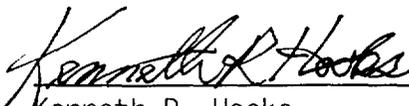
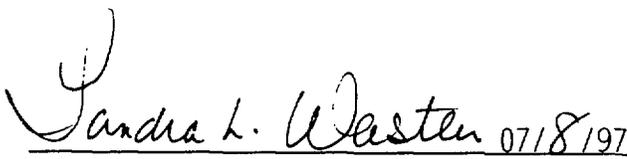


U.S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT NO. 97-02  
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES  
INTERNAL QUALITY ASSURANCE AUDIT NO. 97-01

 08/28/97  
Kenneth R. Hooks  
Uranium Recovery Branch  
Division of Waste Management

Reviewed and Approved by:

 07/8/97  
Sandra L. Wastler  
Performance Assessment and  
High-Level Waste Integration Branch  
Division of Waste Management

## 1.0 INTRODUCTION

From June 9-12, 1997, a member of the U.S. Nuclear Regulatory Commission Uranium Recovery Branch staff participated as an observer in the Center for Nuclear Waste Regulatory Analyses (CNWRA) internal quality assurance (QA) Audit No. 97-01 conducted in San Antonio, Texas. The CNWRA is the NRC's Federally Funded Research and Development Center and is the NRC's primary source of research and technical assistance in the high-level nuclear waste (HLW) program. The CNWRA is also performing various tasks for the NRC such as areas of tank waste remediation (Hanford) and uranium recovery (mill tailings).

The audit evaluated the adequacy and effectiveness of the CNWRA QA program and its implementation. Fourteen QA programmatic areas and eight technical areas were audited, six of which are associated with the HLW program. The technical areas audited included 1) MULTIFLO Software Code Development, 2) Thermal Effects on Flow, 3) Near Field Corrosion Testing, 4) Igneous Activity Software Development, 5) Total Performance Assessment (TPA) Software Development, 6) Isothermal Flow, 7) Tank Waste Remediation System Tasks, and 8) Uranium Recovery Tasks. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA program controls in the audited areas.

## 2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate the implementation of QA controls associated with CNWRA QA programmatic and technical activities in meeting the applicable requirements of Appendix B to Title 10, Code of Federal Regulations (10 CFR), Part 50, as required by its contract with the NRC. The NRC staff's objectives were to determine 1) if the audit was performed in such a manner as to provide confidence in the CNWRA audit process, and 2) whether CNWRA staff were adequately implementing QA program requirements specified in the CNWRA Quality Assurance Manual (CQAM), thus meeting contractual QA requirements.

## 3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the audit process and the CNWRA QA program on 1) discussions with and direct observations of a) the auditors and technical specialists of the audit team [who were on loan from the CNWRA's parent organization, Southwest Research Institute (SwRI)], and b) CNWRA staff being audited and 2) reviews of pertinent audit documentation such as the audit plan, the audit checklist, and other CNWRA documents. The NRC staff determined that CNWRA Audit No. 97-01 achieved its purpose of evaluating the implementation of QA controls of programmatic and technical activities. The audit was conducted in a professional manner. The audit team was well qualified and familiar with the QA requirements of the CNWRA program. The audit schedule and individual assignments were adequately described in the audit plan, and the audit checklist was detailed and complete.

Enclosure

The NRC staff agrees with the audit team's preliminary findings that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated. In addition, the staff believes that the CNWRA audit was thorough and effective. The technical qualifications of CNWRA staff and the technical adequacy of the procedures and work products were found to be generally satisfactory, and are subject to continuing in depth evaluation by NRC technical staff.

CNWRA QA personnel should continue to monitor the 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 independent audit at a later date to determine the adequacy and effectiveness of the CNWRA QA program.

#### **4.0 AUDIT PARTICIPANTS**

Because implementation of the CNWRA QA program includes activities being performed by CNWRA QA staff, the audit was performed by SwRI personnel to avoid any potential conflict of interest.

##### **4.1 NRC**

Ken Hooks                      Observer

##### **4.2 SwRI**

Tom Trbovich	Audit Team Leader (ATL)
Randy Folck	QA Auditor
Bob Mielke	QA Auditor
Dr. Mike MacNaughton	Technical Specialist
Dr. Chris Frietas	Technical Specialist
Dr. Bob Mason	Technical Specialist
Dr. Richard Page	Technical Specialist

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

The CNWRA audit was conducted in accordance with CNWRA Quality Assurance Procedure (QAP)-011, "Audits." The NRC staff observation of the CNWRA audit was based on NRC procedure "Conduct of Observation Audits" issued October 6, 1989.

##### **5.1 Scope of Audit**

The audit was conducted to evaluate the implementation of QA requirements associated with CNWRA programmatic and technical activities. The bases of the audit included Appendix B to 10 CFR Part 50, the CQAM, Research Project Plans, Operations Plans, Technical Operating Procedures, and QAPs.

### 5.1.1 QA Programmatic Elements

The checklists covered the QA program requirements for the applicable fourteen elements listed in Table 1 (page 7). Table 1 lists the applicable sections of the CQAM, the title of the section, and the related criteria of Appendix B to 10 CFR Part 50.

CNWRA does not currently design structures, systems, or components that are important to safety or waste isolation. However, pertinent requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 are applied to CNWRA activities such as software design and the design of experiments.

Criterion X, "Inspection," and the inspection-related requirements of Criterion XIV, "Inspection, Test, and Operating Status," of 10 CFR Part 50 Appendix B are satisfied by the procurement controls of CQAM Section 7 or by treating inspections as "delegated work" in accordance with CQAM Section 1. Criterion XI, "Test Control," and the test-related requirements of Criterion XIV, "Inspection, Test, and Operating Status," of 10 CFR Part 50 Appendix B are satisfied by CQAM Sections 2 and 3.

### 5.1.2 Technical Areas

Specific technical areas to be audited were selected based on their levels of activity and the time since the activity was last audited. The technical areas audited were 1) MULTIFLO Software Code Development, 2) Thermal Effect on Flow, 3) Near Field Corrosion Testing, 4) Igneous Activity Software Development, 5) TPA Software Development, 6) Isothermal Flow, 7) Tank Waste Remediation System Tasks, and 8) Uranium Recovery Tasks.

Technical specialists on the audit team were instructed to evaluate and determine the acceptability/adequacy of items such as:

- 5.1.2.1 Qualifications of personnel performing technical activities
- 5.1.2.2 "Quality Requirements Application Matrix" applicable to the specific key technical area being audited
- 5.1.2.3 Scientific notebooks
- 5.1.2.4 Technical work and the review of technical products
- 5.1.2.5 Appropriateness of conclusions
- 5.1.2.6 Routine calculations
- 5.1.2.7 Samples
- 5.1.2.8 Software.

## 5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate in that a little less than one year had elapsed since the previous audit.

## 5.3 Conduct of Audit

The technical portion of the audit was conducted by sub-teams. Each sub-team included an auditor and a technical specialist. Each sub-team member addressed the checklist items in the members' area of expertise.

## 5.4 Examination of QA Programmatic and Technical Activities

Audit 97-01 was conducted as a performance-based audit. Instead of conducting evaluations focusing on compliance with the QA programmatic criteria, each auditor and audit sub-team focused on the technical activities and evaluated the QA programmatic controls applicable to those activities. Therefore, discussions about the observed QA programmatic controls and the technical activities are combined in this section.

The auditors and technical specialists were guided by the QA programmatic and technical checklist that was developed by the audit team members before the audit. The checklist questions were identified so as to be asked by an auditor and/or a technical specialist.

The audit of all or a portion of the technical areas of 1) Uranium Recovery Tasks, 2) Igneous Activity Software Development, 3) MULTIFLO Software Code Development, 4) Tank Waste Remediation Tasks, 5) Near Field Corrosion Testing, 6) Isothermal Flow, and 7) TPA Software Development was observed by the NRC staff member. For each technical area observed, the audit sub-team reviewed the pertinent scientific notebooks (both "electronic" and handwritten) and discussed these documents with the involved CNWRA staff. When laboratory work was included in an audited area, the auditing personnel reviewed the laboratory and its equipment and discussed the facilities with the responsible CNWRA personnel. The auditors also reviewed calibration records for the laboratory equipment.

During the audit, the audit team identified deficiencies in the program that resulted in two draft Corrective Action Requests (CARs). These are summarized in Section 6.0 of this report. At the post-audit (exit) briefing, as well as discussing the CARs in detail, the ATL stated that the team noted increased CNWRA staff acceptance of and understanding of QA program requirements, improved use of QA surveillance, and improved document and record control.

The audit was effective in determining CNWRA compliance with procedural controls in the areas examined. The audit team concluded that procedures and protocols are generally being followed and the deficiencies noted in the CARs have had no significant affect on the CNWRA QA program. The portion of the

audit that was observed by the NRC staff was thorough and effective in determining CNWRA personnel knowledge of and compliance with procedural controls. The staff agrees with the audit team's assessment that, overall, the CNWRA is acceptably implementing its QA program.

### **5.5 Conduct of the Audit**

The conduct of the audit was productive and the audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the CNWRA program. The auditors, the technical specialists, and the audit sub-teams used the checklist effectively during discussions with CNWRA personnel and review of documents. They asked detailed questions and requested objective evidence as required to support conclusions.

### **5.6 Qualifications of Audit Team Members**

The ATL and auditors were certified to SwRI procedure No. NQAP 2.0-1, "Qualification and Certification of QA Auditors, dated November 1989. Procedure No. NQAP 2.0-1 is used by SwRI to implement Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel," of NQA-1-1986, "Quality Assurance Program Requirements for Nuclear Facilities." Prior to the audit, the technical specialists on the audit team were given specific training in conducting audits by the ATL.

All members of the audit team had participated in one or more previous annual internal QA audits of CNWRA activities, and were thus qualified to judge improvements (or the lack of improvements) over time.

### **5.7 Auditor Preparation**

The ATL, auditors, and technical specialists were adequately prepared to perform the audit. They were familiar with the questions assigned to them in the audit checklist.

### **5.8 Conduct of Meetings**

The audit team conducted professional and appropriate audit entrance and exit meetings with CNWRA personnel. The ATL's statements of the audit purpose and findings at these meetings were clear and concise. In addition, the audit team and observer caucused after each day's audit activities, and the ATL (along with the observer and selected team members) met each morning with CNWRA management personnel to inform them of the audit status. The NRC Program Element Manager participated in daily meetings and the post-audit briefing by telephone. The meetings were of an appropriate length and depth.

### **5.9 Auditor Independence**

The audit team had no involvement with or responsibility for performing any of the activities they audited. Each audit team member was from SwRI (but not CNWRA) and was assigned specific auditing tasks for the sole purpose of performing this CNWRA internal audit.

## 6.0 AUDIT TEAM FINDINGS

Although the audit team identified two deficiencies in the CNWRA QA program which were documented on draft CARs and will be resolved in accordance with Section 16 of the CQAM, the audit team concluded that procedures and protocols are generally being followed and the deficiencies noted in the CARs (and summarized below) have had no significant affect on the CNWRA QA program. The audit team also concluded that, overall, the CNWRA is acceptably implementing its QA program.

### 6.1 CAR 97-02:

Contrary to the requirements of TOP-018, "Development and Control of Scientific and Engineering Software," paragraph 5.8, changes (both "serious" and "minor") were implemented in MULTIFLO, Version 1.0, without completion of a Software Problem/Change Report. Some, but not all, changes were documented in the developer's scientific notebook.

### 6.2 CAR 97-03:

Contrary to the requirements of TOP-018, paragraph 5.7, two versions of the TPA Code, Version 3.0, were delivered to the NRC on two different days prior to the official release date (4/16/97) which indicated completion of all requirements. In addition, the Software Requirements Description was not prepared prior to significant development or modification of the codes as required by paragraph 5.3.1.

## 7.0 NRC STAFF FINDINGS

The NRC staff determined that the audit was effective in determining CNWRA compliance with procedural controls in the areas examined. The portion of the audit that was observed was thorough and effective in determining CNWRA compliance with procedural controls. The staff agrees with the audit team's assessment that, overall, the CNWRA is acceptably implementing its QA program.

Integration of the QA programmatic and technical portions of the audit was very good. The audit team was well prepared and conducted a thorough audit in a professional manner.

The recent problems with the TPA Software Development were discussed at considerable length during the audit. It appears that the problems which occurred were primarily due to lack of effective implementation of TOP-018. The release of one or more versions of TPA Version 3.0 to the NRC prior to completion of the checking and test requirements of TOP-018 was a decision made by CNWRA management and does not represent a failure of the CNWRA QA program. The NRC staff recommends that TOP-018 be thoroughly reviewed by CNWRA technical staff and the Quality Assurance Director and revised, as appropriate, based on their recent experience in code development. To ensure effective implementation of the procedure, the technical staff should assume "ownership" of this technical procedure. As part of this review consideration should be given to submission of SRDs as intermediate milestones which will be approved by NRC prior to the beginning of code development. The level of

detail to be included in the SRDs, as well as when a modification to the design is significant enough to require a revised SRD should also be evaluated and agreed to by the Center Quality Assurance Director and the NRC CNWRA Operations Program Element Manager.

TABLE 1. QA PROGRAM REQUIREMENTS AUDITED

CQAM SECTION	QA PROGRAM REQUIREMENTS	APPENDIX B CRITERION
1	Organization	I
2	Quality Assurance Program	II
3	Scientific Investigation and Analysis Control	III
5	Instructions, Procedures, and Drawings	V
6	Document Control	VI
7	Procurement Control	IV & VII
8	Identification and Control of Items, Software, and Samples	VIII
9	Control of Processes	IX
12	Control of Measuring and Test Equipment	XII
13	Handling, Storage, and Shipping	XIII
15	Nonconformance Control	XV
16	Corrective Action	XVI
17	Records Control	XVII
18	Audits	XVIII

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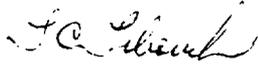
## CORRECTIVE ACTION REQUEST

CAR No: 97-02

Associated AR, SR, NCR No: \_\_\_\_\_

**PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY**

Contrary to the requirements of TOP-018, paragraph 5.8, changes (both "serious" and "minor") were implemented in MULTIFLO, Version 1.0, without completion of a Software Problem/Change Report (SPCR). Some, but not all, changes were documented in the developer's scientific notebook.



Initiated by: T.C. Trbovich

Date: June 12, 1997

**PART B: PROPOSED ACTION**

Responsible EM:

Response Due:

1) Extent of Condition:

2) Root Cause:

3) Remedial Action:

Proposed Completion Date:

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date:

Element Manager:

Date:

**PART C: APPROVAL***Comments/Instructions*

Director of QA:

Date:

**PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION**

Distribution:

Verified by:

Date:

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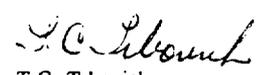
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Associated AR, SR, NCR No: \_\_\_\_\_

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Initiated by: T.C. Trbovich

Date June 12, 1997

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Element Manager:

Date:

**PART C: APPROVAL**  
Comments/Instructions

Director of QA:

Date:

**PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION**

Distribution:

Verified by:

Date:

Letter to: Bruce Mabrito

Dated: July 09, 1997

Subject: OBSERVATION AUDIT OF CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

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