPO) Quality Assurance (QA) Audit No. 89-4 of U. S. Geological Survey (USGS) was useful but only marginally effective. The programmatic auditors seemed well qualified in the QA area and their assignments and checklist items were adequately described in the audit plan. In some instances, the technical auditors did not appear to be fully prepared or have a good understanding of the technical activities they were auditing. The audit's coverage of the USGS QA program implementation consisted of reviews and evaluations of USGS QA procedures, a very limited number of technical procedures and five study plans, and interviews with the USGS personnel to understand and determine the acceptability of the USGS QA and technical programs, including the capabilities of the USGS QA and technical staff. This coverage did allow the DOE/YMPO audit team to make an assessment of the adequacy of the USGS QA controls for continuing the YMP work. However, conditions such as limitations on access to the USGS personnel records due to the Privacy Act, very limited implementation of the USGS QA program, and a lack of proper integration of the programmatic and technical portions of the audit resulted in making the audit less effective.

The NRC staff agrees in general with the DOE/YMPO audit team's conclusion that the USGS QA program has adequate controls in place to continue the YMP work. Although the DOE/YMPO audit team identified several deficiencies in the USGS QA program, these deficiencies are not considered that serious and if corrected in a timely manner should not impact the quality of their work. The USGS management has committed to a timely corrective action for all these deficiencies.

The USGS has just started implementation of their QA program and therefore, the effectiveness of implementation of the USGS QA program could not be determined from this audit. The DOE/YMPO needs to continue an aggressive schedule of audits and surveillances, which the NRC staff will observe, to determine if the USGS is effectively implementing its QA program. The NRC staff will conduct its own independent audit of the USGS QA program to determine the effectiveness of implementation and to assess the acceptability of the USGS QA program.

## 1.0 INTRODUCTION

From August 14 through 18, 1989, and August 21 through 22, 1989, the NRC staff participated as observers in DOE/YMPO QA Audit No. 89-4 of USGS conducted in Denver, Colorado and Las Vegas, Nevada. This audit covered only a very limited implementation of the QA program elements concerning technical products (i.e., study plans and technical procedures) since USGS had not performed much technical work under the QA program for licensing-related activities.

The USGS is responsible for the Yucca Mountain Project (YMP) site characterization activities in the areas of hydrology, geophysics, seismology, and some of the geology and geochemistry investigations. Work in these areas is ongoing at the Nevada Test Site (NTS) and the USGS offices in Denver, Colorado; Menlo Park, California; and Las Vegas, Nevada.

This report addresses the effectiveness of the DOE/YMPO audit and, to a lesser extent, the adequacy of the USGS QA program.

## 2.0 OBJECTIVES

The objective of the DOE/YMPO audit was to determine the effectiveness of the USGS QA program in meeting the applicable requirements of the 88-9 QA Plan for the YMPO. The NRC staff's objective was to gain confidence that DOE and its contractors are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE/YMPO audit and determining whether the USGS QA program is in accordance with the requirements of 10 CFR Part 50, Appendix B and the 88-9 QA Plan.

## 3.0 AUDIT PARTICIPANTS

### 3.1 NRC

Tilak Verma	Observer
James Conway	Observer
John Gilray	Observer
Keith McConnell	Observer
Charlotte Abrams	Observer
Neil Coleman	Observer
Robert Brient	Observer (Center for Nuclear Waste Regulatory Analyses)

### 3.2 DOE

Henry H. Caldwell	Audit Team Leader	SAIC
Sidney L. Crawford	Auditor	SAIC
Neil D. Cox	Auditor	SAIC
James E. Clark	Auditor	SAIC
John C. Friend	Auditor	SAIC
Fred J. Ruth	Auditor	SAIC
Keith M. Kersch	Lead Technical Specialist	SAIC
David Cummings	Technical Specialist	SAIC
Carolyn Rutland	Technical Specialist	SAIC
Joy Fiore	Technical Specialist	SAIC

James Blaylock	Auditor	DOE/YMP
Catherine E. Hampton	Auditor-In-Training (AIT)	DOE/YMP
Mario R. Diaz	AIT	DOE/YMP
Scott G. Van Camp	Observer	DOE/HQ/WESTON
Carl E. Weber	Observer	DOE/HQ/WESTON
Roselunde Klimist	Auditor	DOE/CER/WASHINGTON

### 3.3 State of Nevada

Susan W. Zimmerman      Observer

### 4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The NRC staff evaluated the effectiveness of the audit team and the audit of USGS and, to a lesser extent, the acceptability of the USGS QA program. The NRC staff evaluations are based on direct observations of the auditors; discussions with members of the audit team; review of the audit plan, checklists, background material and the USGS technical and QA programs; and limited discussions with the USGS QA, technical and management personnel. The DOE audit was conducted in accordance with procedures YMPO QMP 18-01, "Audit System for the Waste Management Project Office", Revision 3, and YMPO QMP 16-03, "Standard Deficiency Reporting System," Revision 1.

NRC staff observations are classified in accordance with the following guidelines:

#### (a) Level 1

Failure of the audit team to independently identify either:

- Flaws in completed and accepted work important to safety or waste isolation which renders the work unuseable for its intended purpose. Denotes failure of the QA program to verify quality, or
- A breakdown in the QA program resulting in multiple examples of the same or similar significant deficiencies over an extended period of time in more than one work activity (technical area), or
- Multiple deficiencies of the same or similar significant deficiencies in a single work activity (technical area).

Failure of the audit team to adequately assess a significant area of the QA program or its implementation, such as technical products, applicable 10 CFR Part 50, Appendix B criteria, or quality level classifications, without prior justification, such that the overall effectiveness of the QA program being audited is made indeterminate.

#### (b) Level 2

Failure of the audit team to independently identify an isolated significant deficiency.

(c) Level 3

Failure of the audit team to independently identify deficiencies that have minor significance, or failure of the audit team to follow applicable audit procedures.

Level 1, 2 and 3 NRC staff observations require a written response from DOE to be resolved.

The NRC staff findings may also include weaknesses (actions or items which are not deficiencies but could be improved), good practices (actions or items which enhance the QA program) and requests for information required to determine if an action or item is deficient. Written responses to weaknesses identified by the NRC staff will be requested when appropriate. In general, weaknesses and items related to requests for information will be examined by the NRC staff in future audits or surveillances.

4.1 Scope of Audit

(a) Programmatic Elements - The QA portion of the audit utilized checklists based on the requirements in the 88-9 QA Plan and the USGS Quality Assurance Program Plan (QAPP), QAPP-01, Revision 5. The checklists covered the QA program criteria listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Scientific Investigation Control and Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 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 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

The following criteria were not included in the scope of the USGS audit since they apply to engineered items which are outside the scope of the work done by USGS.

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

The programmatic scope of the audit is acceptable in that it covered the applicable 10 CFR Part 50, Appendix B criteria for which USGS has responsibility. These programmatic elements were found acceptable by the NRC staff in their review of the USGS QAPP (ref. Linehan/Stein letter dated June 20, 1989).

(b) Technical Areas - Technical specialists of the audit team were instructed to review the available information and interview the USGS technical personnel to assess their technical and QA capabilities with regard to the following:

- Understanding of scientific/quality assurance aspects of the program
- Understanding of procedural requirements as they pertain to activities
- Procedural adequacy from a technical standpoint

This assessment was made for the following Site Characterization Plan activities:

- 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 Lane
- 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

These technical activities were selected by the audit team from a large number of technical activities (185) the USGS is conducting or planning to conduct for the Yucca Mountain Project. The selection was based on a number of factors, such as ongoing work for the activity, availability of study plans and technical procedures, priority and importance of the activity, and inclusion of the activity in the 88-4 audit. Some of these technical activities included in the audit scope were subjected to a limited stop work order since July 26, 1988.

The scope included any work done under these technical activities since the approval and the effective date of implementation of the USGS Quality Assurance Program Plan (QAPP-01), Revision 5. The effective date of implementation for the QAPP-01, Revision 5 was May 3, 1989. In addition, the audit scope also included the requirement to determine whether USGS had taken effective corrective actions to resolve discrepancies identified during previous DOE audits and surveillances.

The technical scope of the audit is acceptable in that it includes a sample of activities that are currently being conducted or are important activities, either ongoing or planned, from a data needs point of view.

#### 4.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate. USGS had made a number of improvements in their QA program in the last ten months, and even though implementation has just started, it was beneficial to assess the adequacy of the controls that are in place to do Quality Level I or II work.

#### 4.3 Examination of Technical Activities

The audit team technical specialists reviewed, to varying degrees, the technical areas addressed in 4.1(b). The reviews consisted mainly of interviews with USGS technical personnel due to the very limited quantity of technical work products available for review.

The NRC staff observed portions of the reviews performed by the audit team technical specialists in the following areas:

##### (a) Site Potentiometric - Level Evaluation

The technical specialists interviewed USGS technical staff to determine the status of the work. The USGS is currently monitoring groundwater elevations at the Yucca Mountain Site. A study plan and several technical procedures for this technical activity had been prepared under an earlier version of USGS QA program. The technical specialists questioned the Principal Investigator (PI) regarding the responsibilities and QA training of the technical staff. The PI and his staff seemed knowledgeable of their technical and QA responsibilities.

The technical specialists did not request or review and take objective evidence of the QA and technical procedures being implemented. The NRC technical observer believes that if a QA auditor had participated with the technical specialists, a more in-depth examination of the QA procedures and controls for this technical activity could have been performed. The overall audit of this activity was not adequate to evaluate the effectiveness of QA program controls applied to the activity.

##### (b) Studies of Calcite and Opaline Silica Vein Deposits

The DOE technical specialists discussed the status of activities under these studies with the USGS technical staff. The technical checklist for these studies was quite thorough. The technical specialists did a very thorough job of questioning the PI and his staff and gathered information on the status of technical and QA procedures. The technical specialists, via the questions asked, displayed an in-depth knowledge of the applicable QA and technical procedures, applicable portions of SCP and study plan. The technical specialists asked questions in a very professional and persistent manner and performed a very effective audit. The overall audit of this technical activity was quite effective.

The PI and his staff seemed knowledgeable of and trained in all appropriate QA and technical procedures. All the USGS participants in this activity seemed well qualified, and the activity seemed to involve a well-directed and integrated study. Data handling and storage seemed appropriate. The need for qualification of existing data was recognized along with the need for the importance of staff training in these procedures. It appeared that the PI and the line staff have a commitment to QA.

(c) Mineral and Energy Assessment of the Site

The DOE technical specialists appeared knowledgeable of the appropriate portions of the SCP and were aware of the status of this activity. Due to the fact that this study plan is in a very early stage of development and technical procedures are not yet developed, it was difficult for the technical specialists to ask questions or to follow the checklist. The technical specialists asked questions regarding the qualifications and training of the PI and other staff involved in this study. The PI for this study, although new to the project, appeared to understand his QA responsibilities including the training of investigators before the initiation of work. The audit of this area was effective, although the effectiveness of the QA program could not be determined due to lack of technical products.

(d) Quaternary Faulting Within the Site Area

The DOE technical specialists questioned the PI on the status of the study plan, technical procedures and prototype testing related to this activity. The DOE technical specialists appeared to follow the basics of the checklist and did little in the way of followup questioning. Some technical procedures were available, but the technical specialists did not ask for or review any of the technical procedures and appeared unfamiliar with their contents.

They also questioned the investigators assigned to this activity and the investigators seemed well-qualified. The PI and his staff seemed to have a good understanding of the importance of QA for the work being done for the DOE. The investigators also exhibited a good understanding of their responsibilities with respect to QA. The overall audit of this technical activity was marginally effective because the technical specialists did not probe the work products enough to verify the effectiveness of program controls.

(e) Quaternary Faulting Within 100km of Yucca Mountain

The DOE technical specialists questioned the USGS PI and his staff to ascertain the status of this activity. It was determined that the preparation of the study plan had not begun and technical procedures were under revision. The technical specialists did not seem to have a good knowledge of the activities for this study. The checklist appeared to be superficial in that it did not get into the details of implementation of the QA program. The PI and his staff were not thoroughly questioned on their responsibilities and training for QA procedures and implementation of these procedures. The overall audit of this activity was not effective and the effectiveness of the QA program in this area could not be determined.

(f) Subsurface Geometry and Concealed Extensions of Quaternary Faults at Yucca Mountain

The technical specialists were not effective in auditing this activity. The DOE technical specialists failed to follow the checklist. The checklist appeared superficial in that it did not get into the details of implementation of the QA program. The technical specialists did not ask for or review the study plan and technical procedures. The status of study plan and technical procedures was not ascertained.

The PI appeared to be unaware of the QA requirements for the storage of documents. The overall technical audit of this activity was not effective and the effectiveness of the QA program in this area appears questionable.

(g) Monitor Current Seismicity

The DOE technical specialists questioned the USGS PI and his staff to ascertain the status of this technical activity. The study plan and technical procedures were made available for review by the technical specialists. The technical checklist questions and additional follow-up questions were asked by the DOE technical specialists to assess the qualifications of the USGS investigators and to evaluate their knowledge of required QA and technical procedures and status of implementation of these procedures. The PI and his staff appeared knowledgeable of the QA requirements and procedures for their work and seemed well-qualified. The audit of this technical study seemed effective.

In general, the technical portion of the audit was not performed well and was marginally effective. The technical portion was not well integrated with the programmatic portion of the audit. The technical checklists, in some cases, were not of sufficient detail. Lack of technical products for review and audit may also have been a major reason for making this portion of the audit less effective.

4.4 Qualifications of Technical Personnel

Due to the Privacy Act limitations, the audit team technical specialists were not allowed to examine training folders for objective evidence of personnel qualifications. The Privacy Act concerns also did not allow any review of the USGS personnel folders. Questions were asked of the records maintenance personnel by the technical specialists; however, these personnel and the training coordinator only provided limited information in responding to the auditors' questions. Therefore, the technical specialists could not perform a thorough review, could not follow their checklist, and were not successful in obtaining and reviewing any objective evidence to verify implementation of the USGS QAPP requirements.

In the absence of this specific review of technical qualifications, the audit team technical specialists asked general questions regarding the qualifications of USGS staff. In addition, the USGS management verbally

vouched for the qualifications of its staff. Until the Privacy Act issue is resolved and objective evidence made available to auditors, it will remain an open item with the staff. The overall audit of this area was not effective due to circumstances beyond the control of the auditors.

#### 4.5 Examination of Programmatic Elements

The NRC staff observed the DOE audit team's evaluation of selected programmatic elements of the USGS QAPP.

##### (a) Organization and Quality Assurance Program

The DOE auditors utilized the published audit checklists and were thorough in reviewing objective evidence presented. The auditors utilized in-depth questioning and interviewed the USGS-YMP Manager of Quality Assurance at length. The auditors went beyond the audit checklists in certain areas to ensure USGS activities (organization and QA Program sections) met the intent of the USGS QAPP. The area of training could not be investigated due to the Privacy Act related concerns.

The auditors performed a thorough and comprehensive audit, following the checklists, and were persistent in obtaining objective evidence to verify implementation of the QAPP requirements.

##### (b) Scientific Investigation and Design Control

The DOE auditors used their checklist questions developed from the requirements of the 88-9 QA Plan, Revision 2, and corresponding USGS requirements. Five study plans that were prepared and reviewed under an earlier vintage of USGS QA program were reviewed and checked for implementation of programmatic requirements under Criterion III. The audit team identified a deficiency in the documentation of resolution and close-out of review comments for these four study plans. The auditors were thorough in reviewing objective evidence presented.

The NRC observers believe that this portion of the audit could have been more effective if the audit was expanded to include the audit of those study plans being developed under the control of the current QA program. The acceptability of the USGS QA program and procedural controls for study plans currently under preparation cannot be determined without a further review of the backup documentation of these plans.

The NRC staff believes the preparation of study plans to be a major activity of the USGS QA program and therefore, there is a critical need for auditing this activity for assessing the implementation of USGS QA program controls under this criterion.

##### (c) Instructions, Procedures and Drawings

The DOE auditors utilized the published audit checklist and the requirements of Procedure QMP-5.03, Section 3 "Development and

Maintenance of Quality Management Procedures" and was thorough in reviewing objective evidence presented. The auditors appeared well-qualified and knowledgeable regarding the USGS QA requirements and implementing procedures. The auditors reviewed documentation related to the technical and QA reviews of Quality Management Procedures (QMP).

The Review/Comment Resolution Forms pertaining to 14 QMPs for Chapter 3 "Design/Scientific Investigation Control" and five QMPs for Chapter 5 "Instructions, Plans, Procedures, and Drawings" were satisfactorily completed. All the QMPs were approved by the YMP-USGS/QA Manager and Technical Project Officer, both located in Denver, Colorado and three USGS management personnel located in Reston, Virginia - Chief, Office of Regional Geology; Assistant Chief Hydrologist for Program Coordination and Technical Support; and Assistant Director for Engineering Geology. The programmatic audit under this criterion was quite effective and the QA program controls were effectively implemented.

(d) Control of Purchased Material and Services

The DOE auditors utilized the published audit checklist and were thorough in reviewing objective evidence presented. Surveillance and audit reports were reviewed to assure that all the vendors on the current Approved Vendor List (AVL) had been approved by USGS to supply Quality Level I or II items or services.

The AVL is approved by the QA Manager at least quarterly and is broken down into vendors of analytical services, technical services, and calibration services. The method of qualification for the vendors was by surveillance, review of objective evidence, and audit. The majority of qualifications were done by surveillances; however, the auditor were told that all future qualifications will be accomplished by USGS/YMP audits. USGS/YMP uses personnel from SAIC and the USGS Branch of QA (qualified by USGS/YMP QA Office in April 1986) both in Golden, Colorado to conduct the external surveillances and audits. Objective evidence of the qualifications of these personnel was not made available to the auditors due to the restrictions of the Privacy Act.

The auditors noted that USGS had four analytical service vendors on these AVLs, but there was no objective evidence that they had been qualified by USGS. A QA specialist told the auditors that these four vendors were on the AVL because they were on the USGS National Water Quality Laboratory's AVL, and USGS-YMP QA Office had qualified the Laboratory in May 1988. This potential deviation was downgraded by the auditors upon a verbal commitment by USGS to revise the AVL to correct the problem.

The overall audit under this criterion was effective and determined that sufficient QA controls were in place for the USGS to continue the YMP work.

(e) Control of Measuring and Test Equipment

The DOE auditors utilized the published audit checklist and were thorough in reviewing objective evidence presented. The auditors reviewed several technical procedures and a number of Calibration Forms (CF). Section 5 "Calibration Requirements" of each procedure addressed Calibration Responsibilities, Calibration Procedure, Calibration Records, and Labeling of Equipment Calibration Status. Principal Investigators certify that individuals have been trained to specific technical procedures. These certifications, which are incorporated into an individual's training records, were not made available to the auditors due to the Privacy Act related concerns.

Each PI is responsible for assuring that QA Level 1 and 2 measuring and test equipment (M&TE) are controlled and meet the specific calibration requirements in technical procedures. A CF is completed by the PI for each piece of equipment calibrated, and the CF is sent to the USGS QA Office. The QA Office maintains a calibration tracking system and provides each PI with a quarterly listing of the Calibration Record (CR) and Calibration Due Date Notifications. PIs update the listing and return it to the QA Office. A Non-Conformance Report (NCR) is generated for equipment found to be not in compliance.

The auditors reviewed the CR for the 2nd quarter - 1989 and noted that seven pieces of equipment were past due for calibration, but NCRs had not been written by the PIs. This item was identified as a potential deficiency by the auditors.

The overall audit under this criterion was effective and determined that adequate QA program controls for this element are in place.

(f) Control of Nonconformances

The DOE auditors utilized the published audit checklist questions and reviewed the Procedure QMP-15.01 to determine the adequacy of Control of Nonconforming Items. The auditors were thorough in reviewing objective evidence presented. The auditors learned that USGS personnel working on the YMP read QMP-15.01 as part of their training in QA, but the auditors were unable to obtain objective evidence due to the current restrictions of the Privacy Act. Only four NCRs were generated since Revision 3 of QMP-15.01 became effective in June 1989. Although adequate controls are in place to initiate Level I and II quality work, the verification of compliance to implementing procedures could not fully be determined based on the small sample size.

Two instruments were checked out to verify that the instruments were tagged as documented in two NCRs. It was noted that the "hold tags" were xerox copies of a "hold tag" facsimile from QMP-15.01. Following a verbal commitment by USGS personnel to use actual "hold tags" in the future and the issuance of an NCR addressing this subject, the auditors downgraded the deficiency to a lesser finding (i.e., observation or recommendation).

During a review of the July 1989 "Status of Open Items and Trend

Analysis Report", the NRC Observer noted a negative trend of late responses and untimely corrective action for deficiency reports. With regards to QA Level 1 deficiencies, the time interval from initiation to resolution was eight months for six audit findings, three months for 10 corrective action reports, and seven months for seven NCRs. This was conveyed to the USGS management in the form of a recommendation to improve the timeliness of responses and corrective action for deficiency reports.

The USGS sends copies of NCRs to the DOE/YMPO on a quarterly basis. The individual who works for the SAIC QA Support Group, indicated that the YMPO was not responding in a timely manner to NCRs dispositioned "use as is". The DOE/YMPO agreed to respond to these in a timely manner.

The overall audit under this criterion was effective and determined that adequate programmatic QA controls are in place to allow quality level 1 and 2 work for the YMP.

(g) Audits

The DOE auditors used their audit checklist and some additional follow-up questions to review the USGS internal audits and surveillance reports. The auditors also reviewed the schedules for future audits and surveillances and interviewed personnel from the USGS and USGS/SAIC. The documents reviewed were:

- Records of USGS/SAIC auditor qualifications;
- Schedules for internal and external (suppliers) audits and surveillances;
- Monthly status reports for SDRs; and
- Audit Reports 89-01, 89-02, 89-03, and 89-04.

The NRC observer noted that there were no technical surveillances of on-going monitoring activities at the site during this fiscal year and there were none scheduled. Also, the corrective actions have not been timely. Two recommendations, one for technical surveillance of the on-going activities and one for timeliness of corrective actions, were made by the audit team. The DOE/YMPO audit for this program element was effective and allowed the audit team to make an assessment of the adequacy of QA controls for the YMP work.

(h) Software Configuration Management System (SCM)

The DOE auditors reviewed and evaluated the programmatic controls for the USGS SCM. The audit process and evaluation of the system was quite thorough. A checklist developed from the software management plan was used for questioning the USGS PI.

The SCM governs the development, review, approval, control and modification of computer programs that are used in site characterization and modeling activities by the USGS. The PI

seemed well qualified and knowledgeable about the software configuration management system. He had an excellent understanding of the QA and technical requirements and appropriate training needs for the personnel involved with the use of the SCM. Technical and QA procedures were made available to the auditors for their review and use for objective evidence. The audit of this activity was quite effective and allowed an assessment of the adequacy of QA controls for the YMP work.

(1) Miscellaneous Programmatic Items

The DOE auditors reviewed and evaluated several other programmatic areas (e.g., procurement process; document control and records; and identification and control of items, samples and data). The auditors were knowledgeable and conducted the audits of these areas effectively. Their evaluations of the objective evidence were quite thorough. The evaluation of adequacy of controls appeared sufficient.

In general, the overall programmatic portion of the audit was effective and determined that adequate QA controls are in place for the USGS to continue their YMP work. Since the ongoing activities were limited and the implementation of the current USGS QA program became effective on May 3, 1989, little objective evidence was available to determine the effectiveness of implementation.

4.6 Conduct of Audit

The overall conduct of the audit was useful in determining the adequacy of the QA controls for the USGS YMP work, but was only marginally effective in assessing the technical adequacy and the effectiveness of QA program implementation.

The programmatic portion of the audit was conducted quite well. The QA auditors were well prepared and demonstrated a sound knowledge of the QA aspects of the USGS program. The audit checklists included the important QA controls addressed in the 88-9 QA Plan that are applicable to USGS (see Section 4.1.1). The QA auditors used the comprehensive checklists effectively during the interviews with USGS personnel. In general, the team was persistent in their interviews, challenging certain USGS responses when necessary.

In general, the technical portion of the audit was conducted rather poorly. The technical group seemed less prepared and in several cases, did not seem very knowledgeable regarding the QA requirements. The technical auditors, in some cases, were not sufficiently knowledgeable in the activities they were auditing. The technical checklists, in several cases, appeared superficial or in some cases were not used effectively.

The audit lacked proper integration of its programmatic and technical portions. The audit team remained divided into two groups along the lines of their expertise in technical aspects of the program.

The audit team leader conducted pre-audit and post-audit conferences, daily caucuses and daily USGS review meetings. The daily caucuses were effective in providing a forum for discussions of potential findings and for redirecting the audit when necessary. These daily caucus meetings, however, did not result in a better coordination and integration between the technical and programmatic portions of the audit. For example, when the programmatic auditors were discussing potential findings, the technical specialists did not follow these through in their technical activities. The programmatic auditors were effective in identifying deficiencies and supported them with adequate objective evidence.

#### 4.7 Qualification of Auditors

The qualifications of the QA auditors on the team were previously accepted by the NRC staff (ref. NRC Observation Audit Report for USGS dated August 22, 1988) or were acceptable based on QMP-02-02, the DOE procedure for qualifying auditors.

#### 4.8 Audit Team Preparation

The QA auditors, in general, were well prepared in the areas they were assigned to audit and knowledgeable in the USGS QAPP and implementing procedures. Some of the technical auditors were not that well prepared and did not have a good knowledge of the technical activities they were auditing. Audit Plan 89-4 overall was complete and included: (1) the audit scope, (2) a list of audit team personnel and observers; (3) a list of all the audit activities; (4) the audit notification letter; (5) the USGS QAPP; (6) past audit report; and (7) the QA and technical checklists.

#### 4.9 Audit Team Independence

The audit team members did not appear to have prior responsibility for performing the activities they investigated. Members of the team appeared to have sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence from USGS personnel.

#### 4.10 Review of Previous Audit Findings

The NRC staff reviewed the status of the SDRs and NRC and State of Nevada observations resulting from last year's audits of USGS.

##### (a) DOE/YMPO - Documented SDRs

The previous audit identified 20 SDRs and resulted in the DOE/YMPO imposing a stop-work order on July 26, 1988. The stop-work order is still in effect. All these SDRs have been closed as a result of USGS corrective actions.

##### (b) NRC Staff Findings

The NRC staff reviewed the NRC Audit Observation Reports from the previous audits. DOE response to these observations was also reviewed to prepare for this audit. All these observations were resolved by DOE.

(c) State of Nevada Observations

The NRC staff reviewed the State of Nevada observations resulting from the previous audit (memorandum from S. Zimmerman to Distribution, dated September 6, 1988) and discussed these observations with the State of Nevada Observer. The concerns expressed by these observations are quite similar to those in the NRC Audit Observation Report for the USGS audit (Audit No. 88-04). The State observer indicated that the State of Nevada's concerns from the USGS audits of last year were not responded to by DOE. However, the State did review the DOE's responses to the NRC observations for the last year's audits and the State had no comments.

4.11 Summary of NRC Staff Findings

(a) Observations - No NRC staff observations relating to audit team deficiencies or audited organization deficiencies were identified.

(b) Weaknesses

- The audit scope was limited in that five study plans done under an earlier vintage of the QA program were evaluated, but three study plans currently being developed under a new procedure were not covered.
- Due to the "Privacy Act", the audit team was not able to review the personnel files of the technical and QA personnel to determine if they were trained and qualified to perform quality affecting activities.
- Integration of technical and QA expertise was inadequate during the evaluation of several technical areas covered during the audit.
- The checklists used to evaluate several of the technical activities were incomplete, and one technical specialist did not have the procedures for the technical activities that were audited.
- Technical products were not evaluated to assess the effectiveness of implementation of the QA program.

(c) Good Practices

- The USGS has assigned personnel experienced in QA to various technical groups to assist in the implementation of the QA program.
- Software Configuration Management and implementing procedures should be evaluated for adoption by other DOE contractors.

(d) Requests for Information

None.

#### 4.12 Summary of DOE/YMPO Audit Team Findings

The preliminary finding of the audit team is that the USGS QA and technical organizations and programs appear sufficient to provide adequate control to support QA Level 1 and Level 2 activities. The audit team identified four standard deficiencies pertaining to the USGS program and one standard deficiency pertaining to the DOE/YMPO program.

- (a) USGS: Contrary to the requirements of USGS QMP 12.01, Revision 3, 7 different instruments were found to be out of calibration, and NCRs had not been written identifying this condition.
- (b) USGS: 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.
- (c) USGS: The documentation of technical reviews performed for the study plans reviewed during the audit did not provide evidence of resolution of the reviewer's comments nor the reviewer's acknowledgement of comment resolution.
- (d) USGS: Numerous QA calibration forms were found in the USGS Local Records Center that did not comply with the requirements of USGS - QMP 17.01, Revision 3. Examples included:
  - Corrections made without required date and identification of person(s) making same;
  - No indication of when record was received by QA, therefore making it impossible to determine if record was transmitted prior to equipment use; and
  - Serial number, calibration date, and expiration date are missing from record.
- (e) DOE/YMPO: Contrary to the requirements of AP 1.7Q, USGS has not been permitted to submit QA records to the central records facility (Las Vegas) per written direction from the DOE/YMPO.

In addition to these deficiencies, the DOE/YMPO audit team also identified six observations pertaining to the USGS program and three observations pertaining to the DOE/YMPO program.

These are preliminary findings which will be further evaluated by the auditors and the YMPO prior to becoming final. These deficiencies and observations are not considered serious enough by the DOE/YMPO audit team to render the USGS QA program unacceptable. However, the staff notes that the implementation of the USGS QA program has just begun and the ongoing activities under this program are very limited. Little or no objective evidence was available to determine the effectiveness of the implementation.

## 5.0 CONCLUSIONS

The NRC staff concludes that, overall, the DOE/YMPO QA audit of USGS was useful but only marginally effective in assessing the extent and quality of implementation of the USGS QA program. The DOE/YMPO QA auditors, in general, were well qualified in the QA area and their checklists were of sufficient detail for the QA portion of the audit. Some technical members of the DOE/YMPO audit team seemed less prepared to assess the technical and QA aspects of the technical activities that were audited. The checklists for several technical areas appeared superficial. Although the review and evaluation of the USGS QA program enabled the auditors and the NRC staff to gain an understanding of the QA controls and an appreciation for the qualifications of the QA and technical staff, conditions, such as, limitations on access to the USGS personnel records, a very limited implementation of the USGS QA program and a lack of proper integration of the programmatic and technical portions of the audit made the audit less effective.

The NRC staff is in general agreement with the DOE/YMPO auditors' evaluation that the USGS QA program has adequate controls in place to continue the YMP work. Although the DOE/YMPO audit team identified several deficiencies in the USGS QA program, these deficiencies are not considered that serious and if corrected in a timely manner will not impact the quality of their work. The USGS management has committed to a timely corrective action for all these deficiencies. The USGS has just started implementation of their QA program and therefore, the effectiveness of implementation of the USGS QA program could not be determined from this audit. The DOE/YMPO needs to continue an aggressive schedule of audits and surveillances, which the NRC staff will observe, to determine if the USGS is effectively implementing its QA program. The NRC staff will conduct its own independent audit of the USGS QA program to determine the effectiveness of implementation and to assess the acceptability of the USGS QA program.

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