

SEP 12 1991

Mr. Bruce Mabrito, Director  
Quality Assurance  
Center for Nuclear Waste Regulatory Analyses  
P.O. Drawer 28510  
6220 Culebra Road  
San Antonio, Texas 78228-0510

Dear Mr. Mabrito:

SUBJECT: OBSERVATION AUDIT OF CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

From July 23-26, 1991, a member of the U.S. Nuclear Regulatory Commission (NRC) quality assurance (QA) staff participated as an observer in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. CNWRA 91-1 conducted in San Antonio, Texas. The NRC staff evaluated this audit to gain confidence that the CNWRA is effectively implementing the requirements of its QA program. This letter transmits NRC Observation Audit Report No. 91-10 for the CNWRA audit.

The audit, which was performed as part of the CNWRA's regular audit program, was used to evaluate the implementation of QA controls associated with CNWRA programmatic and technical activities. As indicated in the CNWRA Audit Plan, technical activities to be audited included two tasks associated with Operations Plans and three Research Project Plans tasks.

The auditors and technical specialists, who were from Southwest Research Institute, were well qualified in the QA discipline, and the checklists were adequate for the areas that were evaluated. In general, the NRC staff agrees with the audit team's preliminary findings that the CNWRA QA program controls are being adequately implemented in the areas that were evaluated.

CNWRA QA personnel should closely 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 assess the adequacy and effectiveness of the CNWRA QA program.

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Mr. Bruce Mabrito

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A written response to this letter or the enclosed report is not required. If you have any questions, please call Ken Hooks on 301/492-0447.

Sincerely,

*KS*

Kenneth R. Hooks, Section Leader  
Quality Assurance  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: As stated

- cc: R. Loux, State of Nevada
- C. Gertz, DOE/NV
- S. Bradhurst, Nye County, NV
- M. Baughman, Lincoln County, NV
- D. Bechtel, Clark County, NV
- D. Weigel, GAO
- P. Niedzielski-Eichner, Nye County, NV
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KH/OBS AUDIT CNWRA

U.S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT NO. 91-10  
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES  
AUDIT NO. CNWRA 91-1

*Kenneth R. Hooks* 09/11/91  
Kenneth R. Hooks  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management

ENCLOSURE

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## 1.0 INTRODUCTION

From July 23-26, 1991, a member of the U.S. Nuclear Regulatory Commission (NRC) quality assurance (QA) staff participated as an observer in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. CNWRA 91-1 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 program. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA program controls in both programmatic and technical areas.

## 2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate the implementation of QA controls associated with CNWRA programmatic and technical activities in meeting the applicable requirements of Appendix B to Title 10 Code of Federal Regulations (10 CFR) Part 50. The NRC staff's objective was 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 properly implementing QA program requirements specified in Revision 2 to the Center Quality Assurance Manual (CQAM).

## 3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the audit process and the CNWRA QA program on discussions with and direct observations of the auditors and technical specialists, who were on loan from the CNWRA's parent organization, Southwest Research Institute (SwRI), discussions with CNWRA staff and reviews of pertinent audit information (e.g., audit plan, checklist, and CNWRA documents). The NRC staff has determined that, overall, Audit No. CNWRA 91-1 achieved its purpose of evaluating the implementation of QA controls for programmatic and technical activities. The audit was conducted in a professional manner. The audit team was well qualified in the QA discipline, and their assignments and checklist items were adequately described in the audit plan.

In general, the NRC staff agrees with the audit teams' preliminary findings that the CNWRA program controls are being adequately implemented in the areas that were evaluated. The audit team also determined that the technical procedures reviewed were technically adequate, the technical staff was appropriately qualified, and the technical work was adequate. The absence of NRC technical staff observers at the audit precluded NRC verification of these conclusions based on the audit; however, the technical qualifications of CNWRA technical staff and the technical adequacy of the procedures and work products are subject to continuing evaluation by NRC technical staff.

The CNWRA QA personnel should closely 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 QA program development is currently being accomplished by CNWRA QA staff, the audit was performed by Randolph Folck and Rodney Weber, Lead Auditor and Auditor, and technical specialists R.L. Bessey, M.G. MacNaughton, M.V. Muller and R.A. Page, from SwRI, to avoid any potential conflict of interest. The NRC observer was Kenneth R. Hooks, QA Section Leader.

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

The CNWRA audit was conducted in accordance with 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. NRC staff findings are classified in accordance with the guidelines in that procedure.

#### 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, NQA-1, CQAM, Research Project Plans, Operations Plans, Technical Operating Procedures (TOPs) and QAPs.

##### (a) Programmatic Elements

The programmatic checklist covered the QA program requirements for the 14 elements (related to the 18 criteria of Appendix B to 10 CFR Part 50) listed below:

- 1.0 Organization
- 2.0 QA Program
- 3.0 Scientific Investigation and Analysis Control
- 5.0 Instructions, Procedures, and Drawings
- 6.0 Document Control
- 7.0 Procurement Control
- 8.0 Identification and Control of Items, Software, and Samples
- 9.0 Control of Processes
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Nonconformance Control
- 16.0 Corrective Action
- 17.0 Records Control
- 18.0 Audits

Element 4 is addressed in Section 7 of the CQAM, and 10, 11 and 14 are not presently applicable to CNWRA work.

##### (b) Technical Areas

Specific technical areas to be audited were selected based on their levels of activity and as a representative sample of CNWRA tasks, as follows:

- 20-3702-032 Waste Systems Engineering and Integration (WSE&I) Tasks: Systematic Regulatory Analysis - Regulatory Requirements/Regulatory Elements of Proof
- 20-3702-026 Repository Design, Construction, and Operations (RDCO) Task - Repository Functional Analysis/Repository Operational Criteria
- 20-3704-013 Geochemistry Research Project Task - Experimental Studies
- 20-3704-041 Integrated Waste Package Experiments (IWPE) Research Project Task - Corrosion
- 20-3704-034 Seismic Rock Mechanics Task - Laboratory and Field Studies

Audit technical specialists were instructed to evaluate the technical activities to determine the following:

- a. Technical qualifications of Investigators and Analysts.
- b. Understanding of procedural requirements (by Technical staff) as they pertain to scientific investigations and analysis activities.
- c. Adequacy of Technical Operating Procedures and Scientific Notebooks.
- d. Adequacy of technical work and appropriateness of conclusions.

The technical reviews were scheduled so that, in general, only one was in process at any time. This scheduling was consistent with the scope of the audit and the amount of quality-affecting work performed in the technical areas.

## 5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate. The CNWRA had not previously performed an audit with technical specialists evaluating the technical activities, and it was beneficial to assess performance in these areas.

## 5.3 Examination of Programmatic Activities

Since previous audits of CNWRA programmatic activities were observed by the NRC staff, and the results were generally satisfactory, the NRC observer followed the reviews of CNWRA technical activities whenever possible. The NRC staff observed the audit team's evaluation of activities in the following programmatic elements.

(a) Corrective Action

The auditor evaluated the Corrective Action Requests (CARs) from CNWRA Audit 90-03 to determine whether they had been properly closed and the corrective actions implemented and verified. The date for completion of CAR 90-06 concerning performance of work without approved procedures has been extended several times, with September 30, 1991 being the current date. CAR 90-07 concerning TOP-018 has not been closed.

The audit of this element was effective. Although CNWRA implementation of the QA programmatic controls for this element is generally effective, more management attention should be given to timely closure of CARs.

(b) Control of Measuring and Test Equipment (M&TE)

The audit of this element was based on the checklist and covered essentially all equipment subject to calibration. The auditor checked equipment logs, calibration stickers, and laboratory notebooks and interviewed CNWRA technical personnel. Some minor, correctable deficiencies were identified. One CAR was written concerning lack of calibration of thermometers.

The audit of the technical activities associated with M&TE was effective, and CNWRA implementation of the QA programmatic controls for these activities was generally effective.

5.4 Examination of Technical Activities

The NRC staff observed the audit team's evaluation of the following technical activities.

(a) WSE&I

The technical specialist and auditor used their checklists effectively to focus the audit. They both reviewed objective evidence (documents) and interviewed cognizant personnel. The Program Architecture Support System computer data base was compared to hard copy for eight Regulatory Requirements to verify accuracy and completeness, and an extensive discussion was held on the controls for input to data base. The controls for development of Regulatory Elements of Proof were reviewed, including the control sheets with appropriate signatures. Training for Systematic Regulatory Analysis was also reviewed.

TOP-001-01 is still in effect, but is not being used. Completion of CAR 90-06 is expected to result in a procedure which will supercede TOP-001-01. The technical specialist did not find any problems related to the delay in completing CAR 90-06. The audit of WSE&I activities was thorough and effective in determining CNWRA compliance with procedural controls.

(b) RDCO

The audit of this area was hampered by the preliminary or draft status of both TOP-001-07 and the current Repository Functional Analysis document. However, the technical specialist determined that technical activities in this area were adequate, and reported conclusions were well-supported. The technical specialist's review was effective in determining the status of the technical products, and the probable need for future evaluation to confirm that the products meet QA program requirements.

(c) IWPE

The technical specialist reviewing this area was familiar with QAP and TOP requirements. The checklist was used effectively to structure the audit. Five scientific (laboratory) notebooks were reviewed and the current laboratory activities were discussed. The technical specialist stated his opinion that the CNWRA technical personnel were technically qualified and supportive of the QA program, and that a professional in the same technical area could replicate the experiments based on the notebooks and TOPs.

(d) Geochemistry

The majority of the review of this area was performed during the week prior to the audit, due to a scheduling conflict with the principal investigator. The technical specialist reviewed technical staff qualifications, laboratory notebooks and equipment, and verified suitability of computer codes used in data interpretation. He determined that the technical personnel were qualified, the laboratory notebooks were adequate, and the use of computer codes was appropriate.

(e) Seismic Rock Mechanics

The review of this area was based mainly on interviews, due to the lack of objective evidence other than Research Program Annual and Quarterly Reports. The technical specialist used his checklist as appropriate, reviewed the qualification folders for the technical staff working in this area, and questioned the technical staff regarding the selection and use of computer codes. He determined that the technical staff was qualified, the technical work adequate, and conclusions appropriate.

The reviews of the technical activities were more heavily weighted toward technical evaluation of the activities and work products than evaluation of the effectiveness of the QA controls in assuring the technical adequacy of the work products. This focus was probably to be expected, since none of the technical specialists had previously participated in this type of audit.

### 5.5 Conduct of the 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 CNWRA program. The auditors and technical specialists used their checklists effectively during discussions with CNWRA personnel and review of documents. They asked detailed questions and requested evidence as required to support conclusions.

### 5.6 Qualifications of the Audit Team Members

The two auditors were both certified to SwRI procedure No. NQAP 2.0-1 "Qualification and Certification of QA Auditors" dated November 1989. Procedure No. NQAP 2.0-1 endorses Supplement 2S-3 of NQA-1-1986 "Quality Assurance Program Requirements for Nuclear Facilities." The same auditors performed CNWRA Audit 90-3 in December 1990.

The four technical specialists, two of whom have Ph.Ds in relevant technical specialties, were given specific training in conducting audits by the lead auditor. The NRC observer reviewed their qualification folders; each contained an attendance record for the auditor training, professional resume, and a memorandum attesting to their qualifications to review the specific technical areas assigned to them for the audit.

### 5.7 Auditor Preparation

The auditors and technical specialists appeared adequately prepared to perform the audit. They personally prepared the audit checklist which required review and evaluation of the CQAM, applicable TOPs and QAPs, Research Project Plans, and Operations Plans.

### 5.8 Conduct of Meetings

The audit team conducted professional and appropriate entrance and exit meetings with CNWRA personnel (See Attachment). Its statements of the audit purpose and findings were clear and concise. Other than audit interviews, no meetings were held during the audit.

### 5.9 Auditor Independence

The audit team had no involvement with or responsibility for performing any of the activities they audited. They are from SwRI and were assigned the auditing tasks for the sole purpose of performing this CNWRA internal audit.

## 6.0 SUMMARY - PRELIMINARY AUDIT FINDINGS

During the course of the audit, the auditors identified three deficiencies in the CNWRA QA program which were documented on CARs and will be resolved in accordance with Section 16 of the CQAM.

CAR 91-01 - Draft TOP-001-07 has not been formally approved, but is referenced as being used for quality-affecting activities.

CAR 91-02 - QAP-009 does not address qualification requirements for personnel determining dispositions for nonconformances.

CAR 91-03 - Thermometers have been excluded from calibration and control requirements.

## 7.0 SUMMARY - NRC STAFF FINDINGS

### (a) Observations

The NRC staff did not identify any observations in either the audit process or the CNWRA QA program.

### (b) Weaknesses

CARs 90-06 and 90-07 are still open after seven months.

Integration of the programmatic and technical portions of the audit could be improved.

### (c) Good Practices

Non-QA CNWRA staff involved in the audit were aware of QA requirements and appeared to be supportive of the CNWRA QA program.

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

Audit Meeting

\*\* Rachid Ababou  
\*\* Roger Bessey  
\* Robert Brient  
\*\* Asadul Chowdhury  
\*\* Gustavo Cragolino  
\* Randy Folck  
\*\* Henry Garcia  
\*\* Ron Green  
\* Ken Hooks (NRC)  
\* Simon Hsiung  
\*\* Rawley Johnson  
\* In-Koo Lee  
\* Bruce Mabrito  
\*\* Mike MacNaughton  
\* Pat Mackin  
\* Michael Miklas  
\* Mark Muller  
\*\* Bill Murphy  
\* Prasad Nair  
\*\* Roberto Pabalan  
\* Richard Page  
\*\* Wesley Patrick  
\*\* English Pearcy  
\*\* Herbert Pennick  
\*\*\*James Prikryl  
\*\* Ted Romine  
\*\* Budhi Sagar  
\*\* Narasi Sridhar  
\* Tom Trbovich  
\*\* Dave Turner  
\* Rodney Weber  
\*\* Allen Whiting  
\*\* Stephen Young

\* Attended entrance and exit meetings  
\*\* Attended exit meeting only  
\*\*\*Attended entrance meeting only

Attachment