

U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-02
FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. YMP-91-I-01 OF YUCCA MOUNTAIN SITE
CHARACTERIZATION PROJECT OFFICE

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1.0 INTRODUCTION

From October 28 - November 1, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) Quality Assurance (QA) Audit No. YMP-91-I-01 of the Yucca Mountain Site Characterization Project Office (YMPO) conducted in Las Vegas, Nevada. The audit was performed by auditors from the DOE/OQA Yucca Mountain Quality Assurance Division (YMQAD).

This report addresses the effectiveness of the DOE/OQA audit and the adequacy and effectiveness of implementation of QA controls in programmatic areas of the YMPO QA program.

2.0 OBJECTIVES

The objective of the DOE/OQA audit was to evaluate the implementation and effectiveness of the YMPO QA program in meeting the applicable requirements of DOE/RW-0214, Quality Assurance Requirements Document (QARD), Rev. 3 and DOE/RW-0215, Quality Assurance Program Description (QAPD), Rev. 3. The NRC staff's objective was to gain confidence that YMPO is properly implementing the requirements of the OCRWM QA program in accordance with the QARD, QAPD, and Title 10 Code of Federal Regulations (10 CFR), Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/OQA audit process and the YMPO QA program on direct observations of the auditors, discussions with the audit team and YMPO and contractor personnel, and reviews of pertinent audit information (e.g., the audit plan checklists, and YMPO documents). The NRC staff has determined that DOE/OQA QA Audit No. YMP-91-I-01 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. The audit team was well qualified in the QA discipline, and their assignments and checklist items were adequately described in the audit plan. Although the audit team did not include any technical specialists, some technical areas were audited for compliance to procedural controls (i.e., design and scientific investigation), but no evaluation was made of the technical adequacy of work products.

The NRC staff agrees with the preliminary DOE/OQA audit team findings that the YMPO QA program has adequate procedural controls in place, and that program implementation is adequate in nine of the thirteen areas audited. The other four areas were considered indeterminate due to a lack of quality affecting activities being conducted in these areas.

DOE/OQA should closely monitor the YMPO program to ensure that the seven preliminary deficiencies identified during this audit are corrected in a timely manner and future implementation is carried out in an effective manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess the YMPO QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

James T. Conway	Observation Team Leader	
John T. Buckley	Observer	
John Gilray	Observer	
Robert D. Brient	Observer	CNWRA

4.2 DOE

Richard E. Powe	Audit Team Leader(ATL)	Science Applications International Corp. (SAIC)
Amelia I. Arceo	Auditor	SAIC
Neil D. Cox	Auditor	SAIC
John S. Martin	Auditor	SAIC
Richard L. Maudlin	Auditor	MAC Technical Services Co. (MACTEC)
Sandra D. Bates	Auditor-in-Training	SAIC
Kenneth T. McFall	Auditor	SAIC
Charles C. Warren	Auditor	MACTEC
Wayne Booth	Observer	Roy F. Weston, Inc.

4.3 TRW Environmental Safety Systems

Frank E. Nash	Observer	Duke Engineering & Services, Inc.
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4.4 Clark County, Nevada

Engelbrecht von Tiesenhausen

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE/OQA audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 3 and 16.1, "Corrective Action Requests," Revision 3.

The NRC staff observation of the DOE/OQA audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. NRC staff findings are classified in accordance with this procedure. 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.

5.1 SCOPE OF AUDIT

The DOE/QQA audit scope was to determine whether the YMPO QA program meets the requirements and commitments imposed by the OCRWM QARD and QAPD by verifying compliance with requirements and the extent and effectiveness of implementation of the program. Technical areas were audited for compliance to procedural controls only, since technical specialists were not included on the audit team.

(a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the QARD and QAPD and other applicable documents. The checklists covered QA program controls for 13 of the 18 10 CFR Part 50 Appendix B criteria (14 of 20 QAPD elements/criteria).

Criteria IX, X, XI, XIV and XVIII of 10 CFR Part 50, Appendix B (Sections 9, 10, 11, 14 and 18 of the QAPD) were not included in the scope of the audit since YMPO currently is not performing activities in these areas.

(b) Technical Areas

Technical products from YMPO were not evaluated during this audit; however, some technical areas were audited for compliance with procedural controls.

5.2 TIMING OF THE AUDIT

The NRC staff believes the timing of the QA audit was appropriate. The YMPO QA program was last audited in October 1990, and this audit was useful to determine the adequacy of the YMPO QA program for continuation of quality-affecting activities for Yucca Mountain Project.

5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

The programmatic checklists covered the QA program controls for the 14 elements listed below.

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Plans, Procedures, Instructions, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Materials, Parts, Components, and Samples
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 20.0 Scientific Investigation Control

The NRC staff observed the audit team's evaluation of selected programmatic elements of the QARD and QAPD. Only those elements of the QA program which were observed will be addressed in this report.

(a) Organization (Criterion 1)

The auditor used the published audit checklist which consisted of 11 requirements from Quality Management Procedure (QMP) 01-01 "Organization," Revision 2. The auditor interviewed the YMPO Project Manager (PM), Deputy Project Manager (DPM), Director of Project and Operations Control Division, Program Site Manager, Project Control Branch Chief, Systems Branch Chief, and the Procurement Contracting Officer to verify his/her cognizance relative to functional duties and responsibilities. The auditor utilized the checklist requirements as the basis of his investigation and appeared to be thorough in his evaluation of the YMPO quality system. It was verified that the PM had overall authority and responsibility for the YMPO and was accountable for technical and quality performance and cost and schedule. Part of the responsibilities of the DPM include project training, Information Management System, and records management. It was noted that Division Directors and Branch Chiefs review and approve indoctrination and training requirements for personnel under their supervision. The audit of this area was effective, and Criterion 1 is being adequately implemented.

(b) Quality Assurance Program (Criterion 2)

The NRC staff evaluated the audit portion of Criterion 2 that pertained to training and qualifications of personnel at the YMPO and the readiness review process. With regards to training and qualifications, the auditor utilized approximately 14 requirements from procedures QMP-02-01, "Project Office Indoctrination and Qualification Training" and QMP-02-09, "Development and Conduct of Training." An interview with the YMPO Administrative and Training Officer and the Training Manager from SAIC revealed that SAIC is responsible for the training of personnel at the YMPO and also for the maintenance of their records.

The auditor sampled the training records (TR) by selecting approximately 15 individuals from the YMPO organizational charts of DOE, MACTEC, and SAIC. The TRs contained a job/position description, qualification and proficiency evaluation forms, resumes, copies of certifications, and training and reading assignments. Two levels of training consist of indoctrination (reading assignments and orientation briefings) and training/proficiency (in-depth instruction). All the files that were reviewed appeared to be complete, and each individual had completed the required reading assignments prior to performing quality-affecting activities.

The NRC observer reviewed the certification records for the individuals who were on the audit team. Unlike the other training files retained by SAIC, the auditor certification records are maintained by the YMQAD. These files consist of record of auditor/lead auditor qualification, training assignment, resume, audit participation record, and a qualification statement. Eight files were reviewed, and they were found to satisfy the requirements of procedure QMP-02-02 "Qualification of Quality Assurance Program Audit Personnel."

Based on the depth of the evaluation and the completion of the applicable checklist items, the audit of training and qualification records appeared to be effective, and the implementation by DOE/YMPO appeared to be adequate.

With regards to readiness reviews (RR), the audit consisted of interviewing the team coordinator for the Midway Valley RR and reviewing the RR process. During the interview, the auditor was informed that the Midway Valley RR was the only one conducted since the last audit held in October 1990. In an effort to evaluate the RR process, the auditor examined the RR Board Selection Record, reviewer training records, and review checklists for the Midway Valley RR. A few minor procedural deficiencies were noted by the auditor. The auditor was thorough in completing the published checklist items, and professional in the conduct of the interview. The audit process for this portion of Criterion 2 was effective, and implementation appeared adequate.

(c) Design Control (Criterion 3)

The auditor interviewed the Acting Director of the Regulatory and Site Evaluation Division, and evaluated Test Planning Packages (TPP) 91-32 Neutron Access Boreholes, and 91-34 Evaluation of Natural Infiltration. In evaluating the two TPPs, the auditor noted that prerequisites were not explicitly stated in the TPPs as required by Administrative Procedure (AP) 5.32Q "Test Planning and Implementation Requirements."

After completing the evaluation of the TPPs, the auditor reviewed the QA grading process for procedural compliance with the QARD and AP-6.17Q, "Determination of the Importance of Items and Activities." The audit consisted of interviews with YMPO DOE and SAIC staff and reviews of the Assessment Team (AT) controlled list of documents, AT evaluation assessments, and Quality Assurance Grading (QAG) Log and associated documents. One Corrective Action Request (CAR) was generated by the auditor because the AT Controlled List does not contain the most recent available version of the Work Breakdown Structure dictionary as required by AP-6.17Q. This deficiency was previously identified during the audit conducted in October 1990.

The auditor also reviewed the preparation review and approval of SCP Study Plans (SP). Through interviews, the auditor determined that 15 SPs had been completed since October 1990. The following four SPs were reviewed during the audit:

1. SP 8.3.1.5.2.1 Characterization of Quaternary Regional Hydrology
2. SP 8.3.1.5.2.1.5 Studies of Calcite and Opaline-Silica Vein Deposits
3. SP 8.3.1.3.6.2 Diffusion
4. SP 8.3.1.17.4.2 Location and Recency of Faulting Near Prospective Surface Facilities

No deficiencies were identified regarding SPs. The audit of Criterion 3 was effective. In general, the staff agrees with the preliminary audit team conclusion that adequate controls are in place for design control. The auditor used the published checklists effectively and conducted all interviews in a very professional manner.

(e) Plans, Procedures, Instructions, and Drawings (Criterion 5) and Document Control (Criterion 6)

Criteria 5 & 6 were audited simultaneously. The checklist was comprehensive and the auditors' investigations were thorough. To evaluate implementation of Criterion 5, the auditor verified compliance with two quality affecting administrative procedures through reviews of pertinent records and interviews with cognizant YMPO staff. The auditor identified several cases of noncompliance with specific procedural requirements, resulting in one CAR. Document controls were evaluated at the Document Control Center and by checking distribution to selected individuals, including those personnel processing rock cores.

The auditing of these two areas was effective, and both criteria were found to be adequately implemented with the exception of the area identified in the CAR.

(e) Control of Purchased Items and Services (Criterion 7)

The YMPO is required to interface and work through DOE field offices when procuring contract services. In this regard the DOE/YMPO has written three Management Agreement Letters (MAL) with field offices in Richland, Washington; San Francisco, California; and Las Vegas, Nevada to contract work with such facilities as Pacific Northwest Laboratory (PNL), Lawrence Berkeley Laboratory, and EG&G. The MALs

are very broad and general and are supplemented by YMPO Technical Guidance Letters (TGL) when specific contract work is required. Once the TGLs are submitted to the contractor, the YMPO interfaces directly with the contractor regarding specific technical and quality requirements.

The YMPO Procurement Contract Administrator is responsible for the MALs, modifications to these letters, and interfaces with the DOE field offices concerning these agreements. The YMPO technical personnel, with approval from the Division Director, are responsible for issuing the TGLs directly to the contractors without required interface and concurrence from the YMPO Procurement Contracting Office. This procurement and technical direction process does not apply to contracts and technical directions issued to the Yucca Mountain Site Characterization Project major participants.

The auditor reviewed the MAL packages for the DOE San Francisco and Nevada field offices to determine the extent these letters were written and processed in accordance with QMP-04-02, "YMPO Procurement Actions," Revision 0. In addition, the auditor reviewed a YMPO TGL to Lawrence Berkeley Laboratory. As a result of these reviews, it was determined that the process for preparing and processing these MALs and TGLs was not adequately procedurally controlled. While the auditor's finding is substantive, it was determined by the auditor that very little quality affecting work is being performed by contractors. Still, the YMPO recognized the need to develop a procedure(s) to correct this deficiency.

The ATL initially considered the issuance of a Stop Work Order (SWO) in this area, but after meeting with the Director of the YMQAD, it was decided that completion of the recommended corrective actions for CAR No. YM-92-07 would resolve the areas of concern, and the Director of the YMQAD decided that a SWO was not needed. In addition, the NRC staff is still awaiting DOE's response to an Audit Observer Inquiry regarding the Shelor to Horton memo dated June 25, 1990 pertaining to the transfer of DOE/HQ contracts to the YMPO or one of the YMP participants.

The NRC staff found this area to be audited in a thorough and effective manner, and the auditor conducted in depth interviews and investigations. Effectiveness in this area could not be determined since there was no implementation of YMPO activities.

(f) Identification and Control of Samples (Criterion 8) and Handling, Storage and Shipping (Criterion 13)

Criteria 8 and 13 were audited together and were applied to rock core samples associated with Neutron Borehole Experiments. Drilling was in progress at the Yucca Mountain site, and the auditor traced the core handling and logging process from the drill rig to the Sample Management Facility (SMF) evaluating implementation of procedures

AP-6.2Q, "Management and Operation of Sample Handling Activities at Borehole Sites," and BTP-SMF-013, "Staging, Packaging, Documenting Neutron-Access Borehole Samples." The auditor also determined that special handling and storage considerations were properly incorporated into the procedure for the neutron borehole core samples. Several discrepancies between AP-6.2Q and BTP-SMF-013 were identified, as well as some other relatively minor concerns, and two CARs were written in this area. The audit was extensive and effective. Overall, sample controls appeared adequately implemented, and the SMF staff appeared capable.

(g) Control of Nonconforming Items (Criterion 15)

The OCRWM application of nonconformance control is exclusive to hardware. Since YMPO rarely handles hardware items, nonconformances have not been identified since the previous audit conducted in October 1990, and the implementation of this criterion could not be evaluated.

(h) Corrective Action (Criterion 16)

The YMQAD, which is audited separately from the YMPO, performs most of the administrative and verification activities associated with corrective action. YMPO responsibilities are primarily in regard to timely response to CARs and in verifying the corrective actions. Prior to the beginning of the audit, the auditor and auditor-in-training reviewed corrective action records and identified several cases in which response times exceeded the due date. YMPO staff discussed the management tracking system that has been implemented and showed that there has been improvement in response times since its implementation. The auditor for Criterion 8 independently identified a violation of corrective action requirements when a known nonconformance to procedure BTP-SMF-013 was not addressed through an internal CAR.

Aside from the single failure to initiate a CAR, the audit of this area appeared effective, and this criterion appears to be adequately implemented.

(i) Quality Assurance Records (Criterion 17)

The portion of the audit of records control observed involved examination of records processing at the Local Records Center. Records packages and records package segments were reviewed to verify compliance with procedure QMP-17-01 "Records Management: Record Source Implementation," Revision 3. The checklist and sample of records reviewed were adequate. Later, the auditors encountered difficulty in retrieving records, apparently due to the limitation of retrieving only by title keywords and inconsistencies in record titles. The auditors were informed that YMPO is currently studying this problem, but no internal CAR has been initiated.

Aside from the issue of retrievability, records control appears to be adequately implemented, and this criterion was effectively audited.

5.4 EXAMINATION OF TECHNICAL PRODUCTS

The NRC staff did not include any technical specialists on the NRC audit observation team since the audit team did not include any technical specialists, and assessment of technical adequacy and qualification of technical products was not planned for this audit.

5.5 CONDUCT OF AUDIT

The overall conduct of the audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the YMPO program. The audit checklists included the important QA controls addressed in the OCRWM QARD and QAPD that are applicable to the YMPO program. The audit team used the comprehensive checklists effectively during the interviews with YMPO and contractor personnel and review of documents. In general, the team was persistent in its interviews, challenging responses when necessary. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between YMPO management and the ATL to discuss the potential findings. The auditors who identified findings were included in these meetings to more clearly explain the deficient conditions. The findings were well substantiated and reflected significant rather than trivial issues.

5.6 QUALIFICATION OF AUDITORS

The qualification records of the ATL and the six auditors on the team were reviewed by the NRC staff and were found acceptable in meeting the requirements of QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel," Revision 2.

5.7 AUDIT TEAM PREPARATION

The QA auditors were well prepared in the areas they were assigned to audit and knowledgeable in the YMPO QARD and implementing procedures. Overall Audit Plan 91-I-01 was complete and included: (1) the audit scope; (2) a list of audit team personnel; (3) a list of all the audit activities; (4) the audit notification letter; (5) the QAPD; and (6) the QA checklists.

5.8 AUDIT TEAM INDEPENDENCE

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

5.9 REVIEW OF PREVIOUS FINDINGS

Responses to CARs YM-91-017, -045, -046, -065, -083, -085, -086, and -088 were reviewed to verify that corrective action response due dates were met. It was noted that corrective action due dates were after the date of the audit for CARs YM-91-083, -085, -086, and -088.

CAR-YM-91-017 response due date was originally December 21, 1990. YMQAD has accepted an extension to May 1, 1993 as the estimated completion date for corrective action. The corrective action for CAR -YM-91-045 was considered closed on November 1, 1991. For CAR-YM-91-065, YMQAD received an amended response dated October 28, 1991, and it is under evaluation.

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 the area of YMPO QA program implementation.

(b) Weaknesses

There was some inconsistency between auditors regarding findings which should be written up as CARs. For instance, an auditor reviewed three Comment Report Forms (CRF) and found that two of the CRFs were not filled out correctly, but the auditor did not require remedial action to correct the problems nor generate a CAR.

The ATL did not provide a daily documented summary of the CARs and observations generated by the auditors.

Previous audits have established several audit management techniques that have facilitated the audit and observation activities, but they were lacking during this audit. Examples were:

- 1) Location of audit, criteria being audited, auditor, and observers were not posted (in several instances auditors could not be located at certain times).
- 2) A log of potential deficiencies was not maintained until late in the audit.
- 3) During daily audit team/observer caucuses, observers were not directly asked for their comments.

4) The audit "Command Center" was frequently occupied by YMPO meetings, rather than being established for the exclusive use of the auditors and observers.

(c) Good Practices

The audit team was well prepared and were familiar with the QA program requirements and relevant implementing procedures and conducted a thorough audit in a professional manner.

Personnel qualification records were well documented and accurate to facilitate reviews and audits.

There is a strong commitment and support for an effective QA program at the management level. Both the PM and DPM have a good knowledge of the QA requirements and demonstrated a positive attitude toward an effective QA program.

YMPO staff and support personnel appear familiar with procedural and QA program requirements.

The efforts of YMPO management as well as the technical staff and contractor personnel facilitated the smooth and effective conduct of the audit.

5.11 SUMMARY - DOE/OQA AUDIT FINDINGS

At the formal exit briefing on October 31, 1990, the audit team identified seven potential CARs written against the YMPO QA program. In addition, during the audit, YMPO was able to resolve six remedial deficiencies prior to the post-audit conference. The CARs issued to YMPO can be summarized as follows:

- (a) Test Planning Packages do not address prerequisites.
- (b) The Assessment Team Controlled List did not include the current version of the WBS Dictionary.
- (c) There is no approved procedure(s) which describes the procurement process for soliciting contractors from DOE field operations offices to perform work for YMP.
- (d) There is a lack of verbatim compliance to a number of procedures.
- (e) Footage marks at one-foot intervals were not written on two borehole core samples.
- (f) One borehole core run was not videotaped, and this deficiency was not documented as a CAR.
- (g) A specific requirement in the area of document control was not included in an implementing procedure.