

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-10
FOR THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. YMP-92-13 OF
THE U.S. GEOLOGICAL SURVEY

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1.0 INTRODUCTION

From April 1-2, and April 6-10, 1992, U.S. Nuclear Regulatory Commission (NRC) staff members participated as observers on the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) Quality Assurance (QA) Audit YMP-92-13 of the U.S. Geological Survey (USGS) Yucca Mountain Project (YMP) QA program at the Nevada Test Site (NTS) and in the USGS offices at the Denver Federal Center, Lakewood, Colorado. The audit scope included seven programmatic elements and seven technical areas.

2.0 OBJECTIVES

The objectives of this YMQAD audit were to evaluate the implementation and effectiveness of the USGS YMP QA program in meeting the requirements of the USGS YMP Quality Assurance Program Description (QAPD). The NRC staff's objective was to gain confidence that the YMQAD and the USGS are properly implementing the requirements of their QA programs in accordance with the OCRWM Quality Assurance Requirements Document (QARD), DOE/RW-0214, Revision 4 and Title 10, Code of Federal Regulations (10 CFR), Part 60, Subpart 6.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the USGS QA program on direct observations of the auditors, discussions with the audit team, USGS and contractor personnel, and reviews of pertinent audit information (e.g., audit plan, checklists and USGS documents). The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. The audit team members were well qualified in the QA and technical disciplines, and their assignments and checklist items were, for the most part, acceptably described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team findings that the USGS QA program has adequate procedural controls in place, and program implementation is adequate, in six of the programmatic elements and six of the technical areas audited. Scientific Investigation Control was found to be implemented ineffectively due to deficiencies previously identified by the USGS in an audit of activities associated with Technical Activity 8.3.1.2.2.6.1, "Gaseous Phase Circulation Study." Three preliminary Corrective Action Requests (CARs) were issued by the YMQAD audit team. The deficiencies identified by the YMQAD audit team are not significant in terms of the overall QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

Kenneth L. Kalman	Observer (Denver only)	NRC
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Rex G. Wescott	Observer (Denver only)	NRC
John W. Gilray	Observer (NTS only)	NRC
Robert D. Brient	Observer (Denver only)	Center for Nuclear Waste Regulatory Analyses

4.2 YMQAD

Charles C. Warren	Audit Team Leader	MAC Technical Services (MACTEC)
Kenneth T. McFall	Lead Tech. Specialist	Science Applications Inter- national (SAIC)
Neil D. Cox	Auditor (Denver only)	SAIC
Cynthia H. Prater	Auditor (Denver only)	SAIC
Richard E. Powe	Auditor	SAIC
Paul L. Cloke	Technical Specialist (Denver only)	SAIC
Keith M. Kersch	Technical Specialist (Denver only)	SAIC
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James Blaylock	Auditor	DOE/YMQAD
Robert V. Barton	Technical Specialist (NTS only)	DOE
Christine Barry	Technical Specialist (NTS only)	SAIC

4.3 OTHER

Susan Zimmerman	Observer	State of Nevada
Engelbrecht von Tiesenhausen	Observer (NTS only)	Clark County, Nevada

5.0 REVIEW OF THE AUDITED ORGANIZATION

This audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 5, effective January 3, 1992 and OCRWM QAAP 16.1, "Corrective Action," Revision 4, effective November 12, 1991.

The NRC staff observation audit of this YMQAD audit of USGS was based on the NRC procedure, "Conduct of Audits," issued October 6, 1989.

5.1 Purpose/Scope of Audit

The purpose of the YMQAD audit was to evaluate the implementation and effectiveness of the USGS YMP QA program relative to the seven programmatic elements and seven technical areas listed below.

(a) Programmatic Elements

The audit was based on the requirements in the USGS YMP QAPD Sections 1.0, 3.0, 5.0, 6.0, 17.0, 19.0, and 20.0 (10 CFR Part 50, Appendix B Criteria I, III, V, VI, and XVII), and other applicable documents pertaining to QA controls.

(b) Technical Areas

Seven technical activities (areas) were selected to be reviewed by the technical specialists on the YMQAD audit team.

ACTIVITY NUMBER	TITLE
8.3.1.2.2.1.2 (At NTS)	Evaluation of Natural Infiltration
8.3.1.2.1.2.1 (At NTS)	Surface-Water Runoff Monitoring
8.3.1.2.1.2.2 (At NTS)	Transport of Debris by Severe Runoff
8.3.1.2.2.6.1 (At Denver)	Gaseous-Phase Circulation Study
8.3.1.5.2.1.3 (At Denver)	Evaluation of Past Discharge Areas
8.3.1.2.1.3.2 (At Denver)	Regional Potentiometric Levels & Hydrologic Framework
8.3.1.4.2.2.2 (At Denver)	Surface Fracture Network Studies

Evaluation of the above activities by the technical specialists was to include a determination of adequacy in the following areas:

1. Technical qualifications of scientific personnel,

2. Understanding of procedural requirements as they pertain to scientific investigation activities,
3. Adequacy of technical procedures, and
4. Development of study plans, work supporting the Site Characterization Plan, and any related work.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit of the USGS was acceptable, considering the OCRWM "limited scope" audit program began in fiscal year 1992. Although there was limited quality affecting work done in some of the programmatic elements, the last audit of all these elements was in June 1991.

5.3 Examination of Programmatic Elements

The audit checklists covered the QA program controls for the seven programmatic elements/criteria listed below:

- 1.0 Organization
- 3.0 Design Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 17.0 Quality Assurance Records
- 19.0 Computer Software
- 20.0 Scientific Investigation Control

One programmatic element (1.0 Organization) was added to the audit scope to complete the review begun under the previous audit. The NRC staff observed the YMQAD audit team's evaluation of programmatic elements/criteria 1.0, 3.0/20.0, and 19.0. Only these criteria will be discussed in detail.

(a) Organization (Criterion 1)

The audit of this programmatic element was a follow-up on specific items from YMQAD Audit YMP-92-02 of the USGS YMP QA program. A reorganization was in progress at the time of the previous audit, and thus, implementation of Criterion 1 was indeterminate at that time.

The audit of Criterion 1 was thorough and followed the checklist. Written agreements with the U.S. Bureau of Reclamation (USBR) were reviewed, and it was verified that the USGS audits the USBR QA Program, and has reviewed and approved the USBR QA Program Plan (YMP-USBR-QAPP-01, Revision 1). A potential problem with the USGS review of changes to

the USBR QAPP which was identified by the audit team was also identified during USGS Surveillance 92-S08, prior to this audit. Audit Report USGS-91-12 identified inadequate implementation of Management Agreements between the USGS YMP and organizations performing work for the USGS.

The current USGS YMP organization was reviewed and determined to meet the requirements of the OCRWM QARD. Personnel qualification files for personnel recently assigned to the USGS YMP organization were reviewed by the auditors and found to be satisfactory. The audit of this program element was effective. USGS QA program implementation under Criterion 1 was determined to be adequate by the auditor, a conclusion which is concurred in by the NRC staff.

(b) Design Control (Criterion 3) and Scientific Investigation Control (Criterion 20)

NTS

The technical specialists and auditors utilized a detailed checklist developed from the pertinent portions of the USGS QAPP (YMP-USGS-QAPP-01, Revision 5), USGS Quality Management Procedures, and from the Study Plans for Evaluation of Natural Infiltration; Surface-water Runoff Monitoring; and Transport of Debris by Severe Runoff. Detailed discussions were conducted with the USGS scientists at the USGS Hydrological Research Facility located at the NTS.

In addition, reviews and evaluations were performed of records and procedural controls associated with the implementation of these scientific investigations. The results of these discussions, reviews and evaluations determined that the scientists performing the work were qualified and understood the technical and quality-related procedural requirements, that the technical procedures were adequate and that the documented technical and QA records of completed and in-process work were complete and in accordance with program requirements. In addition, the logging of a neutron bore hole and the monitoring of surface-water runoff was observed by the auditors and technical specialist to determine compliance with procedural controls. No deficiencies were identified.

The audit at the NTS was conducted in an effective manner. USGS implementation of its QA program in the areas observed by the NRC was adequate.

Denver

The audit of these QA program elements was conducted simultaneously with the technical evaluation of activities 8.3.1.5.2.1.3, "Evaluation of Past Discharge Areas" and 8.3.1.4.2.2.2, "Surface Fracture Network Studies." No implementation of design controls was

identified, so the audit focused on implementation of scientific investigation controls.

The technical specialist took the lead during most of the observed portion of the audit, with the auditor occasionally probing the programmatic aspects of the technical activity. The detailed checklists covered work requests, QA grading, study plan control, technical and peer reviews, publication control, scientific investigation verification, and scientific notebook control. The auditor identified two nonconforming conditions: a) some data sheets did not identify measurement instruments by identification number, and b) some major technical review comments were not retained as QA records. In addition, several recommendations were made in regard to data recording and scientific notebook practices. No peer review activities had been conducted.

As discussed in Section 5.4(a) of this report, the USGS identified during USGS QA Audit No. 92-02, a number of deficiencies related to the control of scientific investigations under Study Plan 8.3.1.2.2.6. The YMQAD audit team did not issue a CAR concerning these deficiencies, since the deficiencies were previously identified by the USGS. However, due to the extent of the deficiencies, the audit team determined implementation of this QA programmatic element to be ineffective at this time. The audit team will recommend a YMQAD surveillance of the corrective actions for the deficiencies after the USGS verifies that the corrective actions have been completed. The NRC and State of Nevada observers requested that YMQAD notify them of the surveillance so that they may observe it.

One deficiency identified during USGS QA Audit 92-02 which may require Yucca Mountain Site Characterization Project Office (YMPO) action to resolve is the use of USGS-drilled wells on Yucca Mountain for data collection by organizations and individuals not associated with the Yucca Mountain Site Characterization Project (specifically Southern Methodist University). The NRC staff is concerned that unauthorized or unapproved testing could introduce contaminants that could interfere with future testing. The NRC staff believes that YMPO, or OCRWM, must investigate this question sufficiently to determine whether a project-wide problem exists.

The YMQAD audit team performed an effective audit. The currently assigned technical staff, including that of the USBR (now lead on activity 8.3.1.4.2.2.2), appeared to be familiar with QA requirements and their responsibilities.

(c) Software Controls (19)

The extremely extensive checklist was primarily based on the USGS Software QA Plan (SQAP). A recent interim change to the USGS QAPD has placed the basic criteria of the SQAP into Section 19 of the QAPD, and detailed requirements have been placed in lower tier procedures.

USGS effected these changes because it had determined that the SQAP was too prescriptive and did not reflect reasonable practices, which caused a number of nonconformances.

USGS had 116 items under configuration control, of which the auditor evaluated 19. The auditor concentrated on USGS scientific/engineering software classification, those he thought were most important in site characterization. The codes reviewed constituted virtually all scientific/engineering software likely to be used. In addition, corrective action for CAR-YM-91-077 (initiated during a 1991 surveillance) was verified, and the CAR was closed out. Software documentation packages provided the information necessary to address configuration control and software lifecycle (i.e., software design, verification/validation, and implementation phases) requirements.

Aside from a few very minor discrepancies, the implementation of software controls appeared effective. The audit of this element was particularly thorough and complete.

(d) Conclusions

(1) Audit Effectiveness

The programmatic portion of the YMQAD audit of the USGS YMP QA program was conducted in an effective and professional manner. The DOE/YMPO audit team members used detailed and complete checklists covering their assigned areas and were able to complete all items. The auditors asked appropriate questions to ascertain understanding of the QA program by USGS personnel. Although the technical specialists at times strayed from the specified review defined in the published audit plan into the area of technical review, this did not adversely affect the audit process.

(2) The USGS YMP QA program is being effectively implemented in the areas audited, with the exception of control of scientific investigations. It was apparent during the audit that USGS YMP QA personnel had a complete understanding of their assigned implementation elements, and were familiar with the requirements of the total QA program. The USGS QA personnel have done a good job recently of identifying program deficiencies and initiating corrective actions.

5.4 Examination of Technical Products

The NRC staff observed the audit team's evaluation of selected areas. The technical specialists and auditors working together as a team were involved in all of the technical activity evaluations observed by the NRC staff.

a) Gaseous-Phase Circulation Study

Study Plan 8.3.1.2.2.6, "Characterization of the Yucca Mountain Unsaturated-Zone Gaseous Phase Movement," was used as a basis for technical questions during the interview with the lead technical investigator. Both the present lead investigator and the former lead investigator were questioned regarding field practices and adherence to established technical procedures. The USGS, in an internal audit carried out in January 1992, issued CAR YMP-USGS-92-04. This CAR identified a number of problems with the activity including adherence with sampling procedures, calibration of meteorological instruments, preparation of field notebooks, and software QA. A response to the CAR was prepared on March 24, 1992, outlining changes to be made in administration of the activity. The USGS stated that a strong effort is going to be made to qualify the data collected.

A copy of the field notes from May 1981 to December 1989 and the electronic data from December 1987 to August 1989 for the study was reviewed at the USGS YMP records center. The data collected after May 1989 which should have been in accordance with YMP-USGS-QAPP-01 did not include required entries such as the signature of the data collector on every page nor identification of the instrument used to collect the data.

b) Regional Potentiometric Levels & Hydrologic Framework

Study Plan 8.3.1.2.1.3 "Characterization of the Yucca Mountain Regional Ground Water Flow System," was used as a basis for discussion with the lead technical investigator for this activity. Field records of data collection for publications completed under the study plan were reviewed at the records center and found to be in accordance with the applicable technical procedures. There were no samples of data collected after May 1989 available for review. The staff inquired about observations made during audit NRC-91-01 regarding this activity. The lead investigator stated that the cited weaknesses either have been or are being fixed.

c) Conclusions

(1) Audit Effectiveness

In general, the technical portion of the audit was effective. The sample of work activities selected for the audit was appropriate. The technical checklists were sufficient to determine the technical qualifications of the principal investigators and technical quality of the product. The audit team conducted the audit in a professional manner and asked questions to ascertain complete understanding of the technical program and applicable QA requirements.

(2) USGS Technical Program

The USGS technical personnel appeared well qualified, and in general, were properly trained and had an overall understanding of QA requirements. Problems were noted with development of scientific notebooks; however, revision of the procedures for development of scientific notebooks is expected to alleviate these problems.

5.5 Conduct of Audits

This audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the USGS YMP QA program and the technical areas reviewed. The audit checklists generally included the important controls addressed in the USGS QAPD. The team used the checklists effectively during the interviews with personnel and review of documents. The observers were kept well informed during the entire audit.

5.6 Qualification of Auditors

The qualifications of the QA auditors on this audit team had been previously reviewed by the NRC staff and found to be acceptable, meeting the requirements of OCRWM QAAP 18.1, "Qualification of Audit Personnel," Revision 2.

5.7 Audit Team Preparation

The auditors and technical specialists were prepared in the areas they were assigned to audit and knowledgeable in the USGS QA and technical procedures. Overall, Audit Plan YMP-92-13 was complete and included: (1) the audit scope; (2) a list of audit team personnel; (3) a list of the audit activities; (4) the audit notification letter; (5) the QA and technical checklists.

5.8 Audit Team Independence

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

5.9 Review of Previous Audit Findings

As discussed in Section 5.3(a), Criterion 1 was carried over from Audit YMP-92-02. Four CARs and one Standard Deficiency Report from previous YMQAD audits and surveillances were included in the audit scope. Because of the relatively small amount of time between audits, only one CAR, YMP-91-007, could be verified and closed as a result of this audit.

In addition, the audit team verified corrective actions taken in response to four findings identified during NRC audit NRC-91-01. The audit team determined that the corrective actions were effective, and the NRC staff agreed with this conclusion.

There were no NRC or State of Nevada open issues derived from previous YMQAD audits of the USGS.

5.10 Summary of NRC Staff Findings

(a) Observations

The NRC staff did not identify any Observations relating to deficiencies in either the audit process or of USGS QA program implementation.

The observer from the State of Nevada did not raise any new issues at the audit exit meeting.

(b) Weaknesses

The NRC observers are concerned about the extent of the deficiencies associated with Study Plan 8.3.1.2.2.6, and intend to closely review the corrective actions, and the implementation and verification of the corrective actions (See Sections 5.3(b) and 5.4(a)).

The audit checklists, particularly the technical checklists, should be provided to the observers ten working days prior to the start of the audit. Review of the checklists prior to the start of the audit would enable the observers to be better prepared, and to provide meaningful feedback on the proposed audit scope. This weakness is common to the limited scope audits begun by YMQAD in fiscal year 1992.

(c) Good Practices

The audit team was well prepared, thorough, and displayed acceptable knowledge of the appropriate USGS programmatic and technical procedures.

The USGS YMP QA staff has done a good job recently of identifying program deficiencies and initiating corrective actions. (See Section 5.3 (a)).

5.11 Summary - YMQAD Audit Team Findings

The audit team identified five procedural deficiencies which were corrected by USGS during the audit, and thus were not issued as CARs. The audit team wrote three potential CARs against the USGS YMP QA program.

- (a) Major comments from reviewers were missing from document review files. (See Section 5.3(b)).
- (b) A number of instrument identification numbers were missing. (See Section 5.3(b)).
- (c) A number of revisions to documents had an effectivity date prior to their issue to potential users.

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