

U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-11
FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. YMP-91-04 OF RAYTHEON SERVICES NEVADA

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ENCLOSURE

1.0 INTRODUCTION

From July 29 - August 1, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. YMP-91-04 of Raytheon Services Nevada (RSN) conducted in Las Vegas, Nevada. RSN, a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible for the design and inspection of the Exploratory Studies Facility (ESF), both surface and subsurface. RSN also provides support for the Surface Based Testing Program in the form of drilling engineering, materials testing, and non-destructive examination.

This report addresses the effectiveness of the DOE/YMPO audit and, to a lesser extent, the adequacy of the RSN QA program.

2.0 OBJECTIVES

The objectives of the DOE/YMPO audit were to evaluate the implementation and effectiveness of the RSN QA program. The NRC staff's objective was to gain confidence that DOE and RSN are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE audit and determining whether the RSN QA program is in accordance with the requirements of the DOE/Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD).

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMPO audit process and the RSN QA program on direct observations of the auditors, discussions with the audit team and RSN personnel, and reviews of pertinent audit information (e.g., the audit plan checklists, and RSN documents). The NRC staff has determined that DOE/YMPO QA Audit No. YMP-91-04 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 discipline, and their assignments and checklist items were adequately described in the audit plan. The audit team did not include any technical specialists. Some technical areas were audited for compliance to procedural controls (i.e., computer software), but no evaluation was made of the technical adequacy of work products.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that the RSN QA program has adequate procedural controls in place, and that program implementation is adequate in eight of the thirteen areas audited. The other five areas were considered indeterminate due to a lack of quality affecting activities being conducted in these areas.

DOE/YMPO should monitor the RSN program to ensure that the seven preliminary deficiencies identified during this audit are corrected in a timely manner and future implementation is carried out in an effective manner. 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 RSN QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

James T. Conway	Observer	
Bruce Mabrito	Observer	CNWRA

4.2 DOE

Stephen R. Dana	Audit Team Leader	Science Applications International Corp. (SAIC)
Stephen P. Hans	Auditor	SAIC
Robert H. Klemens	Auditor	SAIC
John S. Martin	Auditor	SAIC
John R. Matras	Auditor	SAIC
Cynthia H. Prater	Auditor-in-Training	SAIC
Charles C. Warren	Auditor	MAC Technical Services Co.

4.3 TRW

George P. Vaslos	Observer
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5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE/YMPO audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, Revision 3, "Audit Program," and 16.1, Revision 3, "Corrective Action Requests."

The NRC staff observation of the DOE/YMPO audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. NRC staff findings are classified in accordance with the procedure guidelines. 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.

5.1 SCOPE OF AUDIT

The DOE/YMPO audit scope was to determine whether the RSN QA program meets the requirements and commitments imposed by the OCRWM QARD by verifying compliance with requirements and the extent and effectiveness of implementation of the program. Technical areas were audited for compliance to procedural controls only, since no technical specialists were included in the audit team.

(a) Programmatic Elements

The audit team utilized checklists developed from requirements in the Yucca Mountain Project Administrative Procedures (Quality) (AP-Qs), RSN Quality Assurance Program Description (QAPD), which implements the requirements of the OCRWM QARD, and applicable implementing procedures. The checklists covered QA program controls for 13 of the 20 programmatic elements or criteria of the RSN QAPD. The 13 elements evaluated were 1, 2, 3, 4, 5, 6, 7, 12, 15, 16, 17, 18, and 19. The remaining seven elements were examined to verify that RSN was inactive in these areas since they were previously identified as not applicable to the scope of work.

(b) Technical Areas

Technical products from RSN were not evaluated during this audit; however, some technical areas were audited for compliance with procedural controls.

5.2 TIMING OF THE AUDIT

The NRC staff believes the timing of the QA audit was appropriate. The RSN QAPD was accepted by OCRWM on February 22, 1991, and even though implementation was limited in some areas, this audit was useful to determine the adequacy of the RSN QA program for continuation of quality-affecting activities for YMP.

5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

The programmatic checklists covered the QA program controls for the 13 elements listed below.

- 1.0 Organization
- 2.0 Quality Assurance
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Instruction, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 12.0 Control of Measuring and Test Equipment
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits
- 19.0 Computer Software

The NRC staff observed the DOE/YMPO audit team's evaluation of selected programmatic elements of the RSN QAPD. Only portions of some elements were observed. Therefore, some programmatic 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) Organization (Criterion 1)

The observed portion of the audit of the RSN Organization consisted of an interview of the RSN Manager of QA Engineering and review of RSN organizational charts. The auditor utilized the checklists as the basis of his investigation and appeared to be thorough in his evaluation of the RSN quality system. The auditor identified a deficiency in the lack of clearly documenting the RSN organizational structure, levels of authority, and lines of communication.

Although the period of observation of this auditor was somewhat abbreviated, it is apparent that he followed the checklist, identified the area of deficiency, and was complete in covering this criterion. The audit of this section was effective. Criterion 1, except for the specific deficiency identified, is being adequately implemented.

(b) Quality Assurance Program (Criterion 2)

The auditor reviewed documentation and interviewed a number of RSN personnel to determine overall programmatic implementation with four Quality Assurance Procedures (QAP) and six Project Procedures (PP) which contained requirements related to Criterion 2.

The auditor interviewed the Manager of QA Audits and reviewed the qualification files for four RSN auditors and verified that required training, audit participation, examination, maintenance of qualification, and proper certification of qualification was completed and maintained. Each file contained a Record of Lead Auditor Qualification, Resume, and Personnel Qualification Evaluation (PQE). The PQE, which was signed by the Manager of Human Resources and the employee's Manager or Supervisor, certified that the relevant education and experience of an individual met the requirements established for the position. A file for one technical specialist indicated that the individual had received proper indoctrination and training including the completion of "Audit Guide for Technical Specialists."

It was noted that RSN has not yet certified any Level I, II, III, or QC inspection personnel, but one individual has been certified to be able to only certify inspection personnel in the future.

Fifteen individuals were selected at random from the organizational charts and their training records (TR) were reviewed. An interview with the Training Coordinator revealed that all employees, except clerical, receive training on OCRWM's QARD and RSN's QAPD. The

classroom sessions on the QARD and QAPD are given by SAIC and RSN, respectively. A data base contains a training matrix (e.g., identifies procedures) that each individual must complete prior to performing quality affecting activities. Each TR contained a Self-Study Record which a person signed and dated acknowledging that the individual read and was cognizant of the requirements contained in a particular procedure, and an Attendance Record showing that the undersigned acknowledged receipt of indoctrination or training on a particular subject (eg, QARD, QAPD). The auditor also verified that position descriptions were developed for the 15 personnel whose files were reviewed.

It was noted that RSN has not performed any management assessments on readiness reviews. Accordingly, these two areas along with the certification of inspection and QC personnel are considered to be indeterminate due to a lack of procedural implementation. Two potential deficiencies were identified dealing with responsibility for identifying individual training needs; and no documented evidence of personnel being trained to AP-Qs or procedural training for one individual.

Based on the depth of questioning and satisfactory completion of the checklist, the audit of Criterion 2 was effective. It appears that RSN is adequately implementing the area of indoctrination and training in their QA program.

(c) Design Control (Criterion 3)

The auditor evaluated the implementation of programmatic requirements for the recently completed North Area Design Study pertaining to the ESF. The auditor's checklist addressed requirements contained in ten procedures related to the design control process. Three grading reports, which cover the design activities that RSN is doing on the ESF, were reviewed. A review of structural drawings indicated that all the output documents such as drawings are in a preliminary draft stage. The drawings will be revised and finalized when all the comments from the ongoing South Area Design Study have been resolved. The design and supporting design information from the ESF Design Study will serve as a basis for the design criteria for the ESF Title II design. It was noted that internal verification of design inputs will take place during Title II. The level of detail of the drawings does not support the traceability of design input to the design output documents. "Traceability" will also be done during Title II.

The auditor verified that design information is transmitted and controlled across the interfaces between RSN and the YMP participants. A sample of a preliminary design analysis which supported the ESF Design Study output documents verified that the design analysis was subject to an interdiscipline review. In discussions with the Manager - Systems Engineering, it was noted that RSN has not submitted any information to the Technical Data Base, and RSN is in the process of putting information into the Reference Information Base. The Management Review of the ESF - North Area Design Study was evaluated, and the auditor verified that QA procedural requirements were adequately implemented.

It appears that RSN design activities are adequately documented and implemented to the extent necessary for the level of detail required for RSN activities that are currently on-going. However, specific design controls (i.e., control of design input, traceability of design input to design output, and design verification) are not yet fully implemented at this time due to the preliminary nature of the ESF design. Although the conduct of the audit in this area was effective, the adequacy of implementation is indeterminate at this time.

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

The audit of Criterion 5 was begun with a review of a controlled document computer listing of 65 sampled PPs, Procedure Interim Changes, and QAPs. The auditor and auditor-in-training (AIT) then sampled a total of 50 of the documents for review. The auditor and AIT worked as a team which was effective. The audit checklist was directly followed, and a matrix form was completed as each document was checked for the required objective evidence. The auditor had written the audit checklist questions and was thoroughly knowledgeable of the checklist requirements. Based upon the population of documents, the sample size selected was appropriate. The audit of Criterion 5 appeared to be effective, and this element of the RSN QA program is being adequately implemented.

(e) Document Control (Criterion 6)

To ensure procedures were being distributed and adequately controlled, the auditor and AIT spot checked five procedure books at various locations in the RSN organization using the RSN controlled document distribution list for the YMP. All the procedure books checked were up-to-date, except for a procedure which was obsolete and had not been removed from a majority of the RSN procedure books checked. The auditor and AIT conducted a detailed investigation of Criterion 6 related-activities, asking questions and requesting

objective evidence beyond the audit checklist questions. This portion of the audit was effective, and the NRC staff agrees with the auditor's conclusion that, except in the one instance where a superseded procedure was not withdrawn from service, the controls in this area are adequate, and program implementation was adequate.

(f) Control of Nonconforming Items (Criterion 15)

The auditor was informed that there had not been any nonconformances issued since February 22, 1991, which was the date that the RSN QA program became effective. Other interview questions were asked to ensure that there would be no activity to audit under Criterion 15, and once that was verified, the auditor promptly concluded this portion of the audit. The auditor's actions were effective and focused. However, the adequacy of the RSN QA program in this area was deemed to be indeterminate since no nonconformance reports have been issued by RSN.

(g) QA Records (Criterion 17)

This portion of the audit involved verification of RSN QA records, their maintenance, and retrievability. The auditor and AIT selected 11 records (8 documents and 3 purchase orders) from the Records Management Center master index for review. The audit team used the audit checklist and matrix they had generated for this Criterion. The RSN Chief of Records Management escorted the auditor to the Project Microfilm Center where he was shown the controls in place to ensure acceptable resolution, legibility and film quality of QA records. The auditor identified the lack of a signature on one minor document which was corrected during the audit. The AIT checked the concrete-lined storage room with a separate air conditioning system where six two-hour safes held RSN, YMP, and Reynolds Electrical & Engineering Company records. RSN has storage for its own records and is not responsible for the QA records control for the other YMP participants. After the completion of the initial records check, a random 22 individual records packages were checked, and two were found with minor problems (eg., no pagination). An additional 12 records were reviewed after they had gone through the Records Management Center, and no discrepancies were noted.

The conduct of the audit was effective, and except for isolated areas concerning records source implementation and processing of illegible records, this element of the RSN QA Program is being adequately implemented.

(h) Computer Software (Criterion 19)

This section had a lengthy audit checklist, and the auditor spent approximately 3 days in interviews and review of objective evidence. The auditor was able to review the requirements document for the computer software and compare this against the work that had been accomplished. At a number of points during the audit, potential deficiencies were identified, but later the objective evidence was produced addressing the question. The software modeling code FLAC SCML-01 was utilized as the test case. The auditor was very systematic and thorough in applying the approved checklist to the area of computer software.

The conduct of the audit of Criterion 19 was effective, and RSN is adequately implementing the portion of its software program which controls the verification of software packages. RSN is not using any validated models in quality affecting activities; therefore, this portion of their program which controls the use of verified software and validated models in quality affecting activities is indeterminate.

5.4 EXAMINATION OF TECHNICAL PRODUCTS

The NRC staff did not include any technical specialists on the NRC audit observation team since the audit team did not include any technical specialists and no assessment of technical adequacy and qualification of any of the technical products was planned for this audit.

5.5 CONDUCT OF AUDIT

The overall conduct of the audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the RSN program. The audit checklists included the important QA controls addressed in the OCRWM QARD that are applicable to the RSN program. The audit team used the comprehensive checklists effectively during the interviews with RSN personnel. In general, the team was persistent in its interviews, challenging certain RSM responses when necessary. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between RSN management and the Audit Team Leader to discuss the potential findings. The auditors who identified findings were included in these meetings to more clearly explain the deficient conditions. The findings were well substantiated and reflected significant rather than trivial issues.

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 DOE procedure for qualifying auditors.

5.7 AUDIT TEAM PREPARATION

The QA auditors were well prepared in the areas they were assigned to audit and knowledgeable in the RSN QAPD and implementing procedures. Overall Audit Plan 91-04 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 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 had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence from RSN personnel.

5.9 REVIEW OF PREVIOUS FINDINGS

This was the initial audit of RSN by DOE/YMPO. Two earlier DOE/YMPO surveillances conducted in March and June 1991 did not identify any deficiencies in the RSN QA program.

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 RSN QA program implementation.

(b) Weaknesses

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

(c) Good Practices

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

Personnel qualification records were well documented and accurate to facilitate reviews and audits.

RSN is adequately implementing that portion of their software program which controls the verification of software packages.

There is a strong commitment and support for an effective QA program at the management level. The Technical Project Officer at RSN has a good knowledge of the QA requirements and demonstrated a positive attitude toward an effective QA program.

5.11 SUMMARY - DOE/YMPO AUDIT FINDINGS

The audit team identified seven potential Corrective Action Requests (CAR) and other deficiencies that required only remedial action and were resolved during the audit. The CARs issued to RSN can be summarized as follows:

- (a) Organizational structure, levels of authority, and lines of communication are not clearly documented (Criterion 1).
- (b) Training needs for personnel are not identified by managers or line supervisors (Criterion 2).
- (c) Appropriate training not being performed (Criterion 2).
- (d) Obsolete procedure found in several controlled manuals (Criterion 6).
- (e) Material Test Laboratory does not maintain a calibration history log (Criterion 12).
- (f) Inadequate processing of QA records to the Central Records File (Criterion 17).
- (g) Implementing procedures do not identify the records package to be generated (Criterion 17).

SEP 26 1991

Mr. Dwight E. Shelor, Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U. S. Department of Energy, RW 30
Washington, D.C. 20585

Dear Mr. Shelor:

SUBJECT: OBSERVATION AUDIT OF RAYTHEON SERVICES NEVADA

I am transmitting the U.S. Nuclear Regulatory Commission (NRC) Observation Audit Report No. 91-11 for the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. YMP-91-04 of Raytheon Services Nevada (RSN) conducted at Las Vegas, Nevada from July 29 - August 1, 1991. The NRC staff evaluated the DOE/YMPO QA audit to gain confidence that DOE and RSN are properly implementing the requirements of their QA programs. The NRC staff based its evaluation of the DOE/YMPO audit process and the RSN QA program on direct observations of the auditors, discussions with the audit team and RSN personnel, and reviews of the pertinent audit information (e.g., audit plan, checklists, and RSN documents).

The NRC staff has determined that DOE/YMPO QA Audit No. YMP-91-04 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 discipline, and their assignments and checklist items were adequately described in the audit plan. The audit team did not include any technical specialists. Some technical areas were audited for compliance to procedural controls (i.e., computer software), but no evaluation was made of the technical adequacy of work products.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that the RSN QA program has adequate procedural controls in place, and that program implementation is adequate in eight of the thirteen areas audited. The other five areas were considered indeterminate due to a lack of quality affecting activities being conducted in these areas.

DOE should monitor the RSN program to ensure that the seven preliminary deficiencies identified during this audit are corrected in a timely manner and future implementation is carried out in an effective manner. 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 RSN QA program.