

U. S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT NO. 91-2  
FOR THE OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
AUDIT NO. 90-08 OF  
SCIENCE APPLICATIONS INTERNATIONAL  
CORPORATION/TECHNICAL & MANAGEMENT  
SUPPORT SERVICES

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FULL TEXT ARCH SCAN

## 1.0 INTRODUCTION

From November 13 through 16, 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 Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit NO. 90-08 of Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) contractors in Las Vegas, Nevada, and at the Nevada Test Site (NTS). SAIC/T&MSS, a participant in the Yucca Mountain Project (YMP), is responsible for the environmental and radiological monitoring activities for the YMP. This report addresses the NRC staff's assessment of the effectiveness of the OCRWM audit and, to a lesser extent, the adequacy and effectiveness of the SAIC/T&MSS QA program.

## 2.0 OBJECTIVES

The objective of the OCRWM audit was to determine the effectiveness of the SAIC/T&MSS QA program in meeting the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD, DOE/RW-0214), Revision 4, (OCRWM QARD) for the YMP. The NRC staff's objective was to gain confidence that OCRWM and SAIC/T&MSS are properly implementing the requirements of their QA programs by evaluating the effectiveness of the OCRWM audit process and determining whether the SAIC/T&MSS QA program is in accordance with the applicable requirements of the OCRWM QARD and 10 CFR Part 50, Appendix B.

## 3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the OCRWM audit process and the SAIC/T&MSS 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, and SAIC/T&MSS documents). Although there was a limited amount of work being conducted by SAIC/T&MSS under the QA program and the SAIC/T&MSS has been a YMP participant for a limited period of time, the NRC staff has determined that, overall, OCRWM Audit No. 90-08 of SAIC/T&MSS was of appropriate scope and achieved its purpose of determining the adequacy and effectiveness of the SAIC/T&MSS QA program. The audit of the criteria observed 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 audit was well organized and was run with minimal logistic delays. The only difficulty encountered was at NTS where there were more auditors and observers than the SAIC/T&MSS personnel to answer questions and to act as escorts to various areas at the site. This caused some audit delays and

frustration. The team leader kept the caucuses brief, but did allow sufficient time for the auditors to express concerns or seek clarification from other auditors. Concerns and questions raised by the observers were addressed during the caucus when possible, or during the following day.

The NRC staff agrees with the audit team's preliminary findings that SAIC/T&MSS has an adequate QA program for most of the areas that were audited, and the SAIC/T&MSS QA program, for the most part, has sufficient controls in place to perform work related to the radiation and environmental monitoring for the YMP. The acceptability of the technical products reviewed by the OCRWM audit team were not evaluated by the NRC staff since technical specialists were not a part of the NRC observation team. The NRC staff also agrees with the OCRWM audit team's conclusion that there was an effective implementation of the SAIC/T&MSS QA program in most areas audited by the audit team. However, in other areas audited, there has been minimal activity since May 1990, therefore, adequacy of implementation in these areas was indeterminate.

#### 4.0 AUDIT PARTICIPANTS

##### 4.1 NRC

Tilak R. Verma	Observer	
John T. Buckley	Observer	
John Gilray	Observer	
Thomas C. Trbovich	Observer	(CNWRA)

##### 4.2 DOE

James Blaylock	Audit Manager	(DOE/YMPO)
Richard L. Maudlin	Audit Team Leader	(MACTEC)
A. Edward Cocoros	Auditor	(MACTEC)
Robert S. Constable	Auditor	(DOE/YMPO)
Mario R. Diaz	Auditor	(DOE/YMPO)
Catherine E. Hampton	Auditor	(DOE/YMPO)
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Charles C. Warren	Auditor	(MACTEC)
Albert C. Williams	Auditor	(DOE/YMPO)
Diane Harrison-Giesler	Technical Specialist	(DOE/YMPO)
Byron Kesner	Technical Specialist	(MACTEC)
Thomas Rogers	Auditor-in-Training	(CER)
Sam Smith	Auditor-in-Training	(WESTON)

##### 4.3 State of Nevada

Susan W. Zimmerman	Observer
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#### 4.4 Clark County (Nevada)

Englebrecht von Tiesenhausen    Observer

#### 4.5 Nye County (Nevada)

Phillip Niedzielski-Eichner    Observer

### 5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The OCRWM audit was conducted in accordance with Quality Assurance Administrative Procedure (QAAP) 18-2, "Audit Program", Revision 1, and QAAP 16.1, "Corrective Action Requests", Revision 1. The NRC staff observation of the OCRWM audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989; NRC staff findings are classified in accordance with the guidelines in 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 or surveillances.

#### 5.1 Scope of Audit

The audit scope was to verify that the SAIC/T&MSS QA program meets the requirements of the SAIC/T&MSS QA Program Description (QAPD), Revision 0, dated May 1, 1990, and to verify the adequacy of implementation of the QA program. The audit also determined whether SAIC/T&MSS had taken effective actions to resolve findings identified during previous audits and surveillances.

##### (a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the OCRWM QARD, the OCRWM Administrative Procedures (APs), and the SAIC/T&MSS QAPD and associated implementing procedures. The checklists covered QA program controls for eighteen of the twenty program elements of the SAIC/T&MSS QAPD. Criteria III and IX of 10 CFR Part 50, Appendix B (Sections 3 and 9 of the OCRWM QARD and the QAPD) were not included in the scope of the audit since SAIC/T&MSS currently is not performing activities in these areas.

The NRC staff is currently reviewing and evaluating the SAIC/T&MSS QAPD, Revision 1, and has not yet determined the applicability or non-applicability of any of the 10 CFR Part 50, Appendix B criteria of the program elements in the SAIC/T&MSS QAPD.

(b) Technical Areas

During the audit, the OCRWM technical specialists reviewed and evaluated the technical activities related to the following areas:

Meteorological Monitoring Plan, Revision 1, June 5, 1989

Radiological Monitoring Plan, Revision 0, May 25, 1988

The OCRWM technical specialists were instructed to include the following areas in their evaluations:

Technical qualifications of scientific investigators;

Understanding of procedural requirements as they pertain to investigation and data analysis activities; and

Adequacy of technical procedures.

5.2 Timing of-the Audit

The NRC staff believes the timing of the QA audit was appropriate. The SAIC/T&MSS QA program became effective on May 21, 1990, and even though implementation was limited, this audit was useful to determine the adequacy of the SAIC/T&MSS QA program for initiation of quality-affecting activities.

5.3 Examination of Programmatic Elements

The OCRWM programmatic checklists covered the QA program controls for the eighteen elements listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 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
- 10.0 Inspection
- 11.0 Test Control
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage

- 14.0 Inspection, Test, and Operating Status
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits
- 19.0 Software Quality Assurance
- 20.0 Scientific Investigation Control

The NRC staff observed the audit team's evaluation of the following selected programmatic elements of the SAIC/T&MSS QAPD. Since only some elements of the QA program were observed, the details of unobserved program deficiencies identified by the OCRWM audit team will not be addressed in this report.

(a) Organization (Criterion 1)

The audit checklist used by the OCRWM auditors adequately covered this area. The auditors conducted interviews in a professional manner adhering closely to the checklist and were thorough in their review of the objective evidence presented.

The auditors interviewed the SAIC/T&MSS management to obtain a description of the SAIC/T&MSS organizational structure and the responsibilities of persons and organizations performing quality affecting activities. The auditors concluded that an organizational structure has been established and relevant procedures put in place which adequately define the organizational responsibilities. Requirements under this criterion have been adequately covered in implementing procedures. The OCRWM auditors noted some areas, such as resolution of disputes, stop work, and quality allegations, where sufficient implementation has not occurred to evaluate effectiveness of the QA program. However, in general, the NRC staff agrees with the audit team's conclusion that implementation in this area was effective for the work performed to date.

(b) Control of Measuring and Test Equipment (Criterion 12)

The audit checklist was adequate to cover this area. The requirements for controls under this criterion are described in Standard Procedure (SP) 2.4. The auditors were told by SAIC/T&MSS that the applicable procedure in this area was not appropriately implemented and that SAIC/T&MSS had written several Quality Finding Reports (QFRs) addressing this condition. The auditors reviewed these QFRs. Since the DOE auditors' concerns were adequately covered in these QFRs, no Corrective Action Request (CAR) was written by the audit team.

The DOE auditors concluded that the implementation under this criterion was inadequate to determine effectiveness. The NRC staff agrees with the audit team's conclusion.

(c) Handling, Shipping, and Storage (Criterion 13)

The DOE auditors used a detailed checklist and conducted a thorough review and evaluation of the process for effectively controlling materials, parts components, and samples under this criteria. The procedures (SP 1.12, SP 1.25, and SP 1.28) adequately cover the requirements of this criterion. The auditors did not identify any problems in this area. There was minimal activity in this area and only one piece of equipment was found in storage. The auditors concluded that due to lack of sufficient implementation, effectiveness in this area was considered indeterminate. The NRC staff agrees with the auditors' conclusion.

(d) Control of Non-Conforming Items (Criterion 15)

The checklist used was adequate to cover this area. This portion of the audit checklist was based on requirements from SP 1.23. The auditors conducted a thorough review of the objective evidence selected from the nonconformance log and the tracking system made available by SAIC/T&MSS. Some minor deficiencies and inconsistencies in use of nonconformance tags were noted by the auditors. The NRC staff agrees with the auditors' conclusion that the controls in this area are adequate and implementation was effective.

(e) Corrective Action (Criterion 16)

SAIC/T&MSS compliance with procedures SP 1.37 Rev. 1, SP 1.22 Rev. 0 and Operating Procedure (OP) 1.6 Rev. 1, was determined by interviewing several SAIC staff members and by reviewing selected QFR's. Ten QFR's were selected for review and evaluation. One CAR was generated as a result of these reviews. It was determined that SAIC/T&MSS is not assigning severity levels to identified deficiencies in accordance with the OCRWM audit procedures. QFR's 90-001, 013, 014 and 015 identify conditions which should be considered severity level one conditions rather than level two as assigned.

The auditor examined 10 of the 24 open QFR's and completed the checklist as presented. The checklist questions were comprehensive and appropriately based on procedures SP 1.37, SP 1.22 and OP 1.6. The auditor conducted effective interviews and probed beyond the checklist questions when appropriate. The audit team concluded that there was effective implementation in this area.

In general, the NRC staff believes that adequate controls are in place in the area of corrective actions. Further, in spite of the identified CAR, we believe that the procedures under Criterion 16 are being effectively implemented at this time.

(f) Quality Assurance Records (Criterion 17)

The checklist used adequately covered this area. The auditor initiated the review by requesting a log of completed record packages. From this computerized log, eight packages were selected for review. Discrepancies

were noted with title page format, i.e., those being used were not in compliance with the example identified in the procedure. The auditor requested samples of the various record packages which were provided with no difficulty.

SAIC/T&MSS has implemented an effective records operation and has been used as an example for other participants to follow.

(g) Audits and Surveillances (Criterion 18)

The checklist adequately covered the criterion. The auditor reviewed two recent audit reports and one surveillance report and determined compliance to the procedure. However, he noted that the audit reports contained "recommendations" that were not addressed in the audit procedure. Overall, the audit of this criterion was effective in determining the level of implementation. The auditor concluded that the SAIC/T&MSS audit and surveillance program is being effectively implemented and is being used to improve the QA program. The NRC staff agrees with the auditor's conclusions.

(h) Scientific Investigations Control (Criterion 20)

The checklist questions were prepared from the procedures presented in SP 2.3 Rev. 0, Administrative Procedure (AP) 1.10Q Rev. 1, AP 5.9Q Rev. 1 and several Work Instructions (WI's). The checklist was comprehensive and complete. The auditors were thorough in completing the checklist questions and probed in depth beyond the checklist when necessary.

The review under this criterion consisted of programmatic and technical evaluations. The auditors conducted interviews with SAIC/T&MSS staff and reviewed several WI's which were prepared to the Environmental Field Activity Plan (EFAP) and Radiological Monitoring Plan (RMP).

SAIC/T&MSS members revealed that the EFAP and RMP are currently in draft form and therefore, have not been approved. However, many of the WI's reviewed were approved and prepared in accordance with the EFAP and RMP. A CAR condition was identified since approved documents were prepared in accordance with nonapproved draft documents. This condition was recognized earlier and written up as SDR-398. This SDR remains open to date.

Many meteorological and radiological monitoring activities have not yet begun, and, therefore, the effectiveness of the program under this criterion will be indeterminate in many areas. For instance, there is nothing to evaluate under the headings of New Processes and Procedures, Data Interpretation and Analysis, and Scientific Investigation Results. Despite the lack of activities under this plan, the auditors identified one potential CAR condition related to documentation at the site. The

auditors determined that the site log book was not being properly controlled since copies were not made periodically for storage in the records center.

In general, the audit process for this criterion was effective. The auditors concluded that the effectiveness of the program related to this criterion is indeterminate mainly due to lack of until activities under the Meteorological and Radiological Monitoring Plans begin. The NRC staff agrees with the auditors' conclusion.

(i) Conclusions

The programmatic audit of the SAIC/T&MSS QA program was effective in evaluating the degree of compliance to the OCRWM QARD, the QAPD and applicable implementing procedures. Status of implementations and effectiveness of the SAIC/T&MSS QA program were also assessed. The audit utilized appropriate checklist questions and in-depth interviews with the SAIC/T&MSS staff and management to obtain the required information in evaluating the SAIC/T&MSS QA program.

The daily caucuses held by the audit team provided good interaction between the technical and programmatic auditors, and the observers.

The audit of the elements observed was conducted in a professional and effective manner. Because the SAIC/T&MSS started doing work under their own QAPD since May, 1990, and the limited time to develop procedures and implement them, the SAIC/T&MSS QA program remains indeterminate regarding its implementation and effectiveness under several QA program elements. The audit checklists were thorough, although more complete review of available procedures and a better scoping prior to the audit might have eliminated some of the audit questions. The management of the audit team was effective, and the formal interfaces with the Yucca Mountain Project Office (YMPO) and the SAIC/T&MSS organizations were appropriate.

The audit team findings were well substantiated and conclusions regarding effectiveness were appropriate. The SAIC/T&MSS personnel appeared to be competent and knowledgeable of QA requirements and responsibilities. In general, the SAIC/T&MSS QA program is adequate and effective to the degree that it has been implemented.

5.4 Examination of Technical Products

The audit team technical specialists reviewed the technical areas listed below. The technical specialists were accompanied by the programmatic auditors during their visit and review of these field activities at the NTS.

Meteorological Monitoring Plan, Revision 1, June 5, 1989

Radiological Monitoring Plan, Revision 0, May 25, 1988

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No review or evaluation of these documents was performed by the technical specialists or auditors at this time mainly due to the facts that these documents have been prepared prior to the approval and implementation of the SAIC/T&MSS QA program, and these documents are the responsibility of the YMPO and therefore are under the YMPO control. The auditors concluded that due to limited activities in the area of meteorological and radiological monitoring, the extent and effectiveness of procedural implementation remain indeterminate. The NRC observation team did not include any technical specialists.

### 5.5 Conduct of Audit

The overall conduct of the QA and technical portions of the SAIC/T&MSS audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA and technical aspects of the SAIC/T&MSS program. The audit checklists included the important QA controls addressed in the OCRWM QARD that are applicable to the SAIC/T&MSS program. The audit team used the comprehensive checklists effectively during the interviews with SAIC/T&MSS personnel and review of documents. In general, the team was persistent in their interviews, challenging certain SAIC/T&MSS responses when necessary. The integration of the technical and programmatic portions of the audit was effective.

### 5.6 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 YMPO procedure for qualifying auditors.

The Technical Specialists for this audit were knowledgeable about the technical and programmatic aspects of the SAIC/T&MSS program.

### 5.7 Audit Team Preparation

The QA auditors and technical specialist were well prepared in the areas they were assigned to audit and knowledgeable in the SAIC/T&MSS QAPD and implementing procedures. Overall Audit Plan 90-08 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 QAPD; and (6) 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. 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 SAIC/T&MSS personnel.

### 5.9 Review of Previous Findings

The SAIC/T&MSS QA program became effective only since May, 1990, and there were no earlier audit findings available for review.

### 5.10 Summary of NRC Staff Findings

#### (a) Observations

The NRC staff did not identify any observations relating to deficiencies in either DOE/OCRWM audit process or the SAIC/T&MSS QA program.

#### (b) Weaknesses

The NRC staff did not identify any weaknesses relating to either the OCRWM audit process or the SAIC QA program.

#### (c) Good Practices

The audit team was well prepared and conducted a thorough audit in a professional manner.

Improved coordination of the QA programmatic and technical reviews and evaluations simultaneously to allow the integration of these two aspects of the audit.

### 5.11 Summary DOE/OCRWM Audit Team Findings

During the course of the audit, the audit team identified five Corrective Action Requests (CARs) in the areas of QA Program; Instructions, Procedures, Plans, and Drawings; Control of Purchased Items and Services (2); and Corrective Action. These CARs were well substantiated and reflected issues important to the quality system. In addition, the audit team also identified nine potential CARs that required only remedial action and were resolved during the audit.