

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 93-05
FOR THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT NO. YMP-93-05 OF THE TECHNICAL AND MANAGEMENT
SUPPORT SERVICES CONTRACTOR

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1.0 INTRODUCTION

During February 1-4, 1993, U.S. Nuclear Regulatory Commission quality assurance (QA) and technical staff members participated as observers of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) QA Audit No. YMP-93-05 of the Technical and Management Support Services contractor (T&MSS), Science Applications International Corporation (SAIC). This audit was conducted at the T&MSS offices in Las Vegas, Nevada and at the Nevada Test Site (NTS). The audit scope included nine QA programmatic areas and one technical area.

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 objective of the YMQAD audit was to evaluate the implementation and effectiveness of the T&MSS QA program in meeting the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD), the T&MSS Quality Assurance Program Description (QAPD), and associated T&MSS implementing procedures.

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

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the T&MSS QA program on direct observations of the auditors; discussions with audit team, T&MSS, and contractor personnel; and reviews of the audit plan, the audit checklists, and pertinent T&MSS documents. The NRC staff has determined that YMQAD QA Audit No. YMP-93-05 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. The audit team was well qualified in the QA and technical disciplines and its assignments and checklists item were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team findings that the T&MSS QA program has adequate procedural controls in place and that QA program implementation in the areas audited is generally effective. Three deficiencies were identified by the YMQAD audit team; however, all of them were acceptably addressed by the T&MSS organization during the audit, and no Corrective Action Requests (CARs) were issued by the audit team.

OCRWM should continue to monitor the T&MSS QA program to ensure that future implementation is carried out effectively. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess the T&MSS QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

| | | |
|----------------------|----------|---|
| Kenneth R. Hooks | Observer | |
| Donald L. Chery, Jr. | Observer | |
| Bruce Mabrito | Observer | Center for Nuclear Waste Regulatory Analyses |

4.2 DOE

| | | |
|---------------------|-------------------------|---|
| Robert B. Constable | Audit Team Leader (ATL) | YMQAD |
| Donald J. Harris | Auditor | SAIC/YMQAD |
| Frank J. Kratzinger | Auditor | SAIC/YMQAD |
| John R. Matras | Auditor | SAIC/YMQAD |
| Kenneth T. McFall | Auditor | SAIC/YMQAD |
| Dale S. Ambos | Technical Specialist | U.S. Geological Survey (Foothills Engineering) |

4.3 Other

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|---------------------------------|----------|----------------------|
| Engelbrecht von Tiesenhausen | Observer | Clark County, Nevada |
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5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This audit was conducted in accordance with OCRWM QA Administrative Procedures 18.2, "Audit Program," Revision 5, and 16.1, "Corrective Action," Revision 4. The NRC staff observation of this YMQAD audit of T&MSS was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of Audit

The audit scope included nine QA programmatic elements and one technical area.

5.1.1 QA Programmatic Elements

The audit checklists covered QA program controls for the nine programmatic elements listed below:

- 3.0 Design Control
- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items, Samples, and Data
- 10.0 Inspection
- 14.0 Inspection, Test, and Operating Status
- 15.0 Control of Nonconforming Items
- 19.0 Software Quality Assurance
- 20.0 Scientific Investigation Control

The audit utilized checklists based on the requirements in the T&MSS QAPD and associated T&MSS implementing procedures. Auditing of QA Programmatic Element 3.0, "Design Control," was conducted simultaneously with auditing of QA Programmatic Element 20.0, "Scientific Investigation Control," and the technical area.

QA Program Element 11.0, "Test Control," was determined by YMQAD to be not applicable at T&MSS because it has no current activities to which this element applies.

5.1.2 Technical Area

Checklists based on T&MSS procedures and the applicable scientific investigation study plan were developed by the auditor and the technical specialist for:

Work Breakdown Structure Number (WBS) 1.2.13.4.2, "Air Quality/Meteorology."

An audit subteam of a QA programmatic auditor and the technical specialist audited the technical area simultaneously with programmatic elements 3.0 and 20.0. The technical specialist on the YMQAD Audit Team evaluated T&MSS personnel technical qualifications, their procedural understanding, and the adequacy of applicable technical procedures and their implementation.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate to verify corrective actions from the previous YMQAD audit and for the staff to evaluate the YMQAD audit process and the T&MSS QA program.

5.3 Examination of Programmatic Elements

The NRC staff observed the YMQAD audit team's evaluation of QA programmatic elements 4.0, 7.0, 19.0 and 3.0/20.0. The NRC staff's observations regarding each of these QA programmatic elements are discussed below. The discussion of the technical area is also included.

5.3.1 Design Control and Scientific Investigation Control (Programmatic Elements 3.0 and 20.0)

Design Control and Scientific Investigation Control were audited as a single programmatic element, simultaneously with the technical activity WBS 1.2.13.4.2, "Air Quality/Meteorology." The audit was performed by a subteam of a QA programmatic auditor and the technical specialist.

The audit subteam used a technical checklist based on Study Plan 8.3.1.12.2.1, "Meteorological Monitoring Plan," and various T&MSS Work Instructions (WIs) and a programmatic checklist based on applicable T&MSS Standard Practice Procedures (SPs) and WIs. The checklists were comprehensive and both the auditor and technical specialist were thorough and persistent in seeking answers to questions through interviews and reviews of pertinent documents.

The audit subteam verified that the WIs by which the technical activity is controlled were developed in accordance with SP 1.1; only WIs are used in this activity (i.e. no scientific notebooks).

The audit subteam conducted interviews and document reviews in the T&MSS offices in Las Vegas, Nevada and at the NTS. At the NTS, the subteam visited the new meteorology office and three meteorological data collection stations: Station 9, "Gate 510;" Station 5, "40 Mile Wash;" and Station 1, "NTS 60." The subteam observed demonstrations of instrument calibration activities and verified that checklists used by T&MSS personnel were in accordance with the requirements of WI-MET-002, Revision 3.

T&MSS technicians visit each meteorological data collection station weekly, and they document each visit by filling out a "Meteorological Site Routine Visit Checklist." The SAIC Air Quality Office in San Diego, California, does a "performance audit" (accuracy check) of the instruments at each meteorological data collection station quarterly; T&MSS QA personnel perform supplier audits of the SAIC Air Quality Office.

At the time of the audit, no qualified data from the T&MSS meteorology program had been submitted for the Yucca Mountain Site Characterization Project (YMP) technical data base, and T&MSS personnel stated that unqualified data is flagged as such. YMP is submitting monthly meteorological data reports to the State of Nevada, in both hard copy and computer disk format.

The T&MSS supervisory and technical personnel were knowledgeable about the procedures controlling their activities, aware of the reasons for the procedures, and supportive of the QA program. Review of the current QA Grading Report, T125428, indicated that many activities under Study Plan 8.3.1.12.2.1 are not quality affecting, since the data being collected at this time are for U.S. Environmental Protection Agency (EPA) and State of Nevada requirements, rather than NRC licensing. However, T&MSS management decided to apply full QA measures to these activities.

The audit subteam performed a thorough and effective audit of the programmatic and technical activities. The NRC staff agrees with the YMQAD audit team finding that T&MSS is effectively implementing its QA program for Programmatic Elements 3.0/20.0 and WBS 1.2.13.4.2.

5.3.2 Procurement Document Control (Programmatic Element 4.0)

The audit checklist was based on SP 1.28, "Procurement of Quality Affecting Items and Services," and SP 1.72, "Upgrade of Items Procured as Non-Quality Affecting." It was determined by the auditor that SP 1.72 had not been implemented at the time of the audit because T&MSS had not had an occasion to use it, so that portion of the audit checklist was not utilized. The auditor initially reviewed the T&MSS Purchase Order Log and selected seven candidate orders, four of which were incomplete (the material had been ordered but not yet received). The auditor thoroughly tracked the seven selected purchase orders through the T&MSS procurement system to verify compliance with procedures. A minor inconsistency regarding reference to a specific form was identified in SP 1.28 and corrected during the audit by T&MSS staff.

The audit checklist was adequate and the auditor was satisfactorily prepared. A sufficient sampling of the T&MSS purchase orders was accomplished, and they were examined in adequate detail to determine compliance with SP 1.28. The audit of this programmatic element was effective, and the NRC staff agrees with the audit team finding that implementation of SP 1.28 and this programmatic element was effective.

5.3.3 Control of Purchased Items and Services (Programmatic Element 7.0)

As a basis for this part of the audit, the following T&MSS procedures were referenced in the audit checklist: Organization Procedure (OP) 1.3, "Supplier Evaluation"; OP 1.7, "Development and Maintenance of the Qualified Supplier List (QSL)"; SP 1.25, "Acceptance of Items and Services"; SP 1.65, "Control of Vendor Manuals and Vendor Technical Information"; and WI-QA-006, "Trend Analysis." The audit checklist had a total of 44 separate items; however, those items dealing with vendor manuals and vendor technical information were determined to be not applicable as there were no T&MSS procurements audited with those requirements. The auditor reviewed the T&MSS QSL Index, which included 37 total suppliers, and requested six recent audits of the suppliers for thorough review. All were found complete and satisfactory. In addition, five different supplier annual evaluations were reviewed, and these documents met the requirements of the appropriate procedures.

Although a few of the T&MSS procedures referenced in the audit checklist were not applicable or had not been used because of the current T&MSS scope of work, the implementation of the program element as a whole was more than sufficient for the auditor to make a judgement of effectiveness. The auditor was thorough, going beyond the checklist to ask questions or examine objective evidence when he thought it necessary.

The application of this programmatic element was sufficient to determine that the QA controls in place are adequate and appropriate for the work being accomplished. The auditor performed his work professionally and Programmatic Element 7.0 was effectively audited. The NRC staff agrees with the audit team that the T&MSS QA program for this programmatic element was effectively implemented.

5.3.4 Software Quality Assurance (Programmatic Element 19.0)

SP 1.56, "Software Configuration Management," was used to develop the audit checklist for this area. The auditor met with the T&MSS Software QA Analyst and the Software Librarian and questioned them on the responsibilities of their positions and the operation of the T&MSS software control system. The auditor reviewed the Software Quality Assurance (SQA) Plan and went over the Configuration Management logs to determine if the appropriate software information was present, and to select certain software development folders for evaluation.

The auditor selected T&MSS software development folders for the following computer codes: DATALOGGER 1.0.B, CONVERSION 1.0.A, ENVAID 5.0.A, ENVICOM 5.0.A, WROSE 2.0.1A, and BEEMET 1.0.A. These codes were identified in several

T&MSS WIs for field meteorology application, so they were chosen for integration with the technical activity being audited.

The auditor determined that no software problem notices were generated in calendar year 1992 or in 1993. Documentation for each of the software codes was checked for the presence of change request forms, software classification forms, user manuals, user access forms, software application records and software summary forms. All such documentation was present and completed in accordance with SP 1.56.

The auditor performed his work professionally, and the audit in this area was effective. The implementation of the T&MSS procedures in SQA were effective, and objective evidence was presented promptly by the audited organization.

5.3.5 Conclusions

The audit of the T&MSS QA program evaluated the adequacy of T&MSS procedures and the effectiveness of implementation of the QA program. The auditors used appropriate checklists, interviewed T&MSS personnel, and reviewed T&MSS documentation. The programmatic portion of the audit was effective, and the NRC staff agrees with the audit team that the T&MSS is effectively implementing its QA program in the areas audited.

5.4 Examination of Technical Products

The auditor and technical specialist subteam reviewed, in a selective and focused way, the technical area listed below by WBS Number and title:

| <u>WBS Number</u> | <u>Title</u> |
|-------------------|-------------------------|
| 1.2.13.4.2 | Air Quality/Meteorology |

The NRC staff observed the audit subteam's evaluation of this WBS. This activity involved auditing Programmatic Elements 3.0 (Design Control) and 20.0 (Scientific Investigation Control). Only those examinations that were observed are described.

5.4.1 Supporting Information for Site Characterization and Performance Assessment

This WBS was audited as "quality-related" work; however, as presently conducted the focus of program is to meet EPA air quality standards and obtain data for air pollution dispersion studies for the repository site. Only in a supplemental or peripheral way would the data be used in the site characterization, design, or performance assessment evaluations.

The technical auditor was well prepared with a comprehensive set of questions derived from Study Plan 8.3.1.12.2.1, "Meteorological Monitoring Plan," Rev. 0, 2/28/91; and pertinent WIs. The questions were followed until all issues were answered completely. Lead technical investigators were questioned about the rationale for determining the location of instruments, instrument calibration, data collection, data processing, and record keeping including

adherence to and knowledge of record keeping procedures. In addition, training records of key project personnel were reviewed and compared against a list of procedures that were considered applicable to the project.

On the first day, auditing was conducted in the T&MSS offices in Las Vegas, Nevada, and then on the second day the subteam travelled to the NTS to review storage, data processing, and instrument calibration activities at the field office. Then three field meteorological stations (#9, #5, and #1 in that order) were visited to observe servicing and calibration of the field instruments. These stations were representative of one of four new 10 meter meteorological stations, an older 10 meter meteorological station, and the main 60 meter tower meteorological station which also has a major air quality monitoring and recording system. There are nine meteorological stations in the network which are visited periodically to collect the recorded data and check the operation of the instruments. On the following two days, the audit was conducted in the T&MSS offices in Las Vegas.

The subteam also reviewed in detail the use of data processing computer programs. The use of these programs was evaluated in accordance with the SQA Plan and adherence to other procedures written to govern the use of computer programs.

5.4.2 Conclusions

The NRC staff determined that the DOE technical specialist was qualified, well prepared for the audit, and pursued the audit with diligence and thoroughness. The technical specialist has more than 20 years experience in meteorology and is involved in a similar program at the NTS. In general, the technical portion of the audit was effective.

The T&MSS technical personnel were well qualified, properly trained, and had a good understanding of the procedures governing their activities. The NRC staff agrees with the audit team that implementation of QA and technical controls in this area is effective.

5.5 Conduct Of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated sound knowledge of the T&MSS QA program. In general, the audit team was persistent in its interviews and challenged responses when necessary. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between T&MSS management and the ATL to discuss the preliminary findings.

5.6 Qualification Of Auditors

The qualifications of the QA auditors on this audit team had been previously reviewed by the NRC staff and found to be acceptable, meeting the requirements of YMPO Quality Management Procedure 02-02, "Qualification of Quality Assurance Program Audit Personnel."

5.7 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the T&MSS QA and technical procedures. The audit plan for this audit included (1) the audit scope, (2) the audit schedule, (3) a list of audit team personnel, (4) a list of the activities to be audited, and (5) the audit checklists.

5.8 Audit Team Independence

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

5.9 Summary of NRC Staff Findings

5.9.1 Observations

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

5.9.2 Summary

The NRC staff agrees with the preliminary audit team findings that the T&MSS QA program has adequate procedural controls in place and implementation in the areas audited is effective.

5.10 Summary of YMQAD Audit Findings

As a result of this audit, the audit team identified three deficiencies in the T&MSS QA program, all of which were resolved during the audit. In addition, the audit team produced several recommendations to improve the T&MSS QA program. No CARs were issued as a result of the audit.