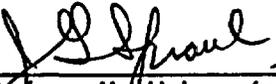


U.S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT 94-05  
OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION  
AUDIT YMP-94-05  
OF TECHNICAL AND MANAGEMENT SUPPORT SERVICES

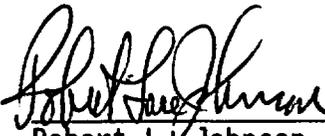
  
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ENCLOSURE

## 1.0 INTRODUCTION

During May 16-20, 1994, members of the Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) audit of the QA program of the YMQAD Technical and Management Support Services Contractor (T&MSS) - Science Applications International Corporation. The audit, YMP-94-05, was conducted at the T&MSS offices in Las Vegas and at the Yucca Mountain Site, Mercury, Nevada. The audit evaluated the adequacy and effectiveness of the T&MSS QA program in all applicable QA programmatic areas and two technical areas. The audit was the first YMQAD audit of the T&MSS since the T&MSS QA program was revised to meet the requirements of OCRWM's "Quality Assurance Requirements and Description" document (QARD - DOE/RW-0333P). The State of Nevada did not participate in this audit.

This report addresses the effectiveness of the YMQAD audit and the adequacy of implementation of QA controls in the audited areas of the T&MSS QA program.

## 2.0 OBJECTIVES

The objectives of the audit by YMQAD were to determine whether the T&MSS QA program and its implementation meet the applicable requirements and commitments of the QARD, the T&MSS Quality Assurance Program Description (QAPD), and associated implementing procedures.

The NRC staff's objective was to gain confidence that YMQAD and T&MSS are properly implementing the requirements of their QA programs in accordance with the OCRWM QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

## 3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that YMQAD Audit YMP-94-05 was useful and effective. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA and technical disciplines, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team finding that implementation of the T&MSS QA program is adequate in the QA programmatic areas audited. One preliminary Corrective Action Request (CAR) was discussed by the YMQAD audit team at the post-audit meeting. Five other potential CARs were acceptably resolved by the T&MSS organization during the audit. Neither the preliminary nor potential CARs identified by the YMQAD audit team are significant in terms of the overall T&MSS QA program.

YMQAD should continue to closely monitor implementation of the T&MSS QA program to ensure that the deficiency identified during this audit is corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the T&MSS QA program.

#### 4.0 AUDIT PARTICIPANTS

##### 4.1 NRC

Pauline P. Brooks	Observer	
John G. Spraul	Observer	
Rodney M. Weber	Observer	Center for Nuclear Waste Regulatory Analyses

##### 4.2 DOE/YMQAD

Richard L. Maudlin	Audit Team Leader (ATL)	Quality Assurance Technical and Support Services Contractor - CER (QATSS)
Stephen R. Masler	Acting ATL	QATSS
Patout H. Cotter	Auditor	QATSS
Fred Bearham	Auditor	QATSS
Kenneth O. Gilkerson	Auditor	QATSS
Thomas E. Rodgers	Auditor	QATSS
Allen E. Barr	Technical Specialist	National Oceanic and Atmospheric Administration

#### 5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This YMQAD audit of T&MSS was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 5 plus Interim Change Notice 1) and QAAP 16.1, "Corrective Action" (Revision 4). The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

##### 5.1 Scope of the Audit and Observations

This audit was designed to be performance-based to the maximum extent possible. The auditors were directed to focus on work products rather than QA programmatic requirements.

###### 5.1.1 QA Programmatic Elements

The audit scope included the QA programmatic elements listed below:

- 1 Organization
  - 2 Quality Assurance Program
  - 4 Procurement Document Control
  - 5 Implementing Documents
  - 6 Document Control
  - 7 Control of Purchased Items and Services
  - 10 Inspection
  - 12 Control of Measuring and Test Equipment
  - 15 Nonconformances
  - 16 Corrective Action
  - 17 Quality Assurance Records
  - 18 Audits
- Supplement III. Scientific Investigation

### 5.1.2 Technical Areas

The following technical areas were reviewed by the YMQAD audit team:

Meteorology (Work Breakdown Structure No. 1.2.13.4.2)  
Monitoring Conditions of Population Centers Relative to Wind Patterns (Work Breakdown Structure No. 1.2.13.5.2)

### 5.1.3 Observations

The NRC staff observed all or part of the YMQAD audit team evaluation of QA Programmatic Elements 4, 7, 12, 15, 16, 17, and Supplement III; only these QA programmatic areas are discussed in detail in this report. The technical area of meteorology was reviewed as part of the QA programmatic reviews.

## 5.2 Timing of the Audit

The NRC staff believes the general timing of this audit was appropriate for YMQAD to evaluate the pertinent QA activities of T&MSS and for the NRC staff to evaluate the YMQAD audit process and implementation of the T&MSS QA program.

## 5.3 Examination of QA Programmatic Elements

The NRC staff observed that each of the auditors reviewed related documentation and interviewed at least a representative sample of T&MSS personnel to determine their understanding and degree of implementation of the procedures. The auditors observed were well prepared and knowledgeable of the QA program requirements. They used their checklists effectively and pursued issues beyond the checklists when appropriate. They solicited comments and questions from the NRC observers in an appropriate manner. The NRC staff observations regarding the audit and the implementation of each appropriate QA programmatic element are discussed below.

### 5.3.1 Procurement Document Control (QA Programmatic Element 4)

The auditor of QA Programmatic Element 4 verified that QARD requirements are incorporated into T&MSS implementing procedures. The auditor interviewed appropriate T&MSS personnel and examined the documentation for the procurement document packages of interest to determine whether the T&MSS requirements were being met. There were 6 active procurements and 7 procurement packages had been completed since the last audit in February 1993. Several minor questions were satisfactorily clarified. The procurement documentation was found to be in compliance with applicable procedural requirements for active procurements and completed procurements that had been transmitted to the Local Records Center.

The auditor was effective in his audit of this QA programmatic element using the checklists effectively and asking appropriate questions. The NRC staff agrees with the YMQAD audit team that T&MSS is adequately implementing QA controls for activities under this QA programmatic element.

### 5.3.2 Control of Purchased Items and Services (QA Programmatic Element 7)

By examining applicable implementing procedures, the auditor determined that DOE's QARD requirements were adequately incorporated in T&MSS procedures. The auditor checked for compliance the purchase orders, supplier evaluations, quality records review and associated documents for the currently active suppliers to determine whether the documentation satisfactorily met SAIC/T&MSS procedures.

The auditor was effective in his audit of this QA programmatic element using the checklists effectively and asking appropriate questions. The NRC staff agrees with the YMQAD audit team that T&MSS is adequately implementing QA controls for activities under this QA programmatic element.

### 5.3.3 Control of Measuring and Test Equipment (QA Programmatic Element 12)

The portion of the audit of Criterion 12 observed involved the calibration and control of measuring and test equipment (M&TE) such as wind direction and wind speed sensors used to collect meteorological data in the field. An audit sub-team of the technical specialist and an auditor interviewed T&MSS personnel involved in the control of this M&TE and investigated their training and experience. A number of different M&TE items in the field were identified by the audit sub-team, and the acceptability of the control and calibration of these instruments was verified. One discrepancy was found in that a nonconformance report was not issued when two wind speed sensors were repaired without determining the "as-found" calibration status so that the validity of previously collected data could be assessed. This minor discrepancy was corrected during the audit.

The audit sub-team made two recommendations regarding Criterion 12. One was that the on-the-job training of T&MSS personnel involved with the control of M&TE in the field be documented to provide more complete objective evidence of their qualification. The other was that procedures used for calibrations and performance checks of M&TE in the field be made more specific; for example, identification of instruments used for these activities.

This portion of the audit was effective, and the QA Programmatic Element appeared to be adequately implemented.

The NRC staff recognized the system that the T&MSS had established to control the "shelf life" of calibrated items of M&TE before they are put into service as a good practice. The system can significantly increase the time between calibrations without reducing the quality of the resulting data.

### 5.3.4 Nonconformances (QA Programmatic Element 15)

All audit activities of this program element were observed. A sample of eight nonconformance reports (NCRs) were reviewed. Minor informational omissions were noted by the auditor. These detail items were discussed with appropriate T&MSS supervisory personnel, and agreement was reached that more details would make the situation described by the NCR clearer. During the auditor's review of QA Programmatic Element 18, "Audits," questions related to the

identification of nonconformances in audit reports were followed-up to verify documentation of those discrepancies within the T&MSS nonconformance system. All questions related to nonconformance reporting were satisfactorily resolved, and no findings in the QA Programmatic area were noted.

The auditor was effective in his audit of this QA programmatic element using the checklists effectively and asking appropriate questions. The NRC staff agrees with the YMQAD audit team that T&MSS is adequately implementing QA controls for activities under this QA programmatic element.

#### 5.3.5 Corrective Action (QA Programmatic Element 16)

The 12 Quality Finding Reports (QFRs) written this year to date were reviewed by the auditor. A number of these has similar root causes, and the auditor expanded his questioning into the area of trending of root causes. As a result, the trend analysis process was described to the auditor and observer. The process was found to be effective in identifying trends and presenting the information to management in a useful manner. The most recent quarterly trend analysis report adequately identified the trend noted by the auditor. The auditor noted that only one QFR remained open from 1993. All checklist items were answered and no items adverse to quality were identified in this QA Programmatic Area.

This portion of the audit was effective, and the QA Programmatic Element appeared to be adequately implemented.

#### 5.3.6 Quality Assurance Records (QA Programmatic Element 17)

The auditor determined that DOE's QARD requirements with respect to QA records were adequately incorporated in SAIC/T&MSS procedures and that these procedures were being followed.

The audit of this element of the T&MSS QA program appeared effective, and implementation was adequate.

#### 5.3.7 Scientific Investigation (QA Programmatic Element Supplement III)

The audit of Scientific Investigations was conducted by the audit sub-team composed of the technical specialist and an auditor. It appeared that the audit sub-team was thorough and followed the audit checklists, asking additional questions as required. Considerable attention was given to data review and verification. No discrepancies were noted by the audit sub-team during the Scientific Investigation portion of the audit.

Programmatically, this portion of the audit was effective, and implementation appeared to be adequate.

#### 5.3.8 Conclusions

The QA programmatic portion of the audit was conducted in a professional manner, and the auditors adequately evaluated activities and objective

evidence. The audit was effective in determining the adequacy and degree of implementation of the T&MSS QA program.

#### 5.4 Examination of Technical Areas

##### 5.4.1 Meteorology (Work Breakdown Structure No. 1.2.13.4.2)

This work is part of Study Plan 8.3.1.12.2.1, "Meteorological Data Collection at the Yucca Mountain Site." The checklist for this portion of the audit was based on the study plan and on work instruction WI-MET-001, "Meteorological Monitoring." The technical procedures for meteorological data gathering and reporting were reviewed by the audit sub-team and found to be adequate. Applicable QA procedures were clearly identified. The audit sub-team also reviewed the raw data, other records, and reports and questioned the investigators on the details of the meteorologic program.

The audit sub-team and an NRC staff observer toured and examined the set-up and instrumentation at the 60 meter meteorological tower near the entrance to the Exploratory Studies Facility and at the 10 meter meteorological tower at 40 Mile Wash. Key technical personnel of T&MSS were questioned by the technical specialist on the details of the meteorological work being done. The technical auditor was satisfied with the QA and technical aspects of the past, ongoing, and planned meteorological work. However, he noted the need for a meteorological model - even if designated as preliminary - in order to help ensure collection of the proper data.

##### 5.4.2 Conclusions

The technical portion of the audit was effective. The technical checklists were followed and were sufficient to determine the technical qualifications of the key technical personnel and technical quality of the product. The audit sub-team conducted this portion of the audit in a professional manner and asked questions to ascertain complete understanding of the technical areas and applicable QA requirements. During this portion of the audit, no CARs related to the technical aspect of work were identified. The T&MSS technical personnel appeared well qualified and were properly trained in and had an overall understanding of QA requirements.

#### 5.5 Conduct Of Audit

The audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the T&MSS QA program. The interview method of auditing, combined with periodic checking of objective evidence, allowed for thorough responses to the questions and permitted many additional questions to be answered. The audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. A caucus of auditors and observers was held at the close of each work day, and a meeting of the ATL and T&MSS management (with an NRC observer present) was held each morning to discuss the audit status and preliminary findings.

## 5.6 Qualification Of Auditors

The qualifications of the ATL and auditors were found to be acceptable in that each auditor and the ATL met the requirements of QAAP 18.1, "Qualification of Audit Personnel."

## 5.7 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The Audit Plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, a list of the activities to be audited, and audit checklist references.

## 5.8 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

## 5.9 Review of Previous Audit Findings

There were no CARs issued as a result of the last OCRWM audit of T&MSS, and thus no follow-up action was required in this regard.

## 5.10 Summary of NRC Staff Findings

The NRC staff agrees with the preliminary YMQAD audit team finding that implementation of the T&MSS QA program is adequate in each of the QA programmatic areas audited. The NRC staff did not observe any deficiencies in either the audit process or the T&MSS QA program.

Several questions on the clarity of documentation arose during the audit. These were satisfactorily answered and did not adversely reflect on the QA program. However, the fact that they arose could lead one to consider whether some guidelines and/or training on the design of forms is appropriate at this time.

During the audit it was noted that the size of the T&MSS QA organization had been reduced from 16 to 6 people, including the manager and a secretary. QA personnel had been performing non-QA activities; but, with this personnel reduction, the current personnel level no longer allow this. QA Programmatic areas do not appear to be adversely affected by this reduction. However, any significant increase in work scope could overload the QA organization.

The NRC staff recognized the system that the T&MSS had established to control the "shelf life" of calibrated items of M&TE before they are put into service as a good practice. The system can significantly increase the time between calibrations without reducing the quality of the resulting data.

### 5.11 Summary of YMQAD Audit Findings

Within the scope of this audit, the audit team concluded that the T&MSS QA procedures are adequate and that T&MSS's QA program implementation is adequate. The NRC staff agrees with these conclusions. At the post-audit meeting, the audit team provided observations of the T&MSS QA program and discussed the preliminary CAR resulting from the audit. The CAR involved the lack of objective evidence that several reviewers of a document had completed required training before performing the review. Five other potential CARs were acceptably resolved by the T&MSS organization prior to the post-audit meeting.