U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 92-12

FOR THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION

AUDIT NO YMP-92-16 OF SCIENCE APPLICATIONS INTERNATIONAL CORPORATION

TECHNICAL & MANAGEMENT SUPPORT SERVICES

06/17/92
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1.0 INTRODUCTION

From May 18-22, 1992, members of the U.S. Nuclear Regulatory Commission quality assurance (QA) staff participated as observers on the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) QA Audit No. YMP-92-16 of Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) in Las Vegas, Nevada. The audit scope was limited to six QA programmatic elements and two technical areas evaluated by QA programmatic and technical specialists.

This report addresses the effectiveness of the DOE/YMQAD audit and the adequacy of the SAIC/T&MSS QA program.

2.0 OBJECTIVES

The objective of the DOE/YMQAD audit was to evaluate the implementation and effectiveness of the SAIC/T&MSS QA program in meeting the applicable requirements of DOE/RW-0214, "Quality Assurance Requirements Document" (QARD), Revision 4. The NRC staff's objective was to gain confidence that SAIC/T&MSS is properly implementing the requirements of its QA program in accordance with Title 10 Code of Federal Regulations (10 CFR) Part 60, Subpart G, (which references 10 CFR Part 50, Appendix B) and the QARD.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMQAD 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). The audit was well organized and conducted in a professional manner with minimal logistic delays. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff has determined that the audit was effective, and agreed with the DOE/YMQAD audit team that implementation of the SAIC/T&MSS QA program was satisfactorily for five of the six QA program elements that were audited. The NRC staff also agreed with the DOE/YMQAD audit team that Criterion 12, "Control of Measuring and Test Equipment," was marginally effective in its implementation. This will not have a significant impact in the overall implementation of Criterion 12. Two preliminary Corrective Action Requests (CARs) were issued by the DOE/YMQAD audit team, one in the area of calibration, and the other in the area of training. These deficiencies are not significant in terms of the overall QA program and did not affect the quality of any SAIC/T&MSS site characterization activities.

4.0 AUDIT PARTICIPANTS

4.1 NRC

William L. Belke	Observation Team Leader
Kenneth L. Kalman	Observer
Bruce Mabrito	Observer (Center for Nuclear Waste Regulatory Analyses)

4.2 DOE

Richard L. Maudlin	MAC Technical Services Co.	Audit Team Leader (ATL)
Thomas J. Higgins	SAIC/YMQAD	ATL-in-Training and Lead Technical Specialist
James Blaylock	DOE/YMQAD	Auditor
Robert B. Constable	DOE/YMQAD	Auditor
Mario R. Diaz	DOE/YMQAD	Auditor
John R. Matras	SAIC/YMQAD	Auditor
Wayne A. Bliss	Reynolds Electrical & Engineering Co., Inc.	Technical Specialist
Dwight Hoxie	U.S. Geological Survey, Denver, CO	Technical Specialist

5.0 REVIEW OF THE AUDITED ORGANIZATION

The DOE/YMQAD audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 5, and OCRWM QAAP 16.1, "Corrective Action," Revision 4.

The NRC staff observation audit of the SAIC/T&MSS audit was based on the NRC procedure, "Conduct of Audits," issued October 6, 1989.

5.1 PURPOSE/SCOPE OF AUDIT

The purpose of the audit was to evaluate and determine whether the SAIC/T&MSS QA program meets the requirements and commitments imposed by the OCRWM QARD by verifying compliance with requirements and the extent and effectiveness of the implementation of the program. Some technical areas were audited for compliance to procedural controls (e.g., radiological monitoring and meteorology), but no evaluation of the technical work products were made by the NRC staff Observation Team members.

(a) Programmatic Elements

The auditors used checklists based on the requirements in the SAIC/T&MSS QA Program Description (QAPD) Sections 5.0, 6.0, 12.0, 17.0, 19.0, and 20.0 (10 CFR 50 Appendix B Criteria III, V, VI, XII, and XVII), and other applicable documents pertaining to QA controls.

(b) Technical Areas

The technical activities selected by the DOE/YMQAD audit team to be reviewed during this audit were:

(1) Work Breakdown Structures (WBS) 1.2.5.4.2, Meteorology, and

(2) WBS 1.2.5.4.5. Environmental Radiological Monitoring.

5.2 TIMING OF THE AUDIT

The NRC staff believes the timing of the SAIC/T&MSS QA audit was acceptable, since the last audit of the programmatic and technical areas was in January 27-30, 1992; however, it appeared that there was limited quality-affecting work being performed in most of the areas being audited.

5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

The programmatic checklists covered the QA program controls for the six criteria or programmatic elements listed below:

5.0 Instructions, Procedures, Plans, and Drawings
6.0 Document Control
12.0 Control of Measuring and Test Equipment
17.0 Quality Assurance Records
19.0 Software Quality Assurance
20.0 Scientific Investigation Control

The NRC staff observed the audit team's evaluation of selected programmatic elements of the SAIC/T&MSS QA program. Only portions of some elements were observed. Therefore, some deficiencies identified by the audit team were not observed by the NRC staff. Such deficiencies will not be discussed in detail in this report.

(a) Instructions, Procedures, Plans, and Drawings (Criterion 5)

The checklist prepared for this portion of the audit was based on T&MSS Standard Practice Procedure (SP) 1.1, Revision 7, "Instructions, Procedures, Plans, and Drawings." The auditor's investigation was thorough in working through the checklist and in performing the necessary verifications.

Of the 15 characteristics to be evaluated on the checklist, the last five could not be responded to initially because they pertained to the use of Verbal Interim Change Notices (VICN). To date, only one VICN has been issued, and it was only in effect for two days. The auditor noted that there appeared to be a lack of a tracking system for the VICNs. As a result of the recommendation from the auditor, SAIC/T&MSS developed a log sheet for tracking VICNs during the audit. The NRC staff did not view this as a concern and believed the checklist was still appropriate for this criterion.

The auditor identified the following problems concerning the identification of document custodians and instructions, procedures, plans, and drawings:

(1) The log maintained by the audited organization listed one individual as the custodian for a particular document. However, interviews with document custodians revealed the custodial function for that particular document actually belonged to an individual other than the one listed. Prompt remedial corrective action was taken on the log to reflect the proper custodial function for this particular document.

(2) Another log listed an individual to be the custodian for SP 1.46 whereas interviews revealed that this individual should actually be the custodian for SP 1.47. Likewise, the custodian for SP 1.47 should have been listed as the custodian for SP 1.46. Prompt remedial corrective action was also initiated to correct these conditions. The "custodial" problems were isolated in nature, and the NRC staff agrees that it did not affect the outcome of the overall effectiveness for this criterion.

(3) The auditor noticed that one page of a two-sided document had been changed by an Interim Change Notice. As a result, it was confusing for a user to determine which page was actually being affected by the change. Consequently, a new Work Instruction was issued requiring the obsolete side or portions of a two-sided page be crossed out to eliminate any confusion in this area in the future.

(4) The auditor recommended that the terms "substantive change," "major change," "mandatory comment," and "major comment" as used in SP 1.1 be clarified to avoid confusion or misinterpretation in the future.

Overall, the SAIC/T&MSS document control staff interviewed appeared to have a good understanding and implementation of their responsibilities. The audit of this area was effective and the implementation was satisfactory as observed by the NRC staff.

(b) Document Control (Criterion 6)

The checklist prepared for this portion of the audit was based on SP 1.34, Revision 5, "Document Control." The auditor's investigation was well organized and thorough in obtaining the necessary information to complete the checklist questions. The auditor adhered to the checklist in addition to probing beyond the checklist in order to gain deeper insight into how well the auditees understood and implemented the procedures. During the course of the audit, several minor errata were found and immediate corrective action was taken. Three other problems were noted and verified as being corrected prior to the close of the audit. These audit findings included:

(1) A part-time employee was on distribution for controlled documents. A review of the part-time employee's files indicated several of the controlled documents were missing. This individual was verified as being removed from controlled distribution.

(2) The Document Control Center records file indicated an individual had received the current controlled copy of revision of Operating Procedure (OP) 1.7. Examination of the individual's file indicated that the current revision of OP 1.7 was missing. Corrective action was initiated to replace the missing copy with another controlled copy of OP 1.7.

(3) In accordance with SP 3.14, if a copy of a "controlled" document was later to be "decontrolled", the document holder was sent a notice of this intent. The document holder would then place this notice in its respective file along with the decontrolled document. Under this procedure, the potential existed for a user to mistake a "decontrolled" document for a "controlled" document and possibly perform an activity with an outdated procedure. As a result of the auditor's recommendation, an Interim Change Notice will be issued to require the document holder to destroy the "decontrolled" document. This will be fully verified on a future surveillance of SAIC/T&MSS.

The auditor was well prepared and knowledgeable in the requirements that were audited and persistent in interviews and document reviews. Overall, the auditor used the published checklist effectively during the audit process and the audit was observed to be effective. The NRC staff agrees with the auditor's conclusion that the implementation of the QA program for Document Control was satisfactorily implemented.

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

This criterion was added to the audit based on the marginal acceptance determination resulting from the previous audit, YMP-92-08, conducted in January 27-30, 1992, and the CAR (YM-92-020) associated with this audit. Portions of this audit observation were performed at the SAIC/T&MSS offices in Las Vegas and at the Nevada Test Site.

The corrective actions associated with CAR YM-92-020 were still in process and unable to be evaluated. The due date for completion of these corrective actions was extended to accommodate subsequent procedural revisions associated with the respective corrective actions for this CAR.

SAIC/T&MSS measuring and test activities mainly apply to meteorology and radiological monitoring. The auditor verified various quality affecting measuring and testing equipment for proper identification,

current calibration status, storage location, calibration frequency, calibration due date, certificate of calibration/conformance, traceability to nationally recognized standards, and appropriate responsibilities.

The auditor issued a potential CAR for certification of calibration reports being modified and corrected by SAIC/T&MSS personnel instead of the personnel that performed the actual calibration.

The auditor was persistent in interviewing responsible personnel and thorough in using the prepared checklist questions and in reviewing the associated objective evidence. The audit of this criterion was effective. The SAIC/T&MSS QA program under this criterion was determined to be marginally satisfactory by the auditor, a conclusion which is concurred in by the NRC staff.

(d) Quality Assurance Records (Criterion 17)

The checklist for this portion of the audit was based on SP 1.36, Revision 8, "Quality Assurance Records." The audit started slowly due to an initial misunderstanding about the organization and responsibilities of the Local Records Center (LRC) and the Central Records Facility (CRF) organization. There had been some recent transitions in the LRC and CRF and, within the next three months, there will be further transitions of the CRF to the Management and Operating Contractor (M&O). Once this transition process was understood, the audit proceeded in a normal satisfactory manner. The auditor did note however, that the upcoming transition to the M&O will necessitate development of a new set of operating procedures. The auditor indicated that this development will be kept under surveillance in the future.

Some difficulty was experienced in locating certain of the technical personnel selected for interviews, since these personnel were scientists working at the Nevada Test Site while this audit was being conducted. The rationale for the unavailability of these personnel was that higher priorities at the Nevada Test Site took precedence over the audit. However, a representative sample of other available technical personnel was selected for interviews and subsequently, provided the necessary information to complete the audit. This did not have an adverse effect on the overall auditor's evaluation of the effectiveness of implementation for this criterion.

The records personnel were well trained and knowledgeable of the procedures and areas in which they were performing QA records activities. The NRC staff agrees with the auditor's conclusion that the implementation of Criterion 17 was satisfactory. The audit of this area was effective and the implementation was adequate.

(e) Software Quality Assurance

The audit checklist was based on the SAIC/T&MSS Software QA Plan and SP's 1.52, 1.53, 1.54, 1.55, and 1.56. The SAIC/T&MSS Configuration Management Log was used to determine the amount and types of computer software that is being used on the project.

The auditor was persistent in tracking down information and went beyond the audit checklist when it appeared that there may be findings or deficiencies generic in nature in other parts of the SAIC/T&MSS QA program. An adequate sample was evaluated and sufficient objective evidence was obtained to show compliance with the SAIC/T&MSS QAPD and related implementing procedures.

Three software codes were selected from the SAIC/T&MSS software library. The auditor was initially concerned that the software was not being classified properly. An internal SAIC/T&MSS audit report revealed findings of a similar nature, and that audit prompted internal corrective actions toward these findings. The auditor agreed that this internal audit report would provide the foundation for appropriate corrective action commensurate with his findings.

The auditor conducted a sufficiently detailed investigation of the software quality assurance element, asked the appropriate questions and evaluated sufficient objective evidence, utilized the audit checklist, and went beyond the audit checklist where necessary, to thoroughly make an assessment of the SAIC/T&MSS software QA program. The audit of this criterion was effective and the implementation was adequate.

5.4 EXAMINATION OF TECHNICAL PRODUCTS

Some technical areas were audited for compliance to procedural controls but this activity was minimal. Some technical products were evaluated for adequacy, however, since the NRC staff did not include any technical specialists on the NRC audit observation audit team, no evaluation of technical products was performed by the NRC staff.

5.5 CONDUCT OF AUDIT

The audit was conducted in a thorough and professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the SAIC/T&MSS QA program. The audit checklists included the important controls addressed in the SAIC/T&MSS QAPD. The audit team used the checklists effectively during the interviews with personnel and review of documents. The observers were kept well informed during the audit.

5.6 QUALIFICATION OF AUDITORS

The qualification files of the entire DOE/YMQAD audit team were reviewed by the NRC staff during this audit and were found to meet the

requirements of QAAP 18.1, Revision 3, "Qualification of Audit Personnel."

5.7 AUDIT TEAM PREPARATION

The auditors were prepared in the areas they were assigned to audit and knowledgeable in the SAIC/T&MSS QAPD and implementing procedures. The Audit Plan/Book for YMP-92-16 included the QA programmatic and technical checklists, list of the daily audit activities, Audit Notification Letter, Summary of Open CARs, and last two audit reports.

5.8 AUDIT TEAM INDEPENDENCE

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

5.9 REVIEW OF PREVIOUS AUDIT FINDINGS

(a) There was one open CAR from previous audit findings. The due date for completion of this CAR was extended to accommodate procedure revisions (see 5.3 (c) above)

(b) The NRC staff did not have any observations from previous audits relating to this audit that required resolution.

5.10 SUMMARY OF NRC STAFF FINDINGS

(a) Observations

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

(b) Weaknesses

The observers received the audit notebook on the day of the audit. It is recognized that NRC agreed with DOE that for the "mini-audit process," the audit notification letter would be furnished to NRC in advance, and the audit books (including the audit checklists, procedures etc.) at the audit. As noted in the NRC Audit Observation Reports for the DOE Oak Ridge and Los Alamos National Laboratory Audits, this system does not allow ample time for adequate preparation for the audit by the NRC programmatic and technical observers. (This matter was also discussed at the April 30, 1992, NRC/DOE QA meeting.) It also becomes difficult for the observers to accurately critique the DOE audit team and audit effectiveness if appropriate information has not been either provided or reviewed. Had the audit book been provided a week in

advance with appropriate background and information, many of the observer's questions could have been answered prior to the audit instead of during the audit.

The NRC staff recommends that DOE reconsider providing the observers the audit book at least a week prior to the audit with adequate information and subject matter to allow ample time for observers to prepare for the audit and facilitate the audit process. By furnishing the audit checklist in an expeditious manner, the NRC staff believes that the intent of item (6) in the policy agreed to by the DOE, State, Tribal, and NRC representatives (referred to in the July 14, 1987 letter from S. Kale to State and Tribal Representatives) will be satisfied.

A response from DOE to this weakness is requested by the NRC staff. This item will also be entered and tracked on the NRC Open Items List.

(c) Good Practices

After the NRC staff Observation Audit Team briefed the DOE/YMQAD Audit Team on the NRC staff observations, weaknesses, and good practices, the NRC staff requested feedback on the NRC Observers, the observation audit process, and in general, any constructive criticism that would help improve the overall audit process. This request was not for the purposes of debate but rather a vehicle to communicate and improve the overall audit/observation process.

5.11 SUMMARY - DOE/YMQAD AUDIT TEAM FINDINGS

The audit team identified two potential CARs written against the SAIC/T&MSS QA program.

(a) Three calibration reports were modified and corrected by SAIC/T&MSS personnel instead of the personnel that performed the actual calibration (see Section 5.3 (b)).

(b) The Software Librarian performed quality affecting activities prior to completing the required training.