October 2, 2001

Mr. Bruce Mabrito, Director
Quality Assurance
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Road, Building 189
San Antonio, TX 78238-5166

SUBJECT: OBSERVATION OF THE AUGUST 2001 INTERNAL AUDIT OF CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Dear Mr. Mabrito:

From August 20 through 23, 2001, members of the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) Internal Quality Assurance (QA) Audit 2001-2, conducted in San Antonio, Texas. The NRC staff evaluated this audit to determine whether the CNWRA is effectively implementing the requirements of its QA program. This letter transmits NRC Observation Audit Report Number OAR-01-02-CNWRA.

This audit was performed to satisfy the CNWRA QA Manual requirement to perform an annual audit of the implementation of the CNWRA's QA program. The scope of the audit included: 1) technical, programmatic, and process reviews of several CNWRA deliverables (e.g., Spent Fuel Project Office-Private Fuel Storage Facility, West Valley Demonstration Project, Uranium Recovery Projects, and several activities for the Division of Waste Management); and 2) reviews of the actions taken as a result of the findings identified during the June 2000, annual internal audit, and the limited-scope internal audit conducted in January 2001. The audit was used to verify proper implementation of the CNWRA QA Manual and the corrective actions and effective close-out of the findings from the June 2000 and January 2001 audits. Further, the audit team reviewed progress made to correct recurring problems.

The NRC observers (hereafter, observers) based their evaluation of the audit process and the CNWRA QA program on: 1) discussions with, and direct observations of: a) the audit team, and b) CNWRA staff being audited; and 2) reviews of pertinent audit documentation, such as the audit plan, the audit checklist, CNWRA deliverables, and other CNWRA documents. The observers determined that, overall, CNWRA Audit 2001-2 achieved its purpose, and was thorough, effective, and performed in a professional manner. The observers agree with the audit team's findings and that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated.

A significant improvement in the implementation of the CNWRA QA Manual and its implementing procedures was observed in all areas audited. Further, there appeared to be a high level of compliance with the provisions contained in the CNWRA QA Manual and its implementing procedures. However, the audit team identified two major concerns:

1) surveillances were not being performed as scheduled and certain activities, such as non-high-level-waste deliverables, had no surveillances scheduled; and 2) significant conditions adverse to quality that are documented on corrective action reports (CARs) were being closed out before the completion of all corrective actions. Also, the audit team identified minor nonconformances in the areas of scientific notebooks and inspection. The audit team provided recommendations, as discussed in the attached report. These findings and recommendations were discussed with the CNWRA management at the post-audit meeting.

The observers discussed their observations with the audit team and CNWRA management during the conduct of the audit and at the post-audit meeting. In addition to the audit team's findings, the observers recommended that the CNWRA review the QA resources allowed for performing QA functions such as surveillances and close out of CARs, and determine if additional resources are needed in these areas. Although not discussed during the audit exit, the observers discussed, with the CNWRA QA Director and CNWRA line management, the need for the CNWRA to continue to improve its process for assuring that all corrective actions are completed and documented before closing out CARs.

We will continue to monitor the CNWRA progress in correcting its QA-related problems. Although a written response to this letter or the enclosed report is not required, we request that the CNWRA provide us with copies of its response to the audit team's findings. If you have any questions, please call Larry Campbell at (301) 415-5000.

Sincerely,

/RA/

Deborah A. DeMarco
NRC CNWRA Deputy Program Manager
Program Management, Policy Development
and Analysis Staff
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-01-02-CNWRA, "Observation Audit of Center for Nuclear Waste Regulatory Analyses"

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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-01-02-CNWRA

OBSERVATION AUDIT OF THE

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

AUDIT 2001-2

/RA/ 09/17/01

Larry L. Campbell
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

/RA/ 09/21/01

Ken Hooks
Uranium Recovery Section
Fuel Cycle Licensing Branch
Division of Fuel Cycle Safety and Safeguards

Reviewed and Approved by:

/RA/ 10/02/01

N. King Stablein, Chief
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Enclosure

1.0 INTRODUCTION

On August 20-23, 2001, members of the U. S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) Internal Quality Assurance (QA) Audit 2001-2, conducted in San Antonio, Texas. The NRC observers (hereafter, observers) evaluated this audit to determine whether the CNWRA is effectively implementing the requirements of its QA program.

This audit was performed to satisfy the CNWRA QA Manual requirement to perform an annual audit of the implementation of the CNWRA's QA program. The scope of the audit included: 1) technical, programmatic, and process reviews of several CNWRA deliverables (e.g., Spent Fuel Project Office-Private Fuel Storage Facility, West Valley Demonstration Project, Uranium Recovery Projects, and several activities for the Division of Waste Management); and 2) reviews of the actions taken as a result of the findings identified during the June 2000, annual internal audit, and the limited-scope internal audit conducted in January 2001. The audit was used to verify proper implementation of the CNWRA QA Manual and the corrective actions and effective close-out of the findings from the June 2000 and January 2001 audits.

2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate whether the implementation of QA controls, associated with CNWRA QA programmatic and technical activities met the applicable QA requirements contained in Appendix B to Title 10, U. S. Code of Federal Regulations (10 CFR), Part 50, as required by its contract with NRC. The audit reviewed the implementation of the CNWRA QA Manual by reviewing the processing and technical adequacy of several CNWRA deliverables, and verified proper implementation of the corrective actions resulting from the June 2000 and January 2001 CNWRA internal QA audits. 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, thus meeting contractual QA requirements.

3.0 SUMMARY AND CONCLUSIONS

The observers based their evaluation of the audit process and the CNWRA QA program on: 1) discussions with and direct observations of: a) the audit team, 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 observers determined that CNWRA Audit 2001-2 achieved its purposes of: 1) verifying proper implementation of corrective actions for the June 2000 and January 2001 audit findings; 2) evaluating the implementation of QA controls in areas identified during the June 2000 audit as requiring improvement; and 3) reviewing recurring CAR closeout problems. Further, the audit team evaluated the processes controlling the various deliverables. The audit was conducted in a professional manner and the audit team was qualified and familiar with the QA requirements of the CNWRA program. The technical specialists assigned to the audit team were very knowledgeable in the technical disciplines they evaluated. The audit schedule and individual assignments were adequately described in the audit plan, and the audit checklists were detailed and complete.

The observers agreed with the audit team's findings and that, overall, the CNWRA QA program controls are being adequately implemented in the areas evaluated. The observers found a significant improvement in the implementation of the CNWRA QA Manual and its implementing procedures in all areas audited, and there appeared to be a high level of compliance with the provisions contained in the CNWRA QA Manual and its implementing procedures. The audit identified several areas of strengths which are described in various sections of this report; examples of these strengths were thorough and technically accurate deliverables (well-supported by documents and records); and good team communication and coordination.

However, the audit team identified two major concerns: 1) surveillances were not being performed as scheduled, and certain activities, such as non-high-level-waste deliverables, had no surveillances scheduled; and 2) corrective action reports were being closed before the completion of all corrective actions. Also, the audit team identified minor nonconformances in the areas of scientific notebooks and inspection. Additionally, the audit team provided recommendations such as: 1) assuring proper turnover of information from departing personnel; 2) consulting with the NRC and determining if there is a need for revising the observation audit training program; 3) capturing good practices so that they can be applied to future deliverables; and 4) revising the procedure controlling software code reviews and testing. The audit team's findings and recommendations were discussed with CNWRA management at the post-audit meeting.

The observers discussed their observations with the audit team and CNWRA management, during the conduct of the audit and at the post-audit meeting. In addition to the audit team findings and recommendations, the observers emphasized that CNWRA management review the QA resources allowed for performing QA activities such as surveillances, and determine if additional resources are needed in these areas. Although not discussed during the audit exit, the observers discussed, with the CNWRA QA Director and CNWRA line management, the need for the CNWRA to continue to improve its process for assuring that all corrective actions are completed and documented before closing out significant conditions adverse to quality documented on corrective action requests (CARs).

4.0 AUDIT PARTICIPANTS

The audit team was staffed with NQA-1 qualified lead auditors, auditors, and technical specialists from the Southwest Research Institute (SwRI), including one consultant from a university. The audit team members were independent of the activities audited, qualified, and trained in auditing techniques.

4.1 SwRI Audit Team

Bob Brient	Audit Team Leader	SwRI
Donald Dunavant	QA Auditor	SwRI
Rodney Weber	QA Auditor	SwRI
Cindy Rucker	Auditor	SwRI
Derrick Coffin	Technical Specialist	SwRI
Steve Dellenback	Technical Specialist	SwRI
Larry Goland	Technical Specialist	SwRI
John Hageman	Technical Specialist	SwRI
Bill Thomann	Technical Specialist	University of the Incarnate Word

4.2 NRC Observers

Larry Campbell	Observer (Team Leader)
Ken Hooks	Observer (Senior Project Manager)

5.0 CONDUCT OF THE AUDIT AND OBSERVATION

The CNWRA audit was conducted in accordance with CNWRA Quality Assurance Procedure (QAP)-011, "Audits." The NRC staff's observation of the CNWRA audit was based on the NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

5.1 Scope of the Audit

The scope of the audit included: 1) technical, programmatic, and process reviews of several CNWRA deliverables (e.g., Spent Fuel Project Office-Private Fuel Storage Facility, West Valley Demonstration Project, Uranium Recovery Projects, and several activities for the Division of Waste Management); and 2) reviewing the actions taken as a result of the findings identified during the June 2000, annual internal audit, and the limited-scope internal audit conducted in January 2001. The audit was used to verify proper implementation of the CNWRA QA Manual and the corrective actions and effective close out of the findings from the June 2000 and January 2001 audits.

5.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team was well-prepared and demonstrated a sound knowledge of the CNWRA QA program and technical areas audited. The audit teams used the checklists effectively during discussions with CNWRA personnel and review of documents. The audit plan was thorough and identified a representative sample of CNWRA deliverables to be audited.

The audit team and observers caucused at the end of each day of the audit. Also, a meeting of the audit team, observers, and CNWRA management was held in the morning of the exit day of the audit to discuss the current audit status and preliminary findings. The observers believe that the timing of the audit was appropriate because sufficient time had been allowed for the CNWRA to act on the June 2000 and January 2001 audit findings.

5.3 Audit Team Qualification and Independence

The audit was conducted in a professional manner and the audit team was qualified and familiar with the QA requirements of the CNWRA program. The audit team was staffed with auditors and technical specialists from the SwRI and a consultant from a university. The qualifications of the auditors were found to be acceptable in that each met the requirements of the CNWRA QA Manual and SwRI Procedure No. NQAP 2.0-1, "Qualification and Certification of QA Auditors." The technical specialists assigned to the audit team were very knowledgeable in the technical disciplines they evaluated.

The audit schedule and individual assignments were adequately described in the audit plan, and the audit checklist was detailed and complete. The audit team members had no involvement with, or responsibility for, performing any of the activities they audited.

5.4 Examination of QA Programmatic Activities

All programmatic elements of the 18 QA criteria contained in Appendix B to Title 10 of the U. S. Code of Federal Regulations (10 CFR) Part 50 were audited, as described in the CNWRA QA Manual, with the exception of Criterion III, "Design Control." Additionally, Section 3, "Scientific/Engineering Investigations & Analysis Control," of the CNWRA QA Manual was audited.

5.4.1 QA Programmatic Elements Audited

The audit found that the documents and records reviewed were well-managed and that training documentation had improved. The audit team recommended that the CNWRA training procedure be revised to better describe how training needs will be identified and documented. Also, the audit team recommended that the CNWRA purchasing procedure be revised to address the control of commercial-off-the-shelf software, and to clarify expectations for inspection of goods from suppliers on the approved supplier list. Additionally, the audit team recommended that CNWRA procedures better describe control of documents and data of external origin.

The audit team identified two major concerns in the areas of performing surveillances and corrective action. The CNWRA's objective to schedule QA surveillances for deliverables for NRC does not appear to have been met because many of the non-high-level waste deliverables were not scheduled for QA surveillance. Further, only eight of the scheduled 24 surveillances scheduled to be performed through July 31, 2001, had been completed. The observers recommended that CNWRA management review the QA resources allowed for performing QA activities such as surveillances, and determine if additional resources are needed in this and other QA functions. Section 5.4.2 of this report discusses the audit team's concerns related to the close-out of CARs before completing the required actions.

There was considerable discussion and some disagreement between the audit team and CNWRA personnel about requirements for receipt inspections. An example of failure to identify/control an incoming external document was also identified. The audit team recommended clarification of CNWRA requirements in these areas.

The observers agreed with the audit team's findings and recommendations.

5.4.2 Closeout of CAR and Nonconformance Report Corrective Actions (from the January 2001 audit)

The audit team found that several CARs from the January 2001 audit were closed out before the completion of prescribed actions. The audit team found that this was a recurring problem and identified this as a major concern and QA problem. Although not discussed during the audit exit, the observers discussed with the CNWRA QA Director and CNWRA senior

management the need for the CNWRA to continue to improve its process for assuring that all corrective actions are completed and documented before closing out significant conditions adverse to quality documented on CARs.

5.5 Review of CNWRA Deliverables

5.5.1 General

The audit team reviewed the following elements, where applicable and contractually invoked, for each deliverable reviewed: Quality Planning; Quality Indoctrination and Training; Scientific Notebook Control; Development and Control of Scientific and Engineering Software; Quality Assurance Records Control; Qualification of Existing Data; Professional Personnel Qualification (including the use of consultants); and Procurement of Products and Services. Further, the audit team reviewed the technical adequacy of the deliverables and whether the deliverable complied with applicable CNWRA procedures.

The contract invoked the QA requirements contained in Appendix B to 10 CFR Part 50, as implemented through the CNWRA QA Manual and implementing procedures. No QA requirements beyond those required by the CNWRA contract were imposed. The audit team investigated the deliverables throughly and in depth. The audit team determined that the CNWRA QA program was adequate and being appropriately implemented for the deliverables reviewed. The observers agree with the audit team's findings and recommendations presented at the audit exit.

5.5.2 Non-High-Level-Waste Deliverables

Spent Fuel Project Office

The audit team reviewed the processing and technical quality of the CNWRA major deliverable, "[Final] Private Fuel Storage Facility Safety Evaluation Report Input, July 2000." During the review of this deliverable, some confusion existed about the scope of the CNWRA activities and what was delivered by the CNWRA. It was later explained that the CNWRA was "verbally" instructed by the NRC project manager to develop only certain sections of the safety evaluation for the Private Fuel Storage Facility (PFSF). Also, the CNWRA was instructed that its deliverable would include the sections of the safety evaluation it prepared as well as the portions prepared by the NRC staff, and that the CNWRA deliverable would include both the CNWRA and NRC staff input. Further, the CNWRA was verbally instructed to perform internal reviews only on the portion of the safety evaluation sections that the CNWRA was instructed to prepare. The audit team and observers expressed concern that these verbal agreements were not clearly documented.

The audit team questioned some of the apparently inconsistent statements made in the various sections of the safety evaluation prepared by the CNWRA and the NRC staff. The CNWRA responded that it did not review the sections prepared by the NRC staff for consistency with the sections prepared by the CNWRA because they were verbally instructed not to review the sections prepared by the NRC staff. Both the audit team and observers expressed concern about this response and the failure of the CNWRA to document the fact that it was verbally told

by the NRC project manager not to review the sections prepared by the NRC staff even though it was part of the CNWRA deliverable.

The audit team made the following recommendations based on its review of the CNWRA input for the safety evaluation for the PFSF: 1) good practices employed in this project should be applied in other and future activities (the audit team recommended using the CNWRA QA program as the framework for capturing and consistently applying these good practices); 2) the CNWRA should develop methods to control joint projects; and 3) the requirements from the CNWRA QA Manual (Section 3.3.11) should be clarified regarding implied requirements for use when developing review practices for deliverables supporting "regulatory reviews" (problems with the use of the term "regulatory review" are also addressed in the discussion for the Unsaturated and Saturated Zone Flow and Transport portion of Section 5.5.3 of this report).

Notwithstanding the above discussion, the audit team found that the high quality of the CNWRA portion of the safety evaluation for the PFSF was the result of good team communication, excellent coordination, use of highly qualified personnel, and good interactions with the NRC staff (even though certain verbal instructions were not well-documented).

The observers agreed with the audit team's findings and recommendations.

West Valley Demonstration Project

The audit team reviewed the processing and technical quality of the CNWRA major deliverable, the West Valley Demonstration Project (WVDP). The CNWRA developed a data visualization system for the WVDP, which took data supplied by the U.S. Department of Energy (DOE) in its Environmental Impact Statement and input this data, from various data packages, into commercially available versions of ArcView and EarthVision software codes. These commercial codes were validated/verified under the CNWRA QA program. The CNWRA was not tasked to verify the quality of the DOE data. There was no processing of data (i.e. calculations) by the CNWRA. The initial version of the software code extensions was developed without preparation of a Software Development Plan (SDP) or a waiver of the SDP, as required by TOP-018, apparently because of a misunderstanding of the requirements. However, there was no effect on the quality of the work. The installation instructions for the code package were incorrect, a minor defect which was corrected during the audit. No scientific notebooks were used. Notes (scripts) pertaining to the development of the "extensions" used to input the data were included in the extensions.

The audit team recommended that the CNWRA improve the ArcView extensions Readme File (user instructions); that the requirements for use of scientific notebooks or alternative documentation be clarified; that a software QA specialist be included in quality planning, and that QA verify that the required SDP or waiver be issued within 30 days of project initiation.

The observers agreed with the audit team's findings and recommendations.

Uranium Recovery

Four separate tasks associated with Uranium Recovery were performed by the CNWRA and reviewed by the audit team. The tasks involved interviews with NRC personnel familiar with the

Uranium Recovery area, participation in public meetings, analysis of NRC regulations, and development of cost-estimating techniques for groundwater cleanup. The work on all four tasks was completed before the audit. The audit team reviewed the qualifications of the CNWRA technical staff who performed the work, and reviewed documents resulting from the work, including scientific notebooks and reports.

The audit team determined that the CNWRA staff members performing the tasks were qualified, and that the scientific notebooks and reports were adequate. Also, the audit team found that there was no documentation of interviews with NRC personnel, and no trip reports for activities supporting this project. Scheduled QA surveillances were not performed for Uranium Recovery activities. An unidentified compact disc (CD) was found in one project file folder, and during the audit was found to contain data associated with the file.

The audit team recommended that efforts be made to better capture verbal instructions . The failure to identify the CD was considered a minor nonconformance. The failure to perform scheduled surveillances, in all areas of CNWRA activities, was considered to be a major nonconformance, perhaps indicative of a need for additional QA resources (Section 5.4.1 addresses this nonconformance).

The observers agreed with the audit team's findings and recommendations..

5.5.3 High-Level Waste Deliverables

Igneous Activity

The audit team reviewed the processing and technical quality of several selected CNWRA deliverables in the igneous area, such as "Software Requirements Description Magma Repository Interaction Simulation Code (SHOCK), February 2001," and ""Technical Basis for Resolution of Igneous Activities Key Technical Issue, December 2000."

The audit team found that the deliverables were high-quality. However, a scientific notebook and other records for work performed by a CNWRA technical specialist could not be located. The notebooks/records should have been captured at both a 6-month interval notebook update required by CNWRA procedures, and on the technical specialist's leaving the CNWRA to return to his/her permanent office location. The audit team considered this finding a minor nonconformance. The CNWRA was in the process of contacting the technical specialist to obtain the missing information. Because this was an isolated instance and the CNWRA was in the process of obtaining the missing information, the observers agreed that this was not a significant condition adverse to quality.

The audit team recommended that CNWRA personnel consider enhancing procedures controlling the turnover of information from departing personnel. During the conduct of the audit, the observers discussed this recommendation with the CNWRA QA Director and requested that this recommendation be incorporated into applicable CNWRA procedures.

The observers agreed with the audit team's findings and recommendations.
Unsaturated and Saturated Flow Under Isothermal Conditions

The audit team reviewed the processing and technical quality of the following two CNWRA deliverables: "Review of the DOE Unsaturated Zone Flow and Transport Model Process Model Report, February 2001"; and "Review of the DOE Saturated Zone Flow and Transport Model Process Model Report, March 2001."

The audit team found the deliverables were high-quality, there was good scientific notebook control; there was very good sample traceability for collection through storage; and there was appropriate control of suppliers providing satellite image products. While reviewing the software for this area, the audit team found that certain software was scheduled for future validation; however, it was unclear whether the entire software code or only certain models required validation. The audit team recommended that the scope of the software validation be clarified.

Several activities require compliance with certain CNWRA QA Manual requirements if the activity is used to support "regulatory reviews." The audit team noted that the CNWRA staff did not clearly understand the use and meaning of "regulatory review," and that it should be better defined.

The observers agreed with the audit team's findings and recommendations.

Review of the Total System Performance Assessment

The audit team reviewed the processing and technical quality of the CNWRA's review of the Total System Performance Assessment Report prepared by DOE. The primary activity reviewed was the development of the software used for this review. The audit team found that a significant evolution, for the approach to process-oriented software development, for this project occurred, and the improvements to this complex software were efficient and thorough. Also, it was found that there was excellent configuration management of the software source code.

The audit team made several recommendations for enhancing the CNWRA's control and processing of software, including: revising applicable procedures to require documentation of code reviews by the software development custodian; providing more guidance regarding the testing process used for software, especially in the area of modifying commercial-off-the-shelf software used; independent reviews of the software development plan by a software specialist; enhancing planning for software maintenance; and quarterly reviews of software supporting the project activities.

The observers agreed with the audit team's findings and considered the recommendations, regarding the various areas, items the CNWRA should review and respond with the appropriate actions.

5.5.3 External QA

The audit team reviewed several of the CNWRA deliverables regarding its support of the NRC staff's observation of DOE's audit activities. The guidance, provided by the NRC, in its September 19, 2000, letter, from NRC (L. Campbell) to CNWRA (B. Mabrito), was used for the audit team's review. Also, the audit team reviewed the training and qualifications of CNWRA personnel assigned as observers.

The audit team identified no nonconformances for the deliverables, training, and qualification activities reviewed. However; the audit team recommended that the CNWRA management review its processing of the observation report deliverables and streamline its internal review to support the scheduled delivery date to NRC. The audit team determined that the observer

training for technical specialists currently offered by the CNWRA does not incorporate the latest NRC guidance, and needs to be revised. The audit team recommended that the training module for personnel performing observations be updated to include the additional guidance contained in NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

The observers agreed with the audit team's findings and recommendations.

6.0 NRC STAFF FINDINGS AND RECOMMENDATIONS

The audit was conducted in a professional manner and the audit team adequately evaluated activities and objective evidence. The audit team focused on confirming the corrective actions from the June 2000 and January 2001 audits and reviewing activities in areas where these audits identified problems. The audit team leader was effective in his presentation to the CNWRA management and staff and provided guidance to the audit team. Both the audit team and CNWRA staff were knowledgeable in their respective disciplines. The checklist was an excellent tool for providing a sound basis from which to conduct the audit.

The observers noted a significant improvement (when compared with the audit results 1 year ago) in the implementation of the CNWRA QA program and its implementing procedures, in all areas audited. This was evident in the high level of compliance with the provisions contained in the CNWRA QA Manual and its implementing procedures, observed during the audit.

The observers determined that CNWRA Audit 2001-2 achieved its purpose, and was thorough and effective. The audit team concluded that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated and that the kinds of nonconformances identified during this audit do not appear to have a significant potential to adversely affect products or the overall effectiveness of the CNWRA QA program. However, the observers are concerned about the potential impact that the recurring problem of closing out CARs, prior to completing all corrective actions, may have on future quality-related activities.

The major nonconformances (failure to perform required surveillances and failure to perform required corrective action), identified as potential significant conditions adverse to quality, may suggest that additional resources are needed for the QA Director and his staff to adequately perform required QA functions. Further, the observers recommend that the CNWRA improve its process for assuring that all corrective actions are completed and documented, before closing out significant conditions adverse to quality reports.