U. S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 91-1

FOR THE INTERNAL AUDIT NO. 90-I-01 OF THE OFFICE OF

CIVILIAN NUCLEAR WASTE MANAGEMENT HEADQUARTERS AND

YUCCA MOUNTAIN PROJECT OFFICE

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1.0 INTRODUCTION

From October 15-19 and October 22-26, 1990, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE) Office of Civilian Nuclear Waste Management (OCRWM) Headquarters (HQ)/Yucca Mountain Project Office (YMPO) Quality Assurance (QA) Internal Audit No. 90-I-01 of HQ in Washington, D.C. and YMPO in Las Vegas, Nevada.

This report addresses the adequacy and effectiveness of the OCRWM QA program as demonstrated by the HQ/YMPO audit team and of implementation of the OCRWM QA program by HQ and YMPO technical and QA staff.

2.0 OBJECTIVES

The objective of the HQ/YMPO internal audit was to evaluate the implementation and effectiveness of the OCRWM 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 HQ and YMPO are properly implementing the requirements of the OCRWM QA program in accordance with the QARD, QAPD, and 10 CFR Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the HQ/YMPO audit process and the OCRWM QA program on direct observations of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., audit plan, checklists, HQ and YMPO documents). The audit was conducted in a professional manner, and the programmatic and technical portions of the audit were generally effective and well integrated. The audit team was well qualified in the QA discipline, and their assignment and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary finding of the audit team that the OCRWM QA program has adequate procedural controls in place for the areas that were audited. However, the number of areas in which the HQ/YMPO audit team identified the OCRWM QA program as ineffective or indeterminate is of concern to the NRC staff, particularly the areas of audits and corrective actions at HQ and the technical baseline documents at both HQ and YMPO. The NRC staff fully supports the audit team's recommendations of actions to be taken to verify the effectiveness of corrective actions prior to the start of any new site characterization activities.

OCRWM management must closely monitor HQ and YMPO implementation of the OCRWM program to ensure that future implementation is carried out in an

adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own audits of HQ and YMPO at a later date to independently determine the adequacy and effectiveness of the QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

Kenneth R. Hooks	Observation Team Leader
William L. Belke	Observer (HQ only)
James T. Conway	Observer (YMPO only)
John T. Buckley	Observer (HQ only)
Bruce Mabrito	Observer (Center for Nuclear Waste Regulatory Analyses - YMPO only)
Robert D. Brient	Observer (Center for Nuclear Waste Regulatory Analyses - HQ only)

4.2 DOE

James Blaylock	Audit Team Manager	DOE YMPO
Stephen R. Dana	Audit Team Leader	SAIC
Martha J. Mitchell	Lead Technical Specialist	SAIC
Charles C. Warren	Lead Auditor	MACTEC
Amelia I. Arceo	Auditor (YMPO only)	SAIC
Paul Bryant	Technical Specialist (HQ only)	SAIC
Robert Clark	Auditor (HQ only)	DOE HQ
A. Edward Cocoros	Auditor	MACTEC
Robert B. Constable	Auditor (YMPO only)	DOE YMPO
Neil Cox	Auditor	SAIC
Mario Diaz	Auditor	DOE YMPO
James J. George	Auditor	CER
William Haslebacher	Technical Specialist	WESTON
John S. Martin	Auditor	SAIC
Marc J. Meyer	Technical Specialist	CER
Arthur W. Spooner	Auditor	WESTON
Richard Weeks	Auditor (YMPO only)	SAIC
Ardell M. Whiteside	Auditor	SAIC

4.3 State of Nevada

Susan Zimmerman	Observer

4.4 Clark County, Nevada

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4.5 Nye County, Nevada

Phillip A. Niedzielski-Eichner	Observer

4.6 Edison Electric Institute

Thomas Colandrea	Observer

4.7 TRW

R. James Brackett	Observer

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The OCRWM internal audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2 "Audit Program," Revision 1 (effective October 15, 1990), and OCRWM QAAP 16.1 "Corrective Action Requests," Revision 2 (effective October 15, 1990).

The NRC staff observation of the HQ/YMPO audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. NRC observer findings are classified in accordance with this procedure. Levels 1, 2, and 3 of NRC Observations require a written response from DOE to be resolved. The NRC 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.

5.1 Purpose/Scope of Audit

The purpose of the audit was to evaluate the implementation and effectiveness of the QA controls applied to OCRWM activities affecting quality. The scope of the audit included those HQ and YMPO activities associated with new site characterization, particularly the program level technical baseline documents.

(a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the QAPD and other applicable documents. The checklists covered QA program controls for fourteen of the eighteen 10 CFR Part 50 Appendix B criteria (fifteen of twenty QAPD elements).

Criteria IX, X, XI, and XIV of 10 CFR Part 50, Appendix B (Sections 9, 10, 11, 14, and 19 of the QAPD) were not included in the scope of the audit since OCRWM currently is not performing activities in these areas.

(b) Technical Areas

Technical activities engaged in by OCRWM were limited. The audit team technical specialists were instructed to include the following areas in their evaluations:

(1) qualifications of technical personnel;

(2) understanding of procedural requirements as they pertain to technical activities;

(3) adequacy of technical plans and procedures; and

(4) development of study plans and any related work products.

NRC technical staff were not included on the NRC observation team, due to the limited technical scope of the audit and, therefore, the NRC did not evaluate the technical adequacy of any technical products.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was less than optimal, since many of the procedures governing both the conduct of the audit and the conduct of the QA program activities being audited had been very recently issued. For example, the Master List of Controlled Documents and the checklists based on Revision 2 of the QARD were replaced after the Audit Books were issued to the observers, and the QA Controls Document had not been issued by October 19, 1990. However, the NRC staff believes that an audit to establish a baseline for the OCRWM program and HQ and YMPO implementation was necessary.

5.3 Examination of Programmatic Elements

The HQ/YMPO programmatic checklists covered the QA program controls for the fifteen elements listed below:

1.0 Organization
2.0 Quality Assurance Program
3.0 Design Control
4.0 Procurement Document Control
5.0 Instructions, Plans, Procedures 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 (YMPO only)
12.0 Control of Measuring and Test Equipment (YMPO only)
13.0 Handling, Storage, and Shipping (YMPO only)
15.0 Control of Nonconforming Conditions

16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits
20.0 Scientific Investigation Control

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

(a) Organization (Criterion 1)

HQ

The auditors utilized the published audit checklists and were generally thorough in reviewing the associated objective evidence. The auditors interviewed the Director and Deputy Director of OCRWM, and the Director of the OCRWM Office of QA. At times, the auditors appeared to spend an unusual amount of their time probing for the desired objective evidence as opposed to obtaining it from direct questioning from the checklist. This could have possibly been due to the recent OCRWM reorganization (the "interim" organization in effect at the time of the audit was implemented July 16, 1990) and certain newly revised procedures (which appeared to frequently contain conflicting requirements). The problems of audit team focus and the HQ organizational and procedural changes caused the audit process to be lengthened somewhat; however, the desired objectives of the audit were eventually achieved.

The NRC staff identified two areas of concern with the HQ organization. First, Section 1, paragraph 1.1.1.(h) of the QAPD requires an annual assessment of the scope, status, adequacy, and compliance of the QA program by management who are independent of the Office of QA. To date, this assessment has not been performed and is tentatively scheduled for June 1991. The NRC staff believes that this assessment should be scheduled earlier since management assessments provide valuable insight in determining major problems and in allocating adequate resources for the project.

Second, the NRC staff noticed that the HQ QA Division appeared to be understaffed, with only two full-time DOE personnel reporting to the QA Division Director. The NRC staff submitted an Audit Observer Inquiry form noting that the QA Division appeared to be understaffed and requested an explanation of how the OCRWM determines whether sufficient resources have been allocated for the HQ QA Division to accomplish its mission. The DOE response to this inquiry indicated that there are currently two positions posted and waiting to be filled. In addition, with the number of contract support personnel available, OCRWM believes QA staffing should be adequate for future activities. The NRC staff agrees with this response.

YMPO

The auditors used the published audit checklist which consisted of twelve requirements from the QARD document. The NRC staff noted that checklist items were not taken from Quality Management Procedure (QMP)-01-01 "Organization." During the audit, two additional requirements from QMP-01-01 were added to the checklist. The auditors interviewed the Director - QA Division; Director and Deputy Director - Regulatory and Site Evaluation Division (RSED); and Branch Chief - Site Investigations Branch to verify the requirements identified on the checklist for Criterion 1. The auditors seemed to have a problem differentiating between the responsibilities of the OCRWM Director, Office of QA and the YMPO Director - QA Division, both positions of which are currently filled by the same individual. The auditors asked specific questions from the checklist, but in many cases, answered their own question before the auditees could give a response.

The NRC staff believes that the auditors could have been better prepared, but they satisfactorily completed the audit checklist and evaluated the YMPO organizational structure for compliance to the QAPD.

(b) Quality Assurance Program (Criterion 2)

HQ

The auditors reviewed and evaluated the adequacy and effectiveness of personnel qualifications for the OCRWM Office of Systems and Compliance. Evaluations of the personnel indoctrination and training matrix, education, experience, position descriptions, and engineering series were performed. In addition, the required annual supervisory evaluations of the employee positions were reviewed to assure appropriateness for the work being performed by the employees.

The auditors used the checklist questions and probed beyond the checklist questions in sufficient detail to accomplish a comprehensive audit. As the auditors proceeded through the checklist and related questions, the auditors explained to the auditees and observers exactly what was being requested, why it was being requested, and whether the information received was acceptable. This type of auditing style facilitated the audit process and was an effective method for expediting the audit. The desired information was produced in a timely manner and questions and clarifications from the auditee and observers were minimal.

Personnel qualification records were complete, accurate, and thoroughly documented. Prior Privacy Act restrictions limiting access to personnel qualification files during this phase of the audit imposed no problems. All personnel qualification files in this area were open and readily available for the auditing process. Information in the personnel qualification files was sufficiently detailed and accurately reflected the education, experience, and specific responsibilities required for the particular position. The indoctrination and training matrix described the required training and the date the individual employee received it. Documentation also indicated that each individual employee had been evaluated

by management on an annual basis to verify the accuracy and appropriateness of the work currently being performed by the employee. However, the NRC staff questioned how training or retraining is accomplished when new or revised procedures are issued. This question was not included in the checklist and appears to be an open issue.

The auditors and auditees were well prepared and knowledgeable of the subject matter in the area being audited. However, the apparent lack of familiarity with procedural requirements displayed by some HQ staff during other portions of the audit suggests that training may not be particularly effective. Consequently, for this element of the audit, the QA Program is adequate and, with the possible exception of QA training, is being effectively implemented. The audit under this criterion was effective.

YMPO

The NRC staff evaluated the audit portion of Criterion 2 that pertained only to training and qualifications of personnel at the YMPO. Procedure QMP-02-01 establishes the requirements for implementing the qualification evaluation process; defining the indoctrination and training program; and documenting qualification, indoctrination, and training activities. The procedure is applicable to the DOE, MACTEC, and Science Applications International Corporation (SAIC) Technical and Management Support Services (T&MSS) personnel who perform quality related activities under the OCRWM QAPD.

Under the qualification process, the individual's manager and personnel from the Human Resources Department of SAIC compare the Position Description (PD) with the individual's accumulated skills, training, and experience. In the indoctrination and training program, the individual's manager determines the training needs and is responsible for assuring that each individual receives and completes the assigned training. The development and conduct of training is covered in procedure QMP-02-09. The two levels of training consist of indoctrination (reading assignments and orientation briefings) and training/proficiency (in-depth instruction).

The auditors' evaluation of personnel qualification, indoctrination and training included a review of personnel records and interviews with training supervisors from DOE, SAIC, and MACTEC. The T&MSS group of SAIC is responsible for the training of personnel at the YMPO and also for the maintenance of their records.

The auditors sampled the training file by selecting a number of individuals from the YMPO organizational charts of DOE and MACTEC. Approximately 18 DOE training files were reviewed. The auditors reviewed six MACTEC training files which consisted of PDs, Qualification and Proficiency Evaluation Forms, Resumes, Copies of Certifications, and Training and Reading Assignments. The auditors were told that the T&MSS training files are similar to DOE's, and they will be reviewed during the audit of SAIC the week of November 12, 1990. 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. It was noted by the NRC observers that the Proficiency Evaluation Form was deleted in an Interim Change Notice dated October 19, 1990, to QMP-02-01. Thus, management's annual or semi-annual evaluation of an individual's performance will not be performed in the future.

The auditors reviewed the certification records for those individuals who have been performing OCRWM external audits of the participant QA programs. Unlike the other training files retained by SAIC, the auditor certification records are maintained by the YMPO QA Division. These files consist of Record of Auditor/Lead Auditor Qualification, Training Assignment, Resume, Audit Participation Record, and a Qualification Statement. Approximately 31 files were reviewed by the auditor, and they were found to be satisfactory.

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.

(c) Design Control (Criteria 3)

The audit team technical specialists and QA auditors performed a limited review of various Study Plans and technical baseline documents including:

(1) Waste Management System Description;

(2) Waste Management System Requirements (WMSR);

(3) Study Plans (SPs) for Calcite and Opaline Silica Vein Deposit Studies (SCP 8.3.1.5.2.1.5) and Midway Valley Faulting Studies (SCP 8.3.1.1.7.4.2); and

(4) Technical Requirements Documents.

The audit team developed separate checklists for the HQ and YMPO portions of the audit, based upon the OCRWM QARD and applicable procedures. The technical portion of the audit was generally focused on adequacy of documents and document review packages in establishing technical requirements and the traceability of such requirements, rather than the correctness (technical adequacy) of the requirements.

HQ

The auditors and technical specialists conducted joint interviews with the HQ personnel. During the initial portion of the audit, a considerable amount of time was spent with the audit team interviewing HQ personnel to come to an understanding of the activities being conducted. The portion of the audit observed consisted of discussion of technical document preparation procedures. Use of the audit checklist was limited. Several of the checklist questions were revised to reflect recently issued procedures and to more accurately evaluate activities.

WMSR Volume IV, Revision 1

The audit team reviewed records for the development, review and resolution of comments on WMSR Volume IV, and interviewed the HQ personnel associated with the document. The Technical Adequacy Assessment Group (TAAG) review records were also evaluated by the audit team.

The documentation was sometimes inadequate, with unclear comment resolution and some illegible pages in document packages. The audit team was unable to consistently trace incorporation of review comments into the WMSR Volume IV. The HQ personnel responsible for the document had been assigned recently, and were not always able to adequately supplement the written record.

The audit team was well prepared, knowledgeable about requirements for documentation, and persistent in both the document reviews and interviews. In a few instances, it appeared to the NRC observers that the auditors had been involved in work closely related to that which was being reviewed, but this possible lack of complete independence did not appear to adversely affect the audit process.

The audit technical specialists encountered significant difficulties in attempting to understand how technical activities are conducted and controlled at OCRWM Headquarters. Therefore, the implementation of QA controls over the technical baseline activities should be considered indeterminate.

YMPO

Technical Requirements for Yucca Mountain Project (Midway Valley Trenching and Calcite/Silica Activities), YMP/CM-0007, Rev. 1

The auditors and technical specialists performed a thorough, in-depth review of the Technical Requirements Document. The review was based on the technical checklist, but the audit team was aggressive in departing from the checklist to clear up questions.

The focus of the review observed by the NRC staff was the traceability of technical requirements in the Technical Requirements Document. The audit team found the traceability of flow down of requirements through the heirarchy of documents to be poor, and documentation often inadequate.

The YMPO technical personnel responsible for the Technical Requirements Document were not clear on the scope of their responsibilities, and there appeared to be items which may not have been assigned. The training received by YMPO personnel on procedures related to the Technical Requirements Document appeared weak, perhaps due in part to the recent issue of a number of these procedures (AP-3.3Q, Rev. 2, 10/17/90; QMP-03-09, Rev. 0, 10/17/90; QMP-06-04, Rev. 1, 10/17/90).

The NRC observers consider the control of development and review of the Technical Requirements Document by YMPO to be inadequate, based on the sample reviewed during the audit.

(d) Instructions, Plans, Procedures, and Drawings (Criterion 5-HQ only)

The audit of Instructions, Plans, Procedures, and Drawings consisted of interviewing HQ staff and reviewing Implementing Line Procedures (ILPs) 5-1, 6-1 and 16-1. Several concerns were identified during the review of the stated ILPs. First, in reviewing ILP 6.1, it was found that changes made to the documents were not always recorded on the revision record. It was determined that only those changes considered to be "major" changes were recorded on the record. Second, in an effort to determine the definitions of "major" and "minor" changes, it was discovered that the definition of "minor change" as presented in ILP 5.1.1 is inconsistent with the definition presented in other procedures and in the supplement to NQA-1.

The auditors conducted the interview and audit in a professional manner and probed beyond the checklist questions as appropriate. Although the auditors did not have the new QARD and QAPD sufficiently before the audit, they were familiar with the new procedures. In spite of the late release of the new QARD and QAPD, the audit is considered to be effective. However, due to the concerns identified above, the effectiveness of procedure implementation is indeterminate at this time.

(e) Procurement Document Control (Criterion 4) and Control of Purchased Items and Services (Criterion 7)

HQ

The portion of the procurement control audit which was observed consisted of approximately equal amounts of interview with HQ personnel and review of documentation. The only procurement documents available to review were those for several services contracts, in which all personnel are operating under the OCRWM QA program. As such, QA program qualification is not applicable to this type of supplier.

While procurement document controls could be evaluated, most of the controls of Criterion 7 were not applicable, so the effectiveness of its implementation is necessarily indeterminate. Although the auditors identified a deficiency in procurement pre-planning, it was reported during the audit team caucus that the implementation of procurement controls was effective. Considering the finding identified and the very small sample available for evaluation, the NRC observers consider that implementation of Criterion 4 is indeterminate and that the effectiveness conclusion stated by the auditors was premature.

YMPO

Although the auditors utilized their checklists in reviewing Criteria 4 and 7, there has been little or no work in these areas by YMPO. There have been no major procurements since 1987. The procurement action in 1987 was for the award of the SAIC contract. Most of the items on the checklists were inconclusive as there was no implementation of activities pertaining to the recent revision of the QAPD and QMP's 04-01, 07-03, and 07-04.

To date, the YMPO QA organization has not qualified any supplier of items or services. This activity has been performed in the past by T&MSS of SAIC. After the DOE/YMPO audit of SAIC the week of November 11, 1990, the Qualified Suppliers List (QSL) of SAIC will be accepted by YMPO who will then be responsible for maintaining the QSL and performing future audits of suppliers. All major procurement activities in the future will be done by YMPO in accordance with QMP-04-02 which will incorporate the federal procurement practices (i.e., "Competition in Contracting Act" of 1984).

Due to the absence of objective evidence available for review, this part of the audit was not effective in evaluating implementation. Therefore, before a conclusion can be reached on the adequacy of the YMPO controls and the competency and cognizance of YMPO staff in their programmatic responsibilities can be determined, additional audits or surveillances will have to be performed.

(f) Identification and Control of Materials, Parts, Components, and Samples (Criterion 8); Control of Measuring and Test Equipment (Criterion 12); Handling, Storage, and Shipping (Criterion 13-YMPO only)

During the initial portion of the audit, the auditors and technical specialists conducted interviews with key Sample Management Facility (SMF) personnel to come to a full understanding of the activities being conducted. The audit consisted of discussion of technical procedures, activities of the Sample Overview Committee, application of calibration controls, methods of controlling SMF quality-affecting activities, and a "walkthrough" explanation of the work areas at the SMF. The review of objective evidence was limited because previous surveillance activities had evaluated SMF controls. During the audit, the prepared checklist was used as the guide for auditor questions and discussions. Overall, the auditors and technical specialists were thorough in their evaluation.

The observers, who were less familiar with the SMF activities than were the auditors, were taken on a short facility tour to learn of the physical controls designed to ensure traceability of core samples. The SMF personnel displayed a knowledge of the procedures and intent of the QA controls, and they demonstrated effective implementation of the controls.

(g) Corrective Action (Criterion 16)

HQ

The checklist used for the corrective action review was adequate and the auditors conducted a thorough, lengthy review and detailed probe of the activities. The auditors were well prepared and pursued beyond the checklist with substantive questions.

Deficiency Reports (DRs) and Corrective Action Reports were reviewed for determination of root cause and timeliness of closeout. The auditors noted instances where corrective action was not always accomplished in a timely manner. Certain of the discrepancies had been in the tracking system in excess of a year with little or no actions to close them. In addition, instances were noted where some of the reports contained an inadequate description of the root cause of the deficiency, and others contained no description at all of the root cause.

The procedure governing Corrective Action Requests (CARs), QAAP 16.1, Revision 2, was effective October 15, 1990. It was not clear to the NRC observers that the HQ personnel were familiar with the procedure requirements, and there was no consideration given to resolving DRs still open under the previous procedure. .

The auditors also reviewed and evaluated DOE's trending procedures. It was determined through interviews with HQ staff that HQ did not perform any trending analysis in 1990 as required by QAAP 2.9. Further, HQ management acknowledged that they were knowingly in non-compliance with the procedure requirements.

Based on the information obtained during the audit it must be concluded that the audit process was effective, but the implementation of procedures by HQ is ineffective.

YMPO

The corrective action portion of the audit which was observed consisted of a sampling of documentation in the form of completed Standard Deficiency Reports (SDRs). Although a few random SDRs were selected, the majority of the SDRs were suggested by audit team members or they were selected based on information the auditors had gained from earlier audits. This was an appropriate approach which focused the audit on the most important SDRs. The NRC observers reviewed about one-half of the audited SDRs and concurred with the auditors' conclusion that implementation was generally effective.

Based upon the auditors' review of the CA criterion, this portion of the audit was conducted in an effective manner. The personnel involved with maintenance and processing of the CA records seemed to be experienced, capable, and familiar with their QA responsibilities.

(h) Quality Assurance Records (Criterion 17)

HQ

The Central Records Facility (CRF), which is run by a contractor (Koh Systems, Inc.) for DOE, was not part of the scope of this audit. The Quality Records Center (QRC) at HQ was opened in June 1990. It receives document packages from OCRWM personnel, reviews them for completeness, obtains missing documents required to complete the packages, and forwards completed packages to the CRF for permanent storage. About ten record packages had been processed and accepted as complete by the QRC at the time of the audit. The QRC records storage facility consisted of two metal file cabinets which were not fire rated, did not meet NQA-1 requirements, and were thus inadequate.

The auditors were obviously familiar with the procedural requirements applicable to records receipt and storage (QAAP 17.1 and IP 12.17.01), and had prepared a detailed checklist. The audit of this area was thorough, and the auditors were persistent in following up on questions. Implementation of QRC precedures was too limited to determine its effectiveness.

YMPO

The YMPO Local Records Center personnel involved with the observed portion of the Criterion 17 audit appeared familiar with applicable procedures and QA requirements and were able to retrieve requested records promptly. Based upon the document retrieval observed and explanations provided, the QA Records procedures appear to be adequately implemented.

The auditors effectively utilized their checklists, evaluated a significant sample, and were extremely thorough in their investigations.

(i) Audits (Criterion 18)

HQ

The audit of this criterion consisted of interviewing HQ staff and evaluating several DRs. The reports reviewed included DR-90-008 and DR-90-014. The auditors identified a number of deficiences with regard to Criterion 18. They included:

1. HQ did not conduct any internal audits or surveillances in 1990. This means that no action was taken to correct the deficiencies described in DR-90-014.

2. The recommended action for DR-90-014 was to schedule and perform audits in accordance with QAAP 18.2. There is no objective evidence to indicate that a final audit schedule was ever prepared.

3. QAAP 18.3 requires that checklists be prepared from the requirements being surveilled. Evaluations of five 1989 surveillance reports indicate that the "Requirements Surveilled" section of the reports reference procedures which are not referenced in the checklists.

The auditors did an effective job of evaluating the OCRWM HQ QA program in the areas of corrective action and audits. The prepared checklist was used and when appropriate the auditors probed with in-depth questions. Implementation by OCRWM HQ under this criterion appears to be ineffective.

YMPO

The NRC observers were involved only in the audit portion of Criterion 18 pertaining to surveillances. The auditors reviewed the surveillance schedules for FY-90 and FY-91 and verified that the schedules were maintained as required. A review of a number of surveillance packages indicated that the surveillance process complied with procedure QMP-18-02 with regards to the use of checklists, documentation of results, and generation of SDRs, Non-Conformance Reports, and/or observations as applicable. The auditor verified that those individuals who participated as surveillance team members had the training and experience to be qualified in accordance with procedure QMP-02-02.

The YMPO program for surveillances, as represented by the sample observed during this audit, appeared to be well planned, implemented, and generally effective. The audit of this area was thorough and professional in nature, emphasizing the use of objective evidence to support statements made by YMPO QA personnel.

5.4 Conduct of Audit

The QA and technical portions of the audit were productive and performed in a professional manner. Despite the late release of the QARD and QAPD, the audit team was generally prepared and demonstrated a sound knowledge of the QA aspects of the program. The audit checklists included the important QA controls addressed in the QARD. The audit team used the comprehensive checklists effectively during the interviews with personnel and review of documents. In general, the team was persistent in their interviews, challenging responses when necessary. The integration of the technical and programmatic portions of the audit was effective.

5.5 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 their meeting the requirements of QMP-02-02, the YMPO procedure for qualifying auditors.

5.6 Audit Team Preparation

In general, the QA auditors and technical specialists were well prepared in the areas they were assigned to audit and knowledgeable in the QARD and implementing procedures. Overall, Audit Plan 90-I-01 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 QARD and QAPD; and (6) the QA and technical checklists.

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they investigated. As discussed in Section 5.3(c), there was some question of total independence of some auditors; however, members of the team appeared to have sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence. Since this was an internal audit, the NRC staff believes sufficient independence of audit team members was demonstrated.

5.8 Summary of NRC Staff Findings

(a) Observations

The NRC staff did not identify any observations relating to deficiences in either the audit process or the other elements of OCRWM QA program implementation.

(b) Weaknesses

Some auditors appeared to spend a disproportionate time conducting interviews rather than evaluating objective evidence, especially during the HQ portion of the audit (Refer to Section 5.3(a)).

The NRC staff believes that the timing of the audit was less than optimal. In some cases, audit checklists were revised up to and after the start of the audit to incorporate requirements from procedures issued just prior to the start of the audit. Further, due to the recent reorganization within HQ, the auditors in several instances were obligated to interview both the personnel currently assigned and those formerly assigned to various functions (Refer to Sections 5.2 and 5.3(c)).

Several of the auditors were OCRWM HQ (or HQ contractor) personnel, and on more than one occasion they appeared more knowledgeable of the activity being audited than the individual being interviewed. These auditors may have been of greater value as auditees. Otherwise, OCRWM and contractor personnel appeared to be competent and generally familiar with QA requirements and their respective responsibilities (Refer to Section 5.3(c)).

A preliminary effectiveness conclusion concerning Criteria 4 and 7 presented by an auditor during a status meeting did not appear to be well supported by the available objective evidence (Refer to Section 5.3(e)).

No annual management assessment of the HQ QA program was performed (Refer to Section 5.3(a)). This is similar to findings from previous audits of High Level Waste (HLW) repository program participants.

The HQ QA Division was not completely staffed prior to and at the time of the audit (Refer to Section 5.3(a)).

There were indications that training was inadequate in some areas (Refer To Sections 5.3(b) and (c)).

No trending analyses had been performed (Refer to Section 5.3(g)). This is similar to findings from previous audits of HLW repository participants.

The HQ CA program did not result in timely and effective closure of conditions adverse to quality (Refer to Section 5.3(g)). This is similar to findings from previous audits of HLW repository participants.

There appeared to be inadequate review of DRs and CARs for root cause and generic implications (Refer to Section 5.3(g)). This is similar to findings from previous audits of the HLW repository program.

The HQ program for internal audits/surveillances was inadequate and ineffective (Refer to Section 5.3(i)). This is similar to findings from previous audits of the HLW repository program.

The problems identified by the audit team with the WMSR Vol. IV and the YMP/CM-0007, Rev. 1 indicates additional management attention is needed in these technical activities (Refer to Section 5.3(c)).

Based on the above, the NRC observers determined that OCRWM management had not adequately evaluated the results of prior audits of the HLW repository program and applied the lessons learned from these audits to the OCRWM QA program.

(c) Good Practices

In general, the auditors and technical specialists used well researched and detailed checklists and extended their investigations beyond the checklists when appropriate. Integration of programmatic and technical portions of the audit was effective due to the simultaneous conduction of the programmatic audits of Criteria 3 and 20 with the technical evaluations.

Daily caucuses were held between auditors and observers, and daily meetings were held between OCRWM management and the Audit Team Leader to discuss potential findings. Auditors identifying potential findings were included in these status meetings to more clearly explain deficient conditions and allow for resolution during the audit as much as possible. Findings were well substantiated and reflected significant rather than trivial issues. The audit team also did a good job of answering observer questions as they were raised.

5.9 Summary - DOE/YMPO Audit Team Findings

At the formal exit briefing on October 31, 1990, the audit team identified 18 potential CARs written against the OCRWM QA program (11 to HQ and 7 to YMPO). In addition, during the audit, OCRWM was able to resolve 29 remedial deficiencies (11 at HQ and 18 at YMPO). The CARs issued to OCRWM can be summarized as follows:

(a) A matrix to cross reference OCRWM procedures & QAPD to QARD does not exist (YMPO).

(b) There are inadequate controls to assure training of personnel prior to initiation of quality affecting activities (YMPO).

(c) The flow down of WMSR Volume IV requirements to other requirements documents is not apparent (YMPO).

(d) Inputs to Technical Requirements Document YMP/CM-0007 are not always traceable (YMPO).

(e) The review process for YMP/CM-0007 is deficient (YMPO).

(f) There was a lack of control procedures for development of YMP/CM-0007 since QMP-03-09 was implemented following completion and processing (YMPO).

(g) Interim Change Notices were incorrectly classified as "minor" changes (YMPO).

(h) A draft of QAAP 2.2 was issued for use prior to formal review and approval (HQ).

(i) Approval of potential interfaces was not in conformance with QAAP 3.7, Rev. 1 (HQ).

(j) TAAG comment sheets were not signed by the TAAG chairperson (HQ).

(k) There was a lack of procedure for addressing review comments for dependent volumes of the WMSR (HQ).

(l) There is inadequate definition of "minor change" in QAAP 5.1, Rev. 2 and QAAP 5.2, Rev. 1 (HQ).

(m) Revisions made to QAAP's 6.1 and 16.1 were not traceable in the revision record (HQ).

(n) Control requirements for the WMSR and WMSD technical management plans are not consistent with stated requirements (HQ).

(o) The reports for tracking deficiencies and monthly actions are ineffective (HQ).

(p) No description of the QRC is present in ILP-12-17.01, and the current storage facility does not meet minimum requirements (HQ).

(q) Ineffective implementation of procedural requirements for auditors and technical specialists (HQ).

(r) Ineffective implementation of verification activities (HQ).

The audit team also found implementation of all, but three of the Criteria reviewed to be ineffective or indeterminate at HQ, or YMPO, or both.

Along with the deficiencies identified above, the audit team also recommended at the formal exit briefing that the OCRWM Office of Quality Assurance conduct several surveillances to verify the effectiveness of the QA program prior to the start of any new site characterization activities. The recommended areas to be surveyed include:

(a) control of technical baseline (HQ),
(b) corrective action system (HQ),
(c) Quality Records Center (HQ),
(d) program overview (HQ),
(e) preparation and review of technical requirements for YMP (YMPO),
(f) SNL activities related to YMP/CM-0007 (YMPO), and
(g) training (YMPO).

The NRC staff fully concurs with these recommendations.