
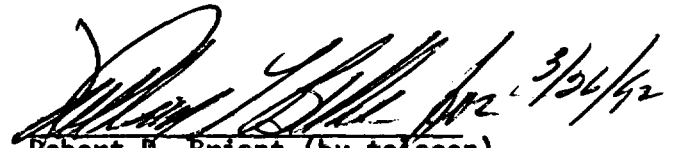



U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-08
FOR THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. HQ-92-02 OF
OAK RIDGE NATIONAL LABORATORY


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1.0 INTRODUCTION

From February 24-26, 1992, 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. HQ-92-02 of Oak Ridge National Laboratory (ORNL) in Oak Ridge, Tennessee. A portion of this audit, which was not observed by NRC staff, was conducted at the offices of E. R. Johnson Associates, Inc., in Oakton, Virginia on February 27, 1992.

This report addresses the effectiveness of the DOE/OCRWM audit and the adequacy of the ORNL QA program.

2.0 OBJECTIVES

The objective of the DOE/OCRWM audit was to evaluate the implementation and effectiveness of the ORNL 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 DOE/OCRWM and ORNL are properly implementing the requirements of their QA programs in accordance with the QARD and Title 10 Code of Federal Regulations (10 CFR) Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/OCRWM audit process and the ORNL QA program on direct observations of the auditors, discussions with the audit team and ORNL personnel, and reviews of the pertinent audit information (e.g., audit plan, checklists, and ORNL 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 assignment and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team findings that the ORNL QA program has adequate procedural controls in place for the items that were audited, and program implementation is adequate for six of the ten criteria that were audited. The audit team found one criterion not being effectively implemented; one criterion indeterminate due to lack of significant quality affecting activities; and two criteria to be not applicable to the ORNL scope of activities.

DOE/OCRWM should monitor the ORNL QA program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own audits at a later date to assess the adequacy and effectiveness of the ORNL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

William L. Belke	Observation Team Leader
Robert D. Brient	Observer (Center for Nuclear Waste Regulatory Analyses)

4.2 DOE

R. Dennis Brown	CER Corp.	Audit Team Leader (ATL)
Fred Bearham	CER Corp.	Auditor
Rodney Schaffer	Roy F. Weston, Inc.	Auditor
Robert Clark	DOE, Headquarters	Observer (Audit Manager)
Tien Nguyen	DOE, Headquarters	Observer (Project Coordinator)

4.3 TRW Environmental Safety Systems, Inc.

Camille Kerrigan	Observer
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5.0 REVIEW OF THE AUDITED ORGANIZATION

The DOE/ORNL 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 ORNL 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 the implementation and effectiveness of the QA controls applied to ORNL activities affecting quality. The scope of the audit included site characterization activities concerning the Waste Stream Analysis Model and Waste Characteristics Data Base, primarily based upon the revisions of the implementing procedures in effect when the particular activity was performed.

(a) Programmatic Elements

The auditors used checklists based on the requirements in the ORNL Quality Assurance Program Description (QAPD) Sections 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 17.0, and 19.0 (10 CFR Appendix B Criteria I, II, III, IV, V, VI, VII, and XVII), and other applicable documents pertaining to QA controls.

(b) Technical Areas

Technical products from ORNL were not evaluated during this audit.

5.2 Timing of the Audit

The NRC staff believes the timing of the ORNL QA audit was appropriate. This audit was originally scheduled in fall 1991, however, during the planning for the 1991 audit, it was found there were no implementing procedures written. In addition, the ORNL QA program was under review by DOE and finally accepted on February 24, 1992. Consequently, procedures were developed and submitted to OCRWM for review and approval. OCRWM plans that the Management and Operating Contractor (M&O) will take over the majority of the ORNL activities in late Fiscal Year 1992 and therefore, only 8 implementing procedures were developed, instead of the originally planned 19. Even though implementation of certain areas was limited, the audit was useful to determine the adequacy of the ORNL QA program for the initiation of quality-affecting activities and capability to do so in the future.

5.3 Examination of Programmatic Elements

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

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control (limited)
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 17.0 Quality Assurance Records
- 19.0 Computer Software

The NRC staff observed the audit team's evaluation of selected programmatic elements of the ORNL 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) Quality Assurance Program (Criterion 2)

The checklist prepared for this portion of the audit was based on procedure QA-SI-02-002, "Indoctrination and Training." The auditor's investigations were thorough, and included a review of a significant number of personnel qualification packages and all three QA Controls Matrices. The NRC observer noticed that QA-SI-02-002 did not include acceptance criteria for several required reviews, which resulted in a recommendation to ORNL from the auditors.

The audit of this area was effective, and ORNL implementation under this criterion was adequate.

(b) Peer Review (Criterion 3)

ORNL is utilizing Peer Review to qualify existing data, specifically to qualify the "Characteristics of Potential Repository Waste" (DOE/RW-0184), which was developed outside of QA program controls. The Peer Review was in progress during the audit, with reviewer qualification, review comments, and comment resolution documentation available for review. A surveillance is planned, with technical specialists on the surveillance team, when the Peer Review activity is complete.

The DOE/OCRWM audit checklist was prepared based on the Peer Review Plan, which provides detailed requirements for all phases of the activity, from reviewer selection and qualification through comment resolution and review report preparation. The auditor evaluated packages for 7 of the 29 reviewers which included reviewer qualification and comment resolution documentation. The auditor identified deficiencies in reviewer qualification documentation, and a Corrective Action Request (CAR) was initiated.

The auditor was well prepared and knowledgeable in the requirements which he was auditing and persistent in his interviews and document reviews. The auditor used the published checklist effectively during the audit process and the audit in the area of Peer Review was observed to be effective. The NRC staff agrees with the audit team's conclusion that the ORNL implementation of the QA program for Peer Review was adequately implemented.

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

The audit checklist was based on procedures QA-SI-05-001, "Procedure Preparation" and QA-SI-05-002, "Document Reviews." The checklist did not cover 10 CFR Part 50 Appendix B Criterion 5 requirements to determine that a) activities affecting quality are prescribed by documented instructions or, b) instructions include quantitative or qualitative acceptance criteria. For a first time audit, these basic Criterion 5 requirements should have been evaluated to determine whether procedures are adequately implementing the requirements established in the ORNL QAPD. However, as the audit progressed, the auditors evaluated the procedures in combination with the audit process.

The eight procedures in effect and associated review documentation were evaluated. All were QA procedures, written by the ORNL/OCRWM Programs QA Specialist, and were reviewed by the (technical) Task Managers. The auditor recommended to ORNL that QA procedures receive an independent QA review.

Controls required by the combination of the ORNL QAPD, ORNL procedures, and DOE/OCRWM HQ QA Administrative Procedures appeared adequate, however they should be reevaluated with the change of tasks to the M&O and with other changes in the scope of work.

The audit of this criterion was effective and the programmatic implementation was adequate.

(d) Software Controls (Criterion 19)

The audit checklist was based on procedures QA-SI-19-001, "Computer Code Verification and Validation," and QA-SI-19-002, "Computer Code Transfer." The majority of this part of the audit was conducted at E. R. Johnson Associates, Inc., a consulting contractor, and was not observed by the NRC staff.

At ORNL, discussions were held with the ORNL Technical staff regarding controls applied or to be applied to the ORIGEN2 computer code. The ORIGEN code is used to predict the concentrations and radiological characteristics of individual isotopes in nuclear fuel and the products (including wastes) of processing spent fuel when their initial compositions and the burnup characteristics are known. The ORIGEN code has been in use in the nuclear industry since its development in 1973. For the application to the ORNL scope of activities toward the high-level waste repository, the ORIGEN code has never been verified or validated. Therefore, to fully qualify the data generated under the ORIGEN2 code, an extensive peer review process has been initiated (see Item 5.3 (b) above).

Although the ORNL QAPD requires that Software QA Plans be developed for each code, the ORIGEN2 development activities have not yet progressed to the point that software controls should be applied, but the DOE/OCRWM HQ staff present during the audit agreed that a hold point should be applied to prevent the use of ORIGEN2 for quality-affecting activities until appropriate software controls are in place. DOE indicated that any future development to the ORIGEN2 code will be accomplished in accordance with the ORNL QAPD controls and will verify this through future programmatic and technical audits and surveillances.

The audit of this area was effective however, the implementation was indeterminate due to the lack of development or implementation of software controls.

5.4 Conduct of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the ORNL QA program. The audit checklists generally included the important controls addressed in ORNL's QAPD. The audit team used the comprehensive checklists effectively during the interviews with personnel and review of documents. In general, the audit team was persistent in its interviews, challenging responses when necessary. Observers were kept informed during the entire audit.

5.5 Qualification of Auditors

The qualification of the QA auditors on the audit team are acceptable to the NRC staff based on meeting the requirements of QMP-02-02, the Yucca Mountain Site Characterization Project Office procedure for qualifying auditors.

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and knowledgeable in the ORNL QAPD and implementing procedures. Overall, Audit Plan HQ-92-02 was complete and included: (1) the audit scope; (2) a list of audit team personnel; (3) a list of the audit activities; (4) the audit notification letter; (5) the ORNL QAPD; (6) the QA programmatic checklists; and (7) the past internal audit report.

5.7 Audit Team Independence

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

5.8 Review of Previous Audit Findings

There were no previous audit findings to resolve since this was the first audit of ORNL by DOE.

5.9 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 ORNL QA program implementation.

(b) Weaknesses

The audit could have been enhanced by evaluating the ORNL procedures for adequacy as well as evaluating for implementation. The checklist would have benefitted from a more comprehensive set of requirements beyond those found in a limited group of procedures.

The observers received the audit notebook just one working day prior to the audit. It is recognized that NRC agreed with DOE that the audit notification letter would be furnished to NRC in advance, and the audit books (including the audit checklists, procedures etc.) at the audit. It appears that this method is not working in an effective manner, since it does not allow time for adequate preparation for the audit by the observers. Observers now need to ask

questions that could have been answered or tracked down had the audit book been provided a week in advance and often interfere with the auditor's time during the audit. Therefore, it is recommended that DOE reconsider providing the observers the audit book at least a week prior to the audit to allow ample time for observers to prepare for the audit.

(c) Good Practices

At the audit entrance meeting, there was a presentation from ORNL personnel to explain their activities and the status of the work being accomplished. Since the audit observers are not part of the audit scoping process, this presentation was beneficial to the audit observers in order to determine whether the audit team has selected the proper sample and scope from which the audit is based on.

The NRC staff recognizes that this audit was not intended to be technical in nature. The DOE audit team was accompanied by two technical observers. When issues of a technical nature surfaced, the two technical observers were able to constructively contribute and assist in resolving questionable issues. The NRC staff recommends DOE continue to include at least one technical observer on future audits of this nature.

The ORNL staff demonstrated a positive attitude and knowledge of the ORNL QAPD and implementing procedures. The ORNL staff took immediate corrective action to correct any deficiencies identified by the auditors.

5.10 Summary - DOE Audit Team Findings

The audit team identified two potential CARs written against the ORNL QA program. These CARs are as follows:

- (a) Procurement documents did not contain applicable ORNL QA program requirements (Criterion 4).
- (b) Several Peer Review packages did not contain the necessary documentation to substantiate the individual's qualification. Also, several examples existed where Certification of Independence forms were not complete (See Section 5.3 (b)).