

**U.S. DEPARTMENT OF ENERGY**  
**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**  
**OFFICE OF QUALITY ASSURANCE**

**AUDIT REPORT OF**  
**OAK RIDGE NATIONAL LABORATORY ACTIVITIES**

**AUDIT NO. HQ-92-02**  
**FEBRUARY 24 THROUGH 26, 1992**

Prepared by: R. Dennis Brown  
R. Dennis Brown  
Audit Team Leader  
Headquarters Quality Assurance Division

Date: April 22, 1992

Approved by: R. W. Horton  
for Donald G. Horton  
Director  
Office of Quality Assurance

Date: 5/29/92

## **EXECUTIVE SUMMARY**

This report contains the results of Audit HQ-92-02 of Oak Ridge National Laboratory (ORNL) that was conducted on February 24-26, 1992. The audit team evaluated ORNL implementation of their Quality Assurance Program Description (QAPD).

The Oak Ridge OCRWM Programs group (also known as Systems Integration) has been performing two quality affecting tasks for approximately one year. One task is to verify that the Waste Stream Analysis (WSA) Computer Program correctly calculates the quantities, identity and characteristics of spent fuel and loaded fuel containers, and correctly selects both fuel and containers for all various transportation/storage options. The other task is to perform a formal peer review of the Waste Characteristics Data Base since the data was not collected in conformance with an OCRWM approved QA program. The Data Base is a single, unified source of detailed technical data on potential repository wastes (such as physical descriptions, chemical compositions, and radiological properties).

Only ten QARD criteria apply to the work being performed and all ten were addressed during this audit.

Six of the ten audited criteria were considered to be satisfactorily implemented. Three criteria were found to be indeterminate and one was found to be unsatisfactory.

In general, the ORNL QA Program is being effectively implemented. Three Corrective Action Requests (CARs) were written to document deficiencies that required more than remedial action to correct. Ten recommendations were written for ORNL management's future consideration.

## 1.0 INTRODUCTION

The OCRWM performed an external quality assurance audit (Number HQ-92-02) of ORNL activities February 24-26, 1992. The audit was conducted by the Headquarters Quality Assurance Division (HQAD). The audit was performed in accordance with Quality Assurance Administrative Procedure (QAAP) 18.2, *Audit Program*, Rev. 5 and the associated audit plan [reference letter from RW-3 to Manager, Office of Civilian Radioactive Waste Programs, ORNL (MMES) dated February 10, 1992].

## 2.0 SCOPE

The audit evaluated compliance to and the effectiveness of the ORNL QA program as described in the ORNL QAPD and supporting procedures.

The audit scope included two tasks which ORNL personnel were working on at the time of the audit. One task was to verify that the Waste Stream Analysis (WSA) Computer Program correctly calculates the quantities, identity and characteristics of spent fuel and loaded fuel containers, and correctly selects both fuel and containers for various transportation/storage options. The other task was to perform a formal peer review of the Waste Characteristics Data Base (CDB) since the data was not collected in conformance with an OCRWM approved QA program. The Data Base is a single, unified source of detailed technical data on potential repository waste (e.g., physical descriptions, chemical compositions, and radiological properties).

### 2.1 QA Program Elements

Implementation of the following criteria was evaluated during the audit:

- |    |   |   |
|----|---|---|
| 1  | - | Organization                            |
| 2  | - | Quality Assurance Program               |
| 3  | - | Design Control                          |
| 4  | - | Procurement Document Control            |
| 5  | - | Instructions, Procedures, and Drawings  |
| 6  | - | Document Control                        |
| 7  | - | Control of Purchased Items and Services |
| 16 | - | Corrective Action                       |
| 17 | - | Quality Assurance Records               |
| 19 | - | Computer software                       |

The audited requirements were drawn from the DOE/RW-0214, *Quality Assurance Requirements Document* (QARD); QAP-X-91-WMRD-045, ORNL *Quality Assurance Program Description Document* (QAPD); the Peer Review Plan for the Waste Characteristics Data Base; and applicable ORNL Quality Assurance Procedures.

## **2.2 Technical Areas**

The inclusion of Technical Specialists on the audit team was not deemed necessary considering the status of activities.

## **3.0 AUDIT TEAM AND OBSERVERS**

The following is a list of audit team members (see Attachment 1 for assigned areas of responsibility) and Observers.

Audit Team Leader	R. Dennis Brown	CER Corporation
Auditors	Fred Bearham Rod Schaffer	CER Corporation Weston
Observers	Robert Clark (Oak Ridge) Bill Belke (Oak Ridge) Bob Brient (Oak Ridge)  Camille Kerrigan (Oak Ridge) Ivan Sacks (Oakton) Tien Nguyen (Oak Ridge)	DOE, HQAD US Nuclear Regulatory Commission US Nuclear Regulatory Commission (Southwest Research Institute) TRW TRW OCRWM DOE, HQ

## **4.0 SUMMARY OF AUDIT RESULTS**

### **4.1 Program Effectiveness**

The audit team concluded that, in general, the ORNL QA Program is being effectively implemented.

The following criteria were being satisfactorily implemented.

- 1 - Organization
- 2 - Indoctrination and Training, QA Controls
- 3 - Peer Review (Characteristics Data Base)
- 5 - Instructions and Procedures
- 6 - Document Control
- 17 - QA Records

Due to the issuance of Corrective Action Request (CAR) HQ-92-007, implementation of Criterion 4, Procurement Document Control, was considered unsatisfactory.

Due to the lack of a significant amount of quality affecting activities, it was not possible (therefore indeterminate) to determine the level of compliance of Criterion 19, Computer Software, for Waste Stream Analysis activities.

During the audit it was also determined that no implementation of the following criteria had occurred.

- 7 - Control of Purchased Services
- 16 - Corrective Action

As identified in the Audit Plan, the following criteria were not applicable to the Oak Ridge scope of work and therefore not applicable to this audit.

- 3 - Design Control (except for peer review)
- 8 - Identification and Control of Materials, Parts, and Components
- 9 - Special Processes
- 10 - Inspection
- 11 - Test Control
- 12 - Control of Measuring and Test Equipment
- 13 - Handling, Storage, and Shipping
- 14 - Inspection, Test, and Operating Status
- 15 - Control of Nonconforming Items
- 18 - Audits

#### **4.2 QA Programmatic Audit Activities**

Details of audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

#### **4.3 Technical Audit Activities**

Even though there were no formal Technical Specialists, several of the Observers were asked to review certain documents for adequacy. This was done under the direct supervision of the Audit Team Leader. These individuals reviewed the qualification records of technical personnel (Peer Reviewers).

#### **4.4 Summary of Deficiencies/Recommendations**

The audit team identified three deficiencies during the audit that have been documented in three CARs as discussed in Subsection 6.1, Corrective Action Requests. Information copies of the CARs are included in Attachment 4. Ten recommendations were identified as discussed in Section 7.0, Recommendations.

#### **4.5 Miscellaneous**

The audit team did pursue one area of inquiry regarding the extent of verification/validation and configuration management controls that were being implemented for the ORIGIN 2 code. Though this area was outside the scope of the audit it was pursued in order to avoid potential future difficulties with future revisions or applications of the code. The resident expert on the code provided clarification on his responsibilities for running the program as well as how the program was controlled by the Radiation Shielding Information Center (RSIC). It was found that no formal QA controls were in place to verify/validate and manage the configuration of the code. One recommendation resulted as a consequence of the discussion. The details are provided in Section 7.0, Recommendations.

#### **5.0 AUDIT MEETINGS AND PERSONNEL CONTACTED**

The preaudit meeting was held at ORNL in Oak Ridge, Tennessee on February 24, 1992. A daily debriefing was attended by ORNL management and staff regarding the status of the audit in their respective areas. The postaudit conference was held in the ORNL Offices on February 26, 1992. A list of personnel contacted during the audit is contained in Attachment 5. (Note: The audit team also visited the offices of E.R. Johnson [subcontractor to ORNL] in Oakton, Virginia on Friday, February 21, 1992.)

#### **6.0 SYNOPSIS OF CORRECTIVE ACTION REQUESTS (CARs) ISSUED**

##### **6.1 Corrective Action Requests (CARs)**

###### **CAR - HQ-92-006**

Peer Review personnel qualification packages did not comply with the requirements in the Peer Review Plan.

###### **CAR - HQ-92-007**

Subcontractor procurement documents did not contain all applicable QA program requirements. In addition, the QA and technical reviews were not being consistently performed for subcontractor procurement documents.

###### **CAR - HQ-92-008**

No evidence was available to indicate that the education and experience of personnel performing quality affecting activities had been verified.

See Attachment 4 for additional details.

## **7.0 RECOMMENDATIONS**

### **Criterion 1**

The reporting relationship of the ORNL Quality Assurance Specialist to the OCRWM Program should be identified and proceduralized.

### **Criterion 2**

Subparagraph 8.8 of Procedure QA-SI-02-001, "Establishing Quality Assurance Controls", requires that a copy of the QA Controls Matrix be forwarded to the appropriate OCRWM Program Manager. Only the matrix for the ORIGIN 2 code had been transmitted (on December 26, 1991) to the appropriate OCRWM Program Manager. It is recommended that the two remaining matrices for the WSA and the CDB be forwarded to the appropriate OCRWM Program Manager as soon as possible.

### **Criterion 3**

Two slightly different versions of the Waste Characteristics Data Base Peer Review Plan are on file. A memorandum to file should be written to identify the correct version.

### **Criterion 5**

QA procedures should receive an independent QA review. Currently the review process is limited to the three principle users.

Acceptance criteria should be established for reviews of QA procedures and other controlled documents.

### **Criterion 17**

It is recommended that a transition plan be prepared by ORNL that addresses the turnover of QA Records to the M&O contractor. The plan should, as a minimum, address the validation of documents and should identify the OCRWM requirements for document transmittals.

Line procedures have not been developed up to this point because they have not yet been necessary. Project personnel have acknowledged that a procedure will be necessary to address the details of the turnover of these QA Records to the M&O contractor. The audit team recommends that the procedure be prepared along with the transition plan referenced above.

ORNL procedure QA-SI-17-001, "Quality Assurance Records", should be revised to require validation of QA records prior to transmittal to storage.

**Criterion 19**

Several items need to be addressed by E.R. Johnson prior to issuance of the final Waste Stream Analysis Verification Report:

- the independence of B. McLeod
- additional discussion on the "Small/Large Pool capacity" (spent fuel pool) related to selection of test case reactors
- hand calculations for verification of "SAS" reports were not being consistently initialled and dated.

The audit team recommends that a hold point be initiated by DOE for controlling the application of the ORIGEN 2 code on activities associated with the Characteristics Data Base; the hold point would provide assurance that work would not begin before controls are established and implemented that address baselining, the verification and validation, and configuration management for the computer software.

**8.0 LIST OF ATTACHMENTS**

- Attachment 1: Audit Team Assignments
- Attachment 2: Audit Details
- Attachment 3: Objective Evidence
- Attachment 4: Corrective Action Requests - Information Copies
- Attachment 5: Personnel Involved in the Audit

**ATTACHMENT 1**  
**AUDIT TEAM ASSIGNMENTS**

Audit Team Leader: R. Dennis Brown

<u>Personnel</u>	<u>Criteria</u>	<u>OAPs/Other Procedures</u>
R. Dennis Brown	1, 3, 4, 7, 16	CDB Peer Review Plan; QAPD
Fred Bearham	5, 6, 17	05-001; 05-002; 06-001; 17-001
Rod Schaffer	2, 3, 19	02-001; 02-002; 19-001; 19-002; Verification Plan for WSA Model

## ATTACHMENT 2

### AUDIT DETAILS

#### **1.0 ORGANIZATION**

The evaluation of this Criterion was based on personnel interviews and a review of the current ORNL organizational structure. Each task group was adequately staffed for their present scopes of work. Lines of authority, responsibility, and organizational interfaces were adequately defined so that quality issues were appropriately identified and acted upon. It was identified that the QA Specialist reporting relationship to OCRWM was not clear.

#### **2.0 QA PROGRAM**

##### **2.1 INDOCTRINATION AND TRAINING**

The audit team reviewed the available training files to verify compliance to ORNL Procedure QA-SI-02-002, "Indoctrination and Training". The folders presented for review contained a letter dated February 7, 1992 to the project team at E.R. Johnson that identified appropriate training requirements. The letter also transmitted the ORNL QAPD and copies of the procedures referenced on attached Indoctrination and Training (I&T) Matrices. The audit team also reviewed the response letter to ORNL that transmitted the completed I&T Matrices, position descriptions, and the resumes of each person identified on an I&T Matrix.

Subparagraph 8.8 of Procedure QA-SI-02-001, "Establishing Quality Assurance Controls", requires that a copy of the QA Controls Matrix be forwarded to the appropriate OCRWM Program Manager. Only the matrix for the ORIGIN 2 code had been transmitted (on December 26, 1991) to the appropriate OCRWM Program Manager. It is recommended that the two remaining matrices for the WSA and the CDB be forwarded to the appropriate OCRWM Program Manager as soon as possible.

It was determined that the qualifications of personnel designated as performing quality affecting activities were not being verified as required by DOE/RW-0214 Paragraph 2.8. No formal ORNL management verifications of education or employment had been performed. See CAR HQ-92-008.

##### **2.2 ESTABLISHING QUALITY ASSURANCE CONTROLS**

The audit team reviewed available documentation to determine compliance with ORNL procedure QA-SI-02-001, titled "Establishing Quality Assurance Controls." The auditors reviewed the QA Controls Matrix initiated for each of the quality affecting activities against the criteria established in the Guidance Letter dated December 13, 1991. During the review of the file the audit team determined that only one of the Matrices had been forwarded to the OCRWM Manager. This was the Matrix for the ORIGIN 2 code. The Matrix for the Waste Stream Analysis had not been sent. The audit team suggested that both of the Matrices be forwarded to correct the oversight.

### **3.0 DESIGN CONTROL (PEER REVIEW)**

The only Criterion 3 activity at ORNL is the peer review of the Waste Characteristics Data Base. A peer review plan was approved and issued in February of 1991. The auditors used the plan as the basis for auditing this area since it was previously established that the plan met the requirements of QAAP 3.3, "Peer Review".

Two slightly different versions of the Waste Characteristics Data Base Peer Review Plan are on file. A memorandum to file should be written to identify the correct version.

Seven sub-review panels were established by the ORNL Task Manager. The audit team reviewed the assignment and subsequent qualification records for the panel members. Several inconsistencies were identified during the review of qualification records for the Peer Reviewers. See CAR HQ-92-006.

### **4.0 PROCUREMENT DOCUMENT CONTROL**

The audit team interviewed ORNL personnel to determine procedural compliance regarding procurements. The team reviewed recent procurements issued to the three subcontractors working on the OCRWM tasks: E.R. Johnson and Associates, ASG, and David Andress and Associates. Several deficiencies were identified during the review of these procurement documents. See CAR HQ-92-007.

### **5.0 INSTRUCTIONS AND PROCEDURES**

The audit team reviewed ORNL QA Procedure QA-SI-05-001, "Procedure Preparation", and interviewed ORNL personnel to determine compliance with the procedure. Eight QA procedures required by DOE to be in place during FY92 were issued during January 1992. Eleven others were delayed until FY93; justification for the delayed issue of each procedure was documented by DOE.

The auditors selected Procedures QA-SI-02-002 ("Indoctrination and Training"), QA-SI-17-001 and QA-SI-19-002 ("Computer Software Transfer") for review and determined that the implementation of QA-SI-05-001 was satisfactory for these procedures. The auditors reviewed the selected procedures for compliance with requirements for style, format, control of draft procedures, comment review controls, and maintenance of records associated with QA procedure preparation.

The auditors selected the same three documents to verify compliance to QA Procedure QA-SI-05-002, "Document Reviews". It was noted the review of draft QA procedures was limited to three ORNL staff and that they did not always respond. However, it was established that prior to issue of the procedures, the preparer and the staff met with the Project Manager to review and comment on the procedures. It was recommended that an independent QA individual be included in the review cycle.

The review of this area identified that no line procedures had been developed. Up to this point there has not been a need to issue any. Responsibility for ORNL activities will eventually be

transferred to the M&O contractor, at which point an implementing procedure will be necessary to control the turnover of records.

#### **6.0 DOCUMENT CONTROL**

The auditors reviewed QA Procedure QA-SI-06-001, Rev. 0, "Document Control", and interviewed ORNL personnel to determine compliance with the procedure. Controlled Document Transmittals (CDT's) were reviewed for distribution of eight QA procedures to eight staff personnel. The auditors verified that the QA Specialist is assigned as the Controlled Document Custodian. The auditors verified that CDTs were retained as quality records.

It was noted that controlled documents are identified as QA Records and that uncontrolled documents are stamped to identify their status.

It was determined that a Task Leader had not been formally designated to control the initiation and issuance of procedures. A memo designating the QA Specialist as the procedures Task Leader was issued by ORNL management prior to the end of the audit.

#### **7.0 CONTROL OF PURCHASED SERVICES**

This area was deemed not applicable because all ORNL subcontractors were working to the ORNL QAPD and its implementing procedures.

#### **17.0 QUALITY ASSURANCE RECORDS**

The auditor reviewed QA procedure QA-SI-17-001, interviewed the ORNL staff, and visited the Duplicate Records Storage Facility (DRSF) located at the Oak Ridge National Laboratory. The QA Specialist is assigned as the records custodian for the Systems Integration (SI) office and the DRSF. The records index was reviewed and a sample of records at the SI and DRSF compared. The sample included I&T Matrices, QA control matrices, audit records, general correspondence, and peer reviews. All records were in compliance with the procedure.

It is recommended that a transition plan be prepared by ORNL that addresses the turnover of QA Records to the M&O contractor. The plan should, as a minimum, address the validation of documents and should identify the OCRWM requirements for document transmittals. Line procedures have not been developed up to this point because they have not yet been necessary. Project personnel have acknowledged that a procedure will be necessary to address the details of the turnover of these QA Records to the M&O contractor. The audit team recommends that the procedure be prepared along with the transition plan referenced above.

Records at the DRSF are stored in locked file cabinets in a secure building with controlled access.

#### **19.0 COMPUTER SOFTWARE**

The audit began at the offices of E.R. Johnson and Associates in Oakton, Virginia on February 21, 1992. E.R. Johnson and Associates is a subcontractor of Oak Ridge National Laboratories.

The audit team concentrated on reviewing computer code(s) associated with the Waste Stream Analysis to verify compliance with two ORNL QA procedures and the approved verification plan. The Waste Stream Analysis was the only ORNL activity being performed at the E.R. Johnson facility.

The audit team reviewed ORNL's "Computer Code Verification Plan for the Waste Stream Analysis Program" to determine compliance to ORNL Procedure QA-SI-19-01, "Computer Code Verification and Validation". The procedure describes the basic requirements for the content and format for the report required by the plan.

The audit team also reviewed E.R. Johnson's "Computer Code Verification Report for the Waste Stream Analysis Program". The audit, the report was not complete and was still only an internal working document, which was not yet a QA record. Personnel at E.R. Johnson indicated that the verification was approximately 98% complete. The draft report was reviewed to the extent possible to the requirements of the procedure (also NUREG-0856). Portions available for review appeared to address the basic requirements.

Personnel were cognizant of requirements and were making efforts to comply with procedures. However, special attention needs to be given concerning the independence of the personnel and initialing of hand calculations supporting the WSA verification effort.

During the review for compliance with ORNL Procedure QA-SI-19-002, "Computer Software Transfer", the audit team was informed that the procedure did not need to be implemented since no software had been transferred to them from Oak Ridge. The software they were using had come from DOE and was controlled by DOE. It was later determined that the software is under the control of the Energy Information Administration (DOE).

The WSA code was "frozen" on 5/6/91 and will remain frozen, until ongoing verification is completed.

Phase I work was essentially completed in November of 1991. Test Cases 2 and 8 still need to be modified slightly.

Work on Phase II has proceeded slowly due to a backlog of other E.R. Johnson work. The Phase II work is expected to be completed by March 31, 1992. At this point, the draft verification report will be completed. The report review should be done by May 31, 1992 and the final verification report should be issued by July 31, 1992.

The audit team verified that Test Cases 1 and 3a included the following items required by the WSA Verification Plan:

- Reactor Base Mix
- Fuel Acceptance Rate
- Configuration
- Test Criteria (fuel discharge rates)
- Reports to be Tested
- Case Perturbations

Several items need to be addressed by E.R. Johnson prior to issuance of the final Waste Stream Analysis Verification Report:

- the independence of B. McLeod
- additional discussion on the "Small/Large Pool capacity" (spent fuel pool) related to selection of test case reactors
- hand calculations for verification of "SAS" reports were not being consistently initialled and dated.

The audit team requested that E.R. Johnson personnel actually input given data to Test Case 3a. Their personnel used a modem to access the DOE mainframe which contained the source code. Sample data was entered into the Test Case (3a). The output for Jobs 2053 and 2187 matched expected values. A hard copy printout for these jobs was later transmitted to CER. The values were checked and found to be accurate.

The audit team verified that B. McLeod has the only account number for accessing the WSA code.

Auditors also reviewed records on verification of approximately 40 "SAS" reports. These reports consisted of numerous hand calculations to verify various computer sub-programs related to the Test Cases.

**ATTACHMENT 3**  
**OBJECTIVE EVIDENCE**

**Documents Reviewed**

1. Computer Code Verification Report for the Waste Stream Analysis Program (undated draft)
2. Computer Code Verification Plan for the Waste Stream Analysis Code, dated April 10, 1991
3. QA Controls Matrices for:
  - Waste Stream Analysis
  - Characteristics Data Base
  - ORIGEN 2
4. Training Files for ORNL staff and contractors (12 separate files)
5. Position Descriptions
6. Memos of Management evaluations of Personnel qualifications
7. Purchase Orders to E.R. Johnson and Associates
  - Feb. 27, 1989
  - Dec. 13, 1989
  - Feb. 8, 1991
  - March 11, 1991
- Purchase Orders to David Andress and Associates
  - Dec. 13, 1989
  - Dec. 11, 1990
  - May 00, 1991
  - June 00, 1991
  - Jan. 6, 1992 (in process)
- Purchase Orders to ASG
  - Feb. 16, 1989
  - Feb. 6, 1991
  - Nov. 27, 1991
8. List of Peer Review Panel Members (all seven Panels - 29 Members)

9. Records of "Certifications of Independence" for Mendel, Watrous, Harrison, Giesler, Leider, M. Smith, Wheeler, Coony, Palmer, Bendixsen, Godbee, and Plodinec.
10. Qualification Records for Mendel, Watrous, Harrison, Giesler, Leider, M. Smith, Wheeler, Coony, Cowart and Pope.
11. Indoctrination and Training Records for Peer Reviewers (Mendel, Watrous, Harrison, Giesler, Leider, M. Smith, Wheeler, Coony, Cowart and Pope).
12. Various schedules for Completion of the Peer Review Plan.
13. Comment Review Sheets for the Peer Review Plan (reviewed ten sets of comments).
14. Letters approving substitution of Panel Members (four letters were reviewed).
15. ORNL QA Procedures
  - QA-SI-02-001
  - QA-SI-02-002
  - QA-SI-05-001
  - QA-SI-05-002
  - QA-SI-06-001
  - QA-SI-17-001
  - QA-SI-19-001
  - QA-SI-19-002

**ATTACHMENT 4**

**CORRECTIVE ACTION REQUESTS - INFORMATION COPIES**

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

CAR NO. HO-92-008  
DATE: N/A  
PAGE: 1 OF 1  
QA

**CORRECTIVE ACTION REQUEST**

<p><sup>1</sup> Controlling Document Peer Review Plan for Revision 1 of DOE/RW-0184, February 15, 1991</p>	<p><sup>8</sup> Related Report No. Audit HQ-92-02</p>
<p><sup>3</sup> Responsible Organization Systems Integration Support, MMES</p>	<p><sup>4</sup> Discussed With Ron Pope, Glenn Cowart</p>

<sup>5</sup> Requirement:

A. The Plan requires that each Peer Reviewer identifies his/her degrees obtained, when and where obtained, areas of specialization, special training courses, brief summary of work experience, and evidence that the individual would be technically capable of having written the section under review.

B. The Plan requires that each Peer Reviewer complete a "Certification of Independence" prior to each review.

C. The Plan requires that the applicable Task Manager confirm the Peer Review Group Chairman's decision to substitute or add panel members.

<sup>6</sup> Adverse Condition:

A. Contrary to the above, the audit team sampled seven (29 qualification packages are on file) and found that four did not have enough of the documentation required above to substantiate the individual's qualification.

B. Contrary to the above, four of eleven sampled Peer Reviewers have not completed their "Certifications of Independence" forms.

C. Contrary to the above, there was no formal evidence that the CDB Task Manager has confirmed the substitution of two Peer Reviewers (Rahimi and Piscitella for Newberry and Jarret). The auditors sampled five panel member substitutions.

<p><sup>9</sup> Does a significant condition adverse to quality exist? Yes <u>    </u> No <u>X</u> If Yes, Circle One: A B C</p>	<p><sup>10</sup> Does a stop work condition exist? Yes <u>    </u> No <u>X</u> ; If Yes - Attach copy of SWC If Yes, Circle One: A B C D</p>	<p><sup>11</sup> Response Due Date:  04/13/92</p>
--	--	---

<sup>12</sup> Required Actions: ☒ Remedial ☒ Extent of Deficiency ☐ Preclude Recurrence ☐ Root Cause Determination

<sup>13</sup> Recommended Actions:

Review all Peer Review qualification packages and update as necessary to comply with requirements.

<p><sup>7</sup> Initiator Dennis Brown <i>Dennis Brown</i> Date 2/26/92</p>	<p><sup>14</sup> Issuance Approved by: QADD <i>R.W. Clark</i> Date 3/11/92</p>
<p><sup>15</sup> Response Accepted QAR Date</p>	<p><sup>15</sup> Response Accepted QADD Date</p>
<p><sup>17</sup> Amended Response Accepted QAR Date</p>	<p><sup>16</sup> Amended Response Accepted QADD Date</p>
<p><sup>18</sup> Corrective Actions Verified QAR Date</p>	<p><sup>20</sup> Closure Approved by: QADD Date</p>

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

**CAR NO.** HO-92-007  
**DATE:** N/A  
**PAGE:** 1 **OF** 1  
**QA**

**CORRECTIVE ACTION REQUEST**

**1 Controlling Document**  
ORNL QAPD, June 1991, Revision 1

**2 Related Report No.**  
Audit HQ-92-02

**3 Responsible Organization**  
Systems Integration Support, MMES

**4 Discussed With**  
Ron Pope, Glenn Cowart

**5 Requirement:**

Section 4.1, Procurement Document Control, states that procurement documents for quality affecting services will contain applicable QA program requirements.

Section 4.2 states, "Procurement documents, for quality-affecting services, will be reviewed by QA and technical personnel..." In addition, the Section states, "Changes to procurement documents are reviewed by the same or equivalent staff, and are initialed to indicate approval."

**6 Adverse Condition:**

Contrary to the above, the recent revision (January 1992) to the procurement document to ASG did not contain the required ORNL QA program requirements. There was also no evidence of a QA review or a technical review by the Program Manager.

In addition, the December 1990 procurement document to David Andress & Associates did not receive a formal QA review either. The QA program requirements in the document refer to the ORNL QAPD, which at the time was in a draft Revision 0 stage.

The latest revision to the procurement document to E.R. Johnson Associates occurred in February of 1991. A letter from the Program Manager was issued in March of 1991 to amend the document but was not processed through the procurement cycle (no formal QA approval).

**9 Does a significant condition adverse to quality exist?** Yes X No       
If Yes, Circle One: (A) B C

**10 Does a stop work condition exist?** Yes      No X ; If Yes - Attach copy of SWO  
If Yes, Circle One: A B C D

**11 Response Due Date:**  
4/13/92

**12 Required Actions:** ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

**13 Recommended Actions:**

Review, revise, and re-issue all subcontractor procurement documents, as necessary. *or modifications, rwc 3/11/92*

**7 Initiator**  
Dennis Brown *Dennis Brown* Date 2/26/92

**14 Issuance Approved by:**  
QADD *R.W. Cleat* Date 3/11/92

**15 Response Accepted**  
QAR Date

**16 Response Accepted**  
QADD Date

**17 Amended Response Accepted**  
QAR Date

**18 Amended Response Accepted**  
QADD Date

**19 Corrective Actions Verified**  
QAR Date

**20 Closure Approved by:**  
QADD Date

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

**CAR NO.** HO-92-008  
**DATE:** N/A  
**PAGE:** 1 **OF** 1  
**QA**

**CORRECTIVE ACTION REQUEST**

<b><sup>1</sup> Controlling Document</b> DOE/RW-0214, Rev. 4, QARD	<b><sup>2</sup> Related Report No.</b> Audit HQ-92-02
---	--

<b><sup>3</sup> Responsible Organization</b> Systems Integration, MMES, ORNL	<b><sup>4</sup> Discussed With</b> Glen Cowart
---	---

**<sup>5</sup> Requirement:**

Paragraph 2.8 requires that relevant education and experience be verified for personnel selected to perform or verify activities affecting quality.

**<sup>6</sup> Adverse Condition:**

There is no evidence that the education and experience of Systems Integration, MMES personnel have been verified.

<b><sup>9</sup> Does a significant condition adverse to quality exist?</b> Yes <u>  </u> No <u>x</u> If Yes, Circle One: A B C	<b><sup>10</sup> Does a stop work condition exist?</b> Yes <u>  </u> No <u>  </u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	<b><sup>11</sup> Response Due Date:</b> 6/15/92
---	--	--

**<sup>12</sup> Required Actions:** ☒ Remedial ☐ Extent of Deficiency ☐ Preclude Recurrence ☐ Root Cause Determination

**<sup>13</sup> Recommended Actions:**

Document the verification of the education and experience of personnel performing quality affecting activities.

<b><sup>7</sup> Initiator</b> <i>R. Dannie Brown</i> Date <u>4/8/92</u>	<b><sup>14</sup> Issuance Approved by:</b> QADD Date
<b><sup>15</sup> Response Accepted</b> QAR Date	<b><sup>15</sup> Response Accepted</b> QADD Date
<b><sup>17</sup> Amended Response Accepted</b> QAR Date	<b><sup>18</sup> Amended Response Accepted</b> QADD Date
<b><sup>16</sup> Corrective Actions Verified</b> QAR Date	<b><sup>20</sup> Closure Approved by:</b> QADD Date

ATTACHMENT 5

PERSONNEL INVOLVED IN THE AUDIT

NAME	ORG	TITLE	PRE	CONTACT	POST
F. Bearham	DOE/CER	Auditor	X		X
J. Begovich	ORNL	Section Head, EC&A	X		
B. Belke	NRC	Observer	X		X
R. Brient	NRC/SWRI	Observer	X		X
D. Brown	DOE/CER	Audit Team Leader	X		X
R. Clark	DOE/OCRWM	Director, HQ QA Div.	X		X
G. Cowart	ORNL/ASG	QA Specialist	X	X	X
D. Joy	ORNL	Task Manager	X	X	X
C. Kerrigan	TRW	Observer	X		X
S. Ludwig	ORNL/MMES	Origin Code Coord.		X	
R. MacDonald	ORNL/E.R. Johnson	WSA Verifier	X	X	X
B. McLeod	ORNL/E.R. Johnson	WSA Verifier	X	X	X
R. Moore	ORNL/ASG	Technical Staff	X	X	
T. Nguyen	DOE/OCRWM	Program Engr.-ORNL	X		
K. Notz	ORNL	Task Manager	X	X	X
M. Payton	DOE/OCRWM	Program Analyst		X	
R. Pope	ORNL/MMES	Mgr., OCRWM Prog.	X	X	X
I. Sacks	TRW	Observer	X		X
R. Schaffer	DOE/Weston	Auditor	X		X