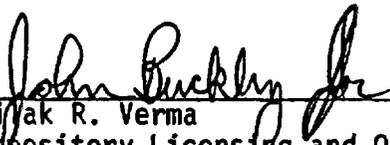
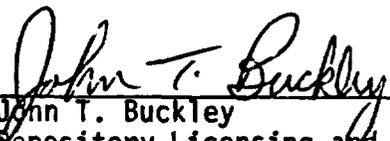
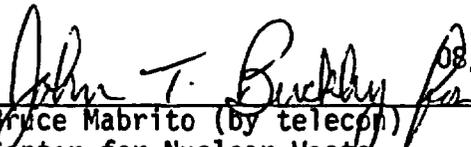
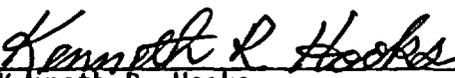


U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-9
FOR THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. 91-06
SCIENCE APPLICATIONS INTERNATIONAL
CORPORATION/TECHNICAL & MANAGEMENT
SUPPORT SERVICES


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1.0 INTRODUCTION

From June 17 through 21, 1991, 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. 91-06 of Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) in Las Vegas, Nevada, and at the Nevada Test Site (NTS). SAIC/T&MSS, a participant in the Yucca Mountain Site Characterization 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 the procedural adequacy and effectiveness of implementation in both programmatic and technical areas 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, 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 Code of Federal Regulations, Title 10, (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 SAIC/T&MSS personnel, 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, the NRC staff has determined that, overall, OCRWM Audit No. 91-06 of SAIC/T&MSS was of appropriate scope and achieved its purpose of determining the adequacy and effectiveness of implementation of programmatic and technical activities conducted under the SAIC/T&MSS QA program. The audit observed was conducted in a professional manner, and the programmatic and technical portions of the audit were 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 Audit Team Leader (ATL) was well prepared and had a good knowledge of the SAIC/T&MSS QA program and the applicable OCRWM QA requirements.

The ATL 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 a procedurally adequate QA program for most of the areas that were audited. Although implementation in the area of Control of Measuring and Test Equipment was not effective, the NRC staff agrees with the OCRWM audit team's conclusion that implementation of the SAIC/T&MSS QA program controls in most areas evaluated by the audit team was adequate. The acceptability of the technical products reviewed by the OCRWM audit team and the concomitant effectiveness of implementation of the QA program controls were not evaluated by the NRC staff since technical specialists were not a part of the NRC observation team.

4.0 AUDIT PARTICIPANTS

4.1 NRC

Tilak R. Verma	Observer	
John T. Buckley	Observer	
Bruce Mabrito	Observer	(CNWRA)

4.2 DOE

Richard L. Maudlin	Audit Team Leader	MAC Technical Services Co. (MACTEC)
James Blaylock	Auditor	Yucca Mountain Site Characterization Project Office (DOE/YMPO)
A. Edward Cocoros	Auditor	(MACTEC)
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Dale S. Ambos	Technical Specialist	(US Geological Survey)
Richard Crawley	Lead Tech. Specialist	(DOE/YMPO)
Frank Nash	Observer	(Duke Engineering Corp)

4.3 State of Nevada

Susan W. Zimmerman Observer

4.4 Clark County (Nevada)

Englebrecht von Tiesenhausen 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 OCRWM QARD which are reiterated and imposed on SAIC/T&MSS through the SAIC/T&MSS QA Program Description (QAPD), Revision 3, dated May 9, 1991, and to verify the adequacy and effectiveness 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 18 of the 20 program elements of the SAIC/T&MSS QAPD. Criteria 9 and 11 of 10 CFR Part 50, Appendix B (Sections 9 and 11 of the OCRWM QARD and the SAIC/T&MSS QAPD) were not included in the scope of this audit since SAIC/T&MSS currently is not performing activities in these areas.

(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; and

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 was last audited by DOE/OCRWM in November 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 18 elements listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items, Samples, and Data
- 10.0 Inspection

- 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 allegations involving inadequate quality, 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 adequate for the work performed to date. The audit of this criterion was effective.

(b) Quality Assurance Program (Criterion 2)

The auditor reviewed selected SAIC/T&MSS personnel records files for compliance to such procedures as Standard Practice (SP) 1.21, SP 1.31, SP 1.32, SP 1.42, SP 1.60, and Operating Procedure (OP) 1.5 requirements relating to qualification, training, education, experience, management assessment, job assignment/quality assurance classification, readiness review and auditor qualifications. Record packages were reviewed for randomly selected personnel or individuals having performed technical activities related to radiological and meteorological monitoring. The NRC observers reviewed some of the personnel records directly, and found the sample the auditors reviewed to be adequate.

Based on the extent of the records reviewed and interviews conducted with the SAIC/T&MSS QA management and training coordinator, Criterion 2 was effectively audited, and the implementation by SAIC/T&MSS appeared to be adequate.

(c) Procurement Document Control (Criterion 4)

A very limited portion of this area was observed. The auditor reviewed several procurement packages to determine the adequacy of the procurement document control system. The auditor did not identify any deficiencies. However, implementation in the area of procurement document control is considered to be marginal due to the large number of procedures that control the procurement process. DOE's audit of SAIC/T&MSS in November 1990 initially identified the confusion created by the myriad of procedures controlling the procurement process. It does not appear that SAIC/T&MSS has made any progress in reducing the number of controlling procedures in this area.

The audit of this criterion was considered to be effective. The auditor utilized the published checklist effectively in conducting a thorough and professional audit.

(d) Instruction, Procedures, Plans and Drawings (Criterion 5)

The audit of Criterion 5 began with a survey of 11 OPs, 49 SPs, and 77 Work Instructions (WIs) found on the SAIC controlled document list. The auditor selected five OPs, and 10 WIs as a representative sample to review. The auditor utilized this same approach for the investigation of Criterion 6.

To determine that SAIC SP 1.39 "Change Control" requirements were followed, the auditor checked the review packages for 23 documents. Each review package had the required document concurrence/approval form, table of contents, record package transmittal form, and the final document ready for copying. All except one package had been processed to the Local Record Center within 10 working days, indicating compliance with the requirement. The auditor conducted a detailed investigation of Criterion 5 related activities and asked questions and requested objective evidence beyond the audit checklist questions. The NRC staff agrees with the auditor's conclusion that the controls in this area are adequate and implementation was adequate. The audit of this criterion was effective.

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

To determine the adequacy of the control of measuring and test equipment, (M&TE) the auditors reviewed a sample of nine calibration history records. The selected calibration history records corresponded to instruments which could be checked in the field for consistency. The audit was conducted in a thorough and professional manner.

One potential Corrective Action Request (CAR) was identified by the auditors noting several adverse conditions as follows:

Contrary to SP 2.4, paragraph 5.1.5.1, a sample of nine items from the M&TE List dated June 17, 1991, indicated the following errors:

1. The M&TE List indicated that Relative Humidity (R/H) Sensor 16403 required an annual calibration; upon investigation it was determined that the R/H Sensor did not belong on the M&TE List.
2. Temperature Sensor 16426 was indicated by the M&TE List to require an annual calibration; when investigated, it was found not to belong on the M&TE List.
3. Barometric Pressure Transducer 16429 shown to be located at the Coyote Wash remote site was not found at this location.
4. Digital Multimeter 16402 indicated by the M&TE List to be active was found in an inactive status in the field.
5. Oscilloscope 09068 indicated by the M&TE List to be active was found in an inactive status in the field.

Contrary to SP 2.4 paragraph 2.5.1.5.2, a sample of nine history files indicated certificates of calibration were not included for the following items:

1. Wind Speed Sensor 03134.
2. Wind Speed/Wind Direction Sensor 09312.
3. Barometric Pressure Transducer 17911.

Contrary to SP 2.4 paragraph 5.3.2, a sample of six items from the M&TE List indicated the following calibration labeling errors:

1. Precipitation Gage 17913- No calibration label applied.
2. Wind Direction Sensor 03130- Inaccurate Calibration Due Date Information.
3. Wind Speed Sensor 03134- Inaccurate Calibration Due Date Information.

The auditors effectively used the published checklists. The NRC staff believes the audit process was effective and agrees with the preliminary conclusions of the auditors that in the area of control of M&TE the SAIC/T&MSS program is ineffective.

(f) Control of Nonconforming Items (Criterion 15)

The auditor utilized the SAIC Nonconformance Report Log to obtain information for evaluating control of nonconforming items. The auditor noted that eight conditional releases were processed since the previous audit (which may suggest a lack of adequate control), however, information was subsequently provided to the auditor to demonstrate that control of the SAIC nonconformances and conditional releases was adequate. The audit of this area was effective and implementation of SAIC audit procedures appeared adequate.

(g) Corrective Action (Criterion 16)

The corrective action program was audited utilizing the interview technique and presentation of objective evidence to the auditor. Trending reports were reviewed and each report covered the length of period required by OP 1.6, Revision 2. The auditor questioned whether YMPO had been supplied a formal copy of the trend report as required by the OP. Such objective evidence was not immediately forthcoming; however, after SAIC personnel searched for the document, the objective evidence was provided to the auditor. The auditor used the published audit checklist, supplemented with a more detailed checklist throughout the auditing process. Although the auditors did identify a deficiency, it appears that implementation of the corrective action procedures is adequate. The audit in this area was effective.

(h) Audits (Criterion 18)

This portion of the audit involved a review of the SAIC auditing activities. The auditor began with questions about auditing staff titles, responsibilities, and the revision of the document to which they were working. Four audit packages had been completed so far in 1991, and the auditor performed a detailed review of all of them. The auditor asked detailed questions regarding each of the audits and information was provided by the SAIC auditing staff. The auditor was focused on the audit checklist questions and utilized worksheets to facilitate recording the results of the document reviews which is considered good practice. The audit of this criterion was effective and implementation of the SAIC audit procedures appeared adequate.

(i) Software Quality Assurance (Criterion 19)

The auditors interviewed the Information System Department Manager and the QA Specialist - Senior Systems Analyst in an effort to determine the adequacy of the SAIC/T&MSS software quality assurance (SQA) program. The auditors effectively used the published checklist and conducted the audit in a professional manner.

Through interviews, it was determined that T&MSS is currently developing software for T&MSS and the YMPO in the areas of configuration management, project management, training and a database for newsclippings. To date, no requests have come to T&MSS for development of scientific software. The auditors reviewed 10 Software Request Classification Forms (SRCF) to verify that development of quality affecting software has not been requested.

The auditors did not identify any potential CARs. However, the auditors did recommend some changes to the definitions "SW defect" and "SW problem." The SAIC/T&MSS staff agreed with the recommended changes.

The audit of this criterion is considered to be effective. The NRC staff agrees with the preliminary conclusions of the audit team that implementation in SQA is indeterminate due to a lack of implementation of the procedures at this time.

(j) Scientific Investigation Control (Criterion 20)

The Scientific Investigation Control portion of this audit was divided between radiological and environmental (meteorological) monitoring. In the area of radiological monitoring activities, the auditor and technical specialist worked well as a team, taking turns in asking questions and writing down the responses. The audit team checked available calibration tags and asked to see specific objective evidence to ensure that process controls were yielding appropriate documentation. Procedures in notebooks at the site were also checked to ensure those that had been declared obsolete had been so marked. The nine radiological counting devices that were in the work area at the time were checked by the auditors to ensure they had been calibrated.

A lengthy interview was held with the radiology technician regarding the SAIC mission, training, available equipment, tasks performed, and procedural requirements. Without exception, the technician went back to the appropriate procedure to verify the answer to the auditor's question. The formal checklists were used, however, there were many follow-on questions, which indicated the auditing team understood the subject matter and had studied the procedures prior to the audit. Site NF-10 was visited in the field to obtain a perspective on how samples are initially taken and captured.

The controls that applied to radiological monitoring, appeared to be adequately implemented and the audit team's work was effective in determining that fact objectively.

Only the field portion of the audit of the meteorological monitoring program was observed. The auditors examined the data storage facilities, instrument calibration stickers, and the data logging and downloading systems. In addition, the auditors observed the calibration of a rain gauge and a wind speed gauge in the field.

The auditors completed their published checklists and conducted the interviews in a professional manner. No CARs were developed with respect to this criterion. Based on the limited portion observed, the audit of the meteorological monitoring program appeared to be effective. Further, the NRC staff agrees with the audit team's preliminary conclusion that scientific investigation controls are adequate.

(k) Conclusions

The programmatic audit of the SAIC/T&MSS QA program was effective in evaluating the degree of compliance to the OCRWM QARD, the SAIC/T&MSS QAPD and applicable implementing procedures. Status of implementation and effectiveness of the SAIC/T&MSS QA program were also assessed. The auditors 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. The management of the audit team was effective, and the formal interfaces with the 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 procedurally adequate and implementation is adequate in most of the areas that were audited.

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

The technical specialists were directed to look at the technical qualifications of scientific investigators, the procedural requirements for investigation and data analysis activities, and, the adequacy of technical procedures.

Due to the limited technical scope of the audit, no NRC technical staff members were included in the NRC audit observation team. The acceptability of the technical products reviewed by the OCRWM audit team was not evaluated by the NRC staff since technical specialists were not a part of the NRC observation team.

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 its 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 YMPD 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 specialists 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 91-06 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 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 OCRWM audit of SAIC/T&MSS conducted in November 1990 identified five CARs. In addition, the audit of Criterion 4 (Procurement Document Control) found the implementation to be marginally effective because a multitude of procedures controlled the procurement process.

SAIC/T&MSS appears to be making significant progress in implementing an effective QA program. Although this audit identified some problems in

the areas of control of M&TE and corrective action, progress has been made in resolving previous audit findings. However, it appears that little progress has been made on reducing the number of procedures which control the procurement process. Without exception, all auditors observed were aware of past audit findings in their areas of responsibility.

5.10 Summary of NRC Staff Findings

(a) Observations

The NRC staff did not identify any observations relating to deficiencies in either the 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.

There was good coordination of the programmatic and technical reviews and evaluations.

5.11 Summary DOE/OCRWM Audit Team Findings

During the course of the audit, the audit team identified two CARs in the areas of control of measuring and test equipment and corrective action. The CAR's were well substantiated and reflected issues important to the quality system.