CNWRA *A center of excellence in earth sciences and engineering*

A Division of Southwest Research Institute™
6220 Culebra Road • San Antonio, Texas, U.S.A. 78228-5166
(210) 522-5160 • Fax (210) 522-5155

September 18, 2001
Contract No. NRC-02-97-009
Account No. 20.01402.159

U.S. Nuclear Regulatory Commission
ATTN: Mrs. Barbara D. Meehan
Contracting Officer
Division of Contracts
TWFN Mail Stop 7-12
Washington, DC 20555

Subject: Transmittal of FY2001 CNWRA QA Audit 2001-2
Letter Report Intermediate Milestone 01402.159.130

Dear Mrs. Meehan:

This letter transmits a copy of the CNWRA Audit 2001-2 Report in fulfillment of the subject milestone as specified in the CNWRA HLW Operations Plans.

This programmatic and technical CNWRA QA audit was planned, executed and reported in accordance with the CNWRA Quality Assurance Manual and associated Quality Assurance Procedures. We appreciated the observation of this audit by the NRC representatives and believe the audit will lead to improvements in our internal practices and procedures. This audit confirms that the CNWRA is implementing an effective quality assurance program, the program continues to improve, and as a result, we are better able to serve the NRC.

Should you have any question regarding this QA audit, please contact Bruce Mabrito at (210) 522-5149.

Sincerely yours,

Wesley C. Patrick
President

BEM/mp

Enclosure
cc:
J. Linehan
D. DeMarco
E. Whitt
T. Carter
L. Campbell
N. Stablein
J. Greeves
W. Reamer

w/o attachment:
CNWRA Directors
CNWRA Element Managers
T. Nagy (SwRI Contracts)
P. Maldonado

Washington Office • Twinbrook Metro Plaza #210
12300 Twinbrook Parkway • Rockville, Maryland 20852-1606

QUALITY ASSURANCE AUDIT REPORT

FOR CNWRA AUDIT 2001-2

OF

THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

SAN ANTONIO, TEXAS

August 20–23, 2001

EXECUTIVE SUMMARY

The annual internal Quality Assurance (QA) audit of the Center for Nuclear Waste Regulatory Analyses (CNWRA) was conducted August 20-23, 2001, fourteen months after the previous audit for the year 2000. The additional time (14 months rather than the usual 12 month interval) between audits provided additional time for implementation of the recently revised CNWRA Quality Assurance Manual (CQAM). The audit team, comprised of technical and quality assurance specialists, determined that the CNWRA QA program was being effectively implemented. Nuclear Regulatory Commission (NRC) representatives (quality assurance and program management) observed the audit, and concurred with the overall findings.

The CNWRA staff was operating in accordance with the CQAM, Operations Plans, Technical Operating Procedures (TOPs) and QA Procedures (QAPs), with the exceptions discussed below. The technical staff was judged to be appropriately qualified through education, experience, and training. The technical work was being conducted in a satisfactory manner. The audit team identified a number of recommendations that may facilitate the CNWRA in maintaining its current excellent level of performance, particularly in light of the increasing tasking of the CNWRA to regulatory reviews.

The results of the audit, including observations and recommendations, were discussed with the CNWRA management and staff during daily management briefings and in a post-audit meeting on August 23, 2001. Two major nonconformances, which will be addressed in Corrective Action Requests (CARs), were identified. Both were associated with quality assurance staff functions, and possibly indicate insufficient resources for quality assurance functions. Three minor nonconformances were identified. The results suggest significant improvements in comparison to the June 2000 audit.

1. AUDIT SCOPE

This audit evaluated the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance (QA) program to determine whether it meets the applicable requirements of ANSI/ASME NQA–1–1986 and is being effectively implemented.

2. PROGRAMMATIC ELEMENTS AUDITED

ANSI/ASME NQA–1–1986 Criteria		Corresponding CQAM Chapter
I	Organization	1
II	QA Program	2
III	Design Control	N/A
	Scientific/Engineering Investigation & Analysis Control	3
IV	Procurement Document Control	4
V	Instructions, Drawings, & Procedures	5
VI	Document Control	6
VII	Control of Purchased Material	7
VIII	Identification and Control of Items	8
IX	Control of Special Processes	9
X	Inspection	10
XI	Test Control	11
XII	Control of Measuring and Test Equipment	12
XIII	Handling, Storage, and Shipping	13
XIV	Inspection, Test, and Operating Status	14
XV	Nonconformance Control	15
XVI	Corrective Action	16
XVII	Records Control	17
XVIII	Audits	18

Design-related activities are not performed by the CNWRA, so ANSI/ASME NQA–1–1986 Criterion III, Design Control, is not applicable. All CNWRA Quality Assurance Manual (CQAM) sections were addressed in this audit.

3. AUDIT APPROACH

A performance-based approach to auditing was applied to evaluate the effectiveness of the QA program in ensuring and improving product quality. This was accomplished by direct evaluation of selected technical activities, assessment of products, and evaluations of key product realization processes and the contributions of these processes to product quality. The performance-based approach consisted of:

- Having teams composed of a programmatic auditor and a technical specialist evaluate activities from their respective perspectives

- Evaluating implementation of procedures and plans associated with key process steps; planning, information gathering, information analysis/code development, and product verification

QA program elements less directly associated with key processes, such as document and records controls, nonconformance and corrective action, etc., were audited separately from the technical activities.

Daily caucuses for the audit team and observers and daily meetings between the audit team leader and CNWRA management were held.

4. TECHNICAL ACTIVITIES AUDITED

A risk-informed approach was applied in selecting the technical activities to audit. Technical and programmatic risk, as determined by CNWRA management, provide the basis for the frequency that an activity is to be audited (conceivably, from one to five years). The assigned risk levels combined with the times since the previous audits determined which technical activities were selected for this audit.

- Igneous Activity
- External Quality Assurance
- Unsaturated & Saturated Flow Under Isothermal Conditions
- Total System Performance Assessment and Integration
- Spent Fuel Project Office-Private Fuel Storage Facility
- West Valley Demonstration Project
- Uranium Recovery Projects

5. AUDIT TEAM

Bob Brient	Audit Team Leader (ATL)	QA Systems, SwRI
Don Dunavant	QA Auditor	QA Management, SwRI
Rod Weber	QA Auditor	QA Management, SwRI
Cindy Rucker	Auditor	QA Systems, SwRI
Derrick Coffin	Technical Specialist	Computational Fluid Dynamics, SwRI
Steve Dellenback	Technical Specialist	Software Engineering, SwRI
Larry Goland	Technical Specialist	Structural Engineering, SwRI
John Hageman	Technical Specialist	Radiation Protection, SwRI
Bill Thomann	Technical Specialist	Geosciences, University of the Incarnate Word

6. APPLICABLE DOCUMENTS

The following documents formed the basis of the audit and for the checklists.

- CNWRA QA Manual (CQAM)
- CNWRA QA Procedures (QAPs)
- CNWRA Technical Operating Procedures (TOPs)
- CNWRA Administrative Procedures (APs)
- Applicable CNWRA Operations Plans
- Title 10 CFR Part 50, Appendix B
- ANSI/ASME NQA-1-1986

7. OBSERVERS

Larry Campbell	USNRC	Senior Quality Assurance Engineer, High-level Waste Branch
Deborah DeMarco	USNRC	Deputy Director, Program Management, Policy Development, and Analysis Branch
Kenneth Hooks	USNRC	Project Manager, Uranium Recovery Branch
John Linehan	USNRC	Director, Program Management, Policy Development, and Analysis Branch

8. SUMMARY OF RESULTS

8.1 Igneous Activity

The objective of this task was to resolve issues related to the probability and consequences of igneous activity (IA) on repository system performance, the recent focus being on consequences. IA task activities included the development of a technical basis for resolution of the large uncertainties associated with key models and parameters used in DOE risk assessments. The staff and consultants were developing alternative numerical models to characterize the possible effects of ascending basaltic magma intersecting repository drifts. Evaluation of wall-rock erosion and conduit development during basaltic eruptions was part of this investigation. Interaction of the magma with waste disposal casks and possible airborne particulate contamination was also studied. Studies were assigned to and conducted by well qualified individuals and their qualifications were appropriately documented. During the two-year period evaluated by this audit activity, work products (Milestones) had been submitted in letter reports and journal articles. An additional task of evaluating specific IA section(s) of the integrated Issue Resolution Status Report (IRSR) had been delayed and therefore no work product in this area was evaluated.

Several milestone deliverables were evaluated during the audit, including "Modeling Magma-Drift Interaction at the Proposed High-Level Waste Repository at Yucca Mountain, Nevada, USA" (Milestone 20.01402.461.155), "Quantifying Hazards from Basaltic Tephra-Fall Eruptions - Poster Session," "Software Requirements Description - Magma Repository Interaction Simulation Code (SHOCK)," "Technical Basis for Resolution of the Igneous Activity Key Technical Issue" (Milestone 20.01402.461.100), and "Explosive Magma-Air Interactions by Volatile-Rich Basaltic Melts in a Dike-Drift Geometry" (Milestone 20.01402.461.040).

The IA principal investigator and the element manager were interviewed. Discussions centered on the work associated with numerical modeling and included discussions of consultant qualifications and roles in this activity. Management was addressing the issue of the departure of a key principal investigator by actively seeking a suitable replacement.

Personnel qualification packages, document review packages, scientific notebooks, quality assurance requirements matrixes, operations plan, and surveillance reports were reviewed. No field investigations had been conducted for this phase of the IA task. A planned laboratory visit was waived due to the inability of the CNWRA to locate documentation (i.e., a scientific notebook) for

the laboratory investigations conduced on-site by a consultant. (See the minor nonconformance, section 9 and recommendations, immediately following this paragraph.)

Recommendations:

- The document review process (QAP-002) might be revised to accommodate types of documents not clearly addressed by the review requirements matrix, such as software requirements documents or development plans. If not deliverable, some documents may not need format reviews.

- When personnel (including consultants and limited-term employees) depart the CNWRA, the processing should assure the proper turnover of quality affecting information (i.e., notebooks, computer files, etc).

8.2 External Quality Assurance

This task involved participation in observations of DOE audits and training of NRC and CNWRA staff for audit observation performance. CNWRA and SwRI Quality Systems staff, qualified in audit observations, were used for these activities.

Interviews with the element manager, support staff and report contributors were held. The milestones reviewed were input to five NRC audit observation reports (Milestones 20.01402.331.111, 20.01402.331.113, 20.01402.331.019, 20.01402.331.017, and 20.01402.331.016). The deliverable reports, review packages, and qualification records were audited. Report content and delivery were compared to NRC guidance. One of the five reports was delivered beyond the time limit due to difficulties with team input and word processing (see Recommendations). Report content was acceptable, and reviews were properly conducted.

The audit also reviewed the training for NRC and CNWRA personnel in audit observations. Training materials were reviewed, and discussions were held with staff that had prepared and presented the training. Training material appeared to be thorough, and appropriate CNWRA and NRC personnel had received the training.

Recommendations

- The CNWRA should carefully study the proposed turn-around time commitments in the FY 2002 Operations Plans. The seven working-day limit may not be achievable under the current process, so the process or the time limit may need to be revised.

- The NRC's Inspection Manual chapter regarding audit observations had several inconsistencies with the training materials previously used. The CNWRA should consult with NRC to determine if tasking is needed so that the training materials can be updated. The impact of the Inspection Manual issuance on qualification of the staff trained in audit observations should also be evaluated to determine if re-training is necessary.

8.3 Unsaturated & Saturated Flow Under Isothermal Conditions

The objective of this activity for FY2001 was to resolve outstanding issues related to identifying features and processes important to repository performance and treating DOE modeling uncertainties.

The audit involved document reviews and interviews with the element manager, principal investigator, and technical staff. The deliverables evaluated consisted of "Review of the DOE Unsaturated Zone Flow and Transport Model Process Model Report" (Milestone 20.01402.861.100) and "Review of the DOE Saturated Zone Flow and Transport Model Process Model Report" (Milestone 20.01402.861.110). Both milestones had been met satisfactorily. Planning, information gathering, analysis, and review processes had been executed in accordance with applicable procedures. Personnel had been indoctrinated, trained, and qualified. Due to the nature of the milestones (i.e., reviews of DOE reports) no original data from CNWRA laboratory or field activities were involved.

The audit also evaluated other task activities. Scientific notebooks were appropriately used and under QA program control. A purchase of satellite imagery was properly specified in purchase documents and was inspected by a principal investigator upon receipt (and rejected). Field samples were properly identified in a scientific notebook when gathered and were properly logged, identified, and stored at the CNWRA laboratory. The measuring equipment used in this task was limited to balances, which were calibrated, labeled, and under the SwRI Calibration Laboratory recall system. Surveillance of this task had not been scheduled nor performed. (See the major nonconformance in section 9 of this report.)

Recommendations

- The scope and extent of testing and validation of specific software should be clarified, particularly for multi-function codes. Technical staff members were not certain whether an entire code (GMS in this case) or just certain often used modules had been tested or would be validated.

- The term "regulatory review" may need additional definition or its definition may need to be more clearly communicated to the staff. Several technical staff were not certain of the meaning of this term that is so important to the timing of validation in TOP-018.

8.4 Total System Performance Assessment and Integration

The Total Systems Performance Assessment (TSPA) software system is a collection of scientific applications that can be utilized to evaluate the interactions of geologic phenomena and engineered systems. The software has evolved over the last several years. During 2001, the CNWRA issued several maintenance releases but no major releases of the application. The TSPA application is designed and implemented to execute in multiple environments (e.g., Windows or UNIX).

Deliverables that were the focus of the audit were the TPA Version 4.0 Code Software Development Plan and the following Software Release Notices (SRNs): version 4.1 SRN #229, dated Sept 27, 2000, (Fortran Source tape and Win NT CD sent to NRC), version 4.1e SRN #232,

dated Jan 31, 2001, (Fortran Source tape and Win NT CD sent to NRC), and version 4.1j SRN #243, dated May 02, 2001, (Fortran Source tape and Win NT CD sent to NRC).

The audit consisted of document reviews and interviews with the element manager, principal investigator, and software development custodian. The audit team found that the TPA code has significantly evolved over the last several years to a process oriented software development approach. Improvements to a complex of piece of software were being made efficiently and thoroughly. The TSPA team had excellent configuration management of the source code.

Recommendations

- TOP-018 should require that code reviews performed by the development custodian (R. Janetzke in this case) be documented, specifically the date and content of the reviews.

- Software Change Requests (SCRs) should be associated with specific changes in the source code. This may be accomplished by placing the SCR number "around" the changed area of the code.

- TOP-018 should provide more guidance regarding the software testing process, especially testing of changes to commercial off the shelf (COTS) software. The auditors noted that most of this issue was addressed in the proposed revision to TOP-018.

- TOP-018 should require independent reviews of Software Development Plans (SDP) by a software specialist.

- TOP-018 should require that quarterly project review meetings be held, with the objective of revising the project SDP as necessary. Provisions to more easily amend the SDP (e.g., addenda rather than full revisions or changes) should be also be considered.

- TOP-018 should be able to address planning for maintenance oriented software projects (such as for the TPA code during much of FY 2001) as well for projects involving development of major software releases.

8.5 Spent Fuel Project Office (SFPO)-Private Fuel Storage Facility (PFSF)

This task supports the NRC in reviewing the proposed PFSF Safety Analysis Report (SAR) that had been submitted to the NRC by Private Fuel Storage, LLC. Detailed reviews had been conducted to evaluate revised submittals of this SAR. The staff has prepared draft and final input to NRC's Safety Evaluation Report (SER), worked interactively with NRC staff to prepare the final SER, and will provide support to the NRC staff for the Atomic Safety Licensing Board hearings. The audit assessed activities involving the CNWRA's multi-disciplinary technical reviews of the SAR.

Several milestone deliverables along with supporting letter reports were evaluated during the conduct of interviews and documentation reviews. These included the CNWRA contributions to the "Private Fuel Storage Facility Safety Evaluation Report – Input Letter Report." This deliverable had been satisfactorily completed, along with documented technical issues, calculations, and an appropriate literature search. The reviews conducted of the geology, hydrology, geohydrology, soil

properties and mechanics, seismology, and meteorology portions of the SAR were determined by the audit team to be thorough and comprehensive.

CNWRA staff interviewed during the audit included the element manager, the principal investigator, and the geotechnical and radiation safety contributors to the SAR review. No laboratory or field activities had been conducted for this task. Several laboratory notebooks were reviewed and found to be conforming to Scientific Notebook controls. The computer code Probabilistic Seismic Hazard Analysis (EZ-FRISK, v. 3.0) referenced in Scientific Notebook #224 was verified as being under TOP-018 control, as were the commercial codes GMSYS (2-D modeling) and OASIS MONTAGE (3-D modeling). All of the staff were well qualified to perform the assigned technical work.

No recent surveillance of SFPO activities had been conducted (see the major nonconformance, section 9).

Recommendations:

- The good practices employed in this multi-disciplinary, regulatory review type activity should be applied in similar current and future projects. The QA program could be used as the framework for systematically and consistently applying such practices. Specific practices noted included: (1) developing task-specific competence for technical staff performing the regulatory reviews as well as for the support staff formatting and checking the reports, (2) assuring that specific versions of documents important to consistency and accuracy of the regulatory reviews are provided to the staff, and (3) effectively communicating NRC directives to affected staff under changing conditions.

- The CNWRA should assure that the QA program adequately addresses regulatory review activities as the tasking of the CNWRA shifts more toward this type of work, and less so toward investigational activities.

- The CQAM, section 3.3.11, should be clarified in the intent of "develop review practices," whether the intent is to acknowledge that the CNWRA will develop review procedures when tasked to do so, or if the CNWRA is required to do so, even without explicit tasking.

- Additional effort and project management may be necessary to assure consistency of multi-disciplinary products with multiple authors from two (CNWRA and NRC) organizations, perhaps through specific integration steps and through the review process.

- The CNWRA and NRC should clarify responsibilities for jointly developed products (i.e., products with contributors from both organizations). The clarification should consider questions such as the scopes of reviews (covering only CNWRA or both NRC and CNWRA contributions) and how consistency and integration can be assured.

8.6 West Valley Demonstration Project

The West Valley Demonstration Project (WVDP) utilized two commercial-off-the-shelf (COTS) software tools (ArcView and EarthVision) to visualize data that was provided by the NRC. The data files presented to the CNWRA were not provided in an organized fashion. The effort did not involve any validation of the data that was provided. Various scripts were written to allow ArcView to be

utilized to visual the data provided. The data files provided were organized so that the above ground topology (e.g., buildings) could be visualized with the below ground information (provided in the data files).

The deliverables that were the focus of the audit were the "Software Development Plan for the West Valley Demonstration Project Geographic Information System/Three Dimensional Modeling System" (dated July 2001), "West Valley Demonstration Project Task 2: Geographic Information System (GIS)–Subtask B: Modeling Strategy Development," "(Beta) Final Report–Geographic Information System and Three-Dimensional Modeling System, for the West Valley Site," and "Final Report–Geographic Information System and Three-Dimensional Modeling System, for the West Valley Site."

The audit consisted of document reviews and interviews with the element manager and principal investigator. The audit found that the task involved a very interesting application of COTS tools. ArcView effectively utilized to visualize complex data in a simple-to-view perspective. The tool appeared to be easily extensible as new data sets become available. The Software Development Plan (SDP) developed by the CNWRA provided good guidance for project management. In addition, scripts (and their documentation) were handled well.

Recommendations:

- The CNWRA should clarify when scientific notebooks must be used, or if alternative methods of documentation, (e.g., comments or scripts in source code) are acceptable.

- A software QA specialist should be involved in quality planning (QAP-013) to assure that software development and/or use controls are applied when appropriate to the anticipated scope of activities.

- Minor modifications to the ArcView Readme file need to be made to clarify the software installation process.

- In order to verify that the requirement to produce an SDP (or waiver) within 30 days of project initiation, CNWRA QA should perform surveillance on tasks that require TOP-018 compliance.

8.7 Uranium Recovery Projects

Uranium Recovery Projects span a broad range of activities to support NRC in efforts to meet its regulatory role. CNWRA's assigned tasks required the use of qualitative, quantitative, and probabilistic methods to conduct analyses.

The audit consisted of interviews with the element manager, principal investigators, and technical contributors. The deliverables reviewed during this audit consisted of milestones from task orders 08 and 10: "CNWRA Draft Final Report on Baseline Risk-Informed, Performance-Based Approach for *In Situ* Leach Uranium Extraction Licenses" (Milestone 20.01620.081.005), and "CNWRA Surety Estimation Methodology for Groundwater Corrective Actions at Title II Conventional Mills" (Milestone 20.01620.101.000). Both milestones were met satisfactorily. Supporting documentation was thorough and clear. Planning, information gathering, analysis, and review processes were

executed consistent with the relevant QA procedures. Deliverable document review comments were appropriately documented and resolved.

Uranium Recovery task activities included site visits (to *in situ* leach operations), however no field or laboratory operations were conducted by the CNWRA. Scientific notebooks, including those in electronic form, appropriately documented analyses and appeared to be sufficiently detailed so that a technically competent individual could repeat the work. Personnel were indoctrinated to the QA program, trained, and were well qualified. Surveillance was planned just once per year (for March 2001, versus the objective of two surveillances per year) and had not been performed (see nonconformances in section 9).

Recommendation:

- Meetings with NRC representatives (i.e., trips) should be documented to capture important information.

8.8 General Quality Assurance

QA program elements not directly associated with the specific technical areas were audited separately. Elements of the program audited in this fashion included surveillance planning and management, indoctrination and training, document control, nonconformance control, corrective action, audits, records control, and procurement. The audit was conducted through interviews with quality assurance and administrative staff and through records reviews.

The reviews of document and record controls indicated mature, effectively operating systems. Staff assigned to these functions were knowledgeable and capable. Improvements have been made in training, specifically in identification of training needs and periodic reassessment. Significant changes to procurement have been made in the CQAM and in QAP-016, however two minor nonconformances were identified, both being inconsistencies between QAP-016 and the CQAM in related program elements, specifically, inspection (CQAM Section 10) and inspection status (CQAM Section 14). Major nonconformances were identified in (1) surveillances not meeting schedules or objectives, and (2) in premature close-out of corrective actions. The nonconformances are described in detail in section 9 of this report.

Follow-up of the deficiencies identified in the June, 2000 audit was also performed. Most corrective actions were confirmed during a January, 2001 follow-up audit (CNWRA 2001-1). This audit identified several CARs that had been closed-out without having completed all of the prescribed actions, so CAR 2001-01 was issued. The actions called out by CAR 2001-01 appeared to be appropriately implemented.

Recommendations

- Training - QAP-005 should be revised to reflect the current practices in identifying and periodically reassessing training needs. The form documenting training needs, QA-11-1, should include an area to document that (and when) training is accomplished.

- Procurement - QAP-016 should (1) clarify how controls will be applied to commercially available software used in quality affecting activities and (2) clarify the extent of receiving

inspection necessary for goods purchased from approved suppliers (usually, verification of kind, quantity, and condition). QAP-016 should also require that purchase orders indicate whether the goods/services are quality affecting, the one factor that determines applicability of QAP-016.

- Documents and data of external origin, including information from NRC, DOE, and other sources should be brought under quality assurance program controls. Current practices of archiving documents and data, and notifying staff of information receipt should be formalized. Practices of citing information sources in CNWRA products should be formalized. Controls should be identified that assure that staff are aware of and have access to the correct documents and data. Controls should also address timely notification and access to document and data revisions, particularly when the revisions affect ongoing activities and products.

9. NONCONFORMANCES

Significance	Reference Report	Requirement Reference	Description of Condition
Major	CAR 2001-05	Surveillance: QAP-004, 3.2.1	1. FY 2000 and FY2001 surveillance schedules did not meet the objective of twice per year for each technical activity. Most non high-level waste technical activities were not scheduled for surveillance. 2. Surveillances performed did not meet schedules: 8 performed of 24 scheduled through July, 2001 in FY2001, similar level of surveillances performed in FY 2000.
Major	CAR 2001-06	Corrective Action: QAP-010, 4.3	CARs 2001-02 and 2001-03 had been verified and closed-out, however the specified actions had not been completed. Corrective actions for several nonconformances from the June 2000 audit were also prematurely closed-out (addressed in CAR 2001-01).
Corrected during audit	N/A	Scientific Notebooks: QAP-001	Electronic data was not identified or referenced in the notebook. Remedial action was taken during the audit.
Minor	NCR 2001-13	Receipt Inspections: CQAM 10.6	1. Receipt inspection instructions were not included on purchase documents as required by CQAM 10.6. 2. Implementing procedure for purchase document control (QAP-016) does not make mandatory the inclusion of receiving inspection criteria (i.e., does not flow down the requirement of CQAM 10.6).

Significance	Reference Report	Requirement Reference	Description of Condition
Minor	NCR 2001-14	Inspection Status: CQAM 14.4.2	1. Inspection status was not indicated on purchased goods after receipt inspection as required by CQAM 14.4.2. 2. Implementing procedure addressing receipt inspection (QAP-016) does not address inspection status identification.
Minor	NCR 2001-15	Scientific Notebooks: QAP-001	1. No documentation could be located for the quality affecting activities of a former consultant. 2. The assigned scientific notebook was not used. 3. Bi-annual capture of documentation was not accomplished.

Copies of the Corrective Action Requests and Nonconformance Reports are attached to this report.

10. QUALITY ASSURANCE PROGRAM EFFECTIVENESS

The quality assurance program applied by the CNWRA was being effectively implemented. The nature of the nonconformances identified in the audit did not appear to have a significant potential to adversely affect products or the overall effectiveness of the program. The major nonconformances associated with the quality assurance staff functions of surveillance and corrective action verification may suggest that additional resources are needed.

The audit identified opportunities to enhance the program effectiveness and further assure successful products through the audit team's recommendations. The nature of the tasks assigned to the CNWRA has shifted increasingly toward regulatory reviews. This shift may necessitate a commensurate shift in the focus and approach of the quality assurance program.

11. PERSONS CONTACTED

	Attended Pre-audit Meeting	Contacted during Audit	Attended Post-audit Meeting
Ard, Roseanne	X	X	
Chowdhury, Asad	X	X	
Daruwalla, Darius		X	X
Deborah DeMarco	X	X	X
Ehnstrom, Mark	X	X	X
Farrell, David		X	X
Fedors, Randall		X	
Folck, Randy	X	X	
Garcia, Henry		X	X
Ghosh, Amitava		X	X
Gute, Doug			X
Hill, Brittain	X	X	
Hill, Melissa		X	
Holt, Amos			X
Ken Hook	X	X	X
Hsiung, Simon			X
Hughson, Debra		X	
Jain, Vijay	X		
Janetzke, Ron	X	X	
Linehan, John			X
Mabrito, Bruce	X	X	X
Mackin, Pat		X	X
Maldonado, Paul	X	X	
Manepally, Chandrika		X	
Mayer, Stefan			X
McKague, Larry		X	X
Mohanty, Sitikanta	X	X	
Padilla, Maria			X
Painter, Scott		X	
Patrick, Wesley		X	X
Patton, Cheryl			X
Pearcy, English			X
Pickett, David		X	
Russell, Blaine			X
Sagar, Budhi		X	X
Seely, Perry		X	
Sridhar, Narasi	X		
Stamatakos, John		X	
Trbovich, Tom		X	
Turner, David		X	X
Weldy, James		X	
Winterle, Jim		X	X
Wittmeyer, Gordon	X		X

12. APPROVALS

Robert Brient
Audit Team Leader — September 5, 2001
Date

Derrick Coffin
Technical Specialist — Sept 5, 2001
Date

Steven Dellenback
Technical Specialist — 6 Sep 2001
Date

Donald Dunavant
Auditor — 5 Sept 01
Date

Lawrence Goland
Technical Specialist — Sept. 6, 2001
Date

John Hageman
Technical Specialist — Sept 6, 2001
Date

for William Thomann
Technical Specialist — September 6, 2001
Date

Rod Weber
Auditor — 6 Sept 2001
Date

Cindy Rucker
Auditor — Sept 6, 2001
Date

APPROVED:

Bruce Mabrito
CNWRA Director of Quality Assurance — Sept 7, 2001
Date

[s:\doc\audits\2001audits\01-2CNWRArpt.wp]

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2001-05 **Associated AR, SR, NCR No:** AR2001-02

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

FY 2000 and FY 2001 surveillance schedules did not meet the objective of twice per year for each technical activity. Most non high-level waste technical activities were not scheduled.
Surveillances performed did not meet schedules: 8 performed of 24 scheduled through July, 2001 in FY 2001, similar level of surveillances performed in FY 2000.

Initiated by: Robert Brient RDB **Date** 8/24/2001

PART B: PROPOSED ACTION

Responsible EM: B. Mabrito
Response Due: 9/24/2001

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

Verified by: **Date:**

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
ELEMENT MANAGERS

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2001-06 **Associated AR, SR, NCR No:** AR2001-02

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

CARs 2001-02 and 2001-03 had been verified and closed-out, however the specified actions had not been completed. This finding is similar to one identified during the January 2001 follow-up audit (see CAR 2001-01).

Initiated by: Robert Brient **Date** 8/24/2001

PART B: PROPOSED ACTION

Responsible EM: B. Mabrito
Response Due: 9/24/2001

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

Verified by: **Date:**

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
ELEMENT MANAGERS

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

NONCONFORMANCE REPORT

Project No. 20.01402.158 **NCR No.** 2001-13

PART 1: DESCRIPTION OF NONCONFORMANCE

1. Receipt inspection instructions were not included on purchase documents as required by CQAM 10.6.
2. Implementing procedure for purchase document control (QAP-016) does not make mandatory the inclusion of receiving inspection criteria (i.e., does not flow down the requirement of CQAM Section 10.6).

Initiated by: Robert Brient **Date:** 8/24/2001

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION : H. Garcia/B. Mabrito
Response 9/10/2001

Disposition:

Basis of Disposition:

Action to correct nonconformance:

Target date for completion: _____

Proposed by: _____ **Date:** _____

PART 3: APPROVAL

Element Manager: _____ **Date:** _____

Director of QA: _____ **Date:** _____

Comments/Instructions:

PART 4: CLOSE OUT

Comments:

Verified by: **Date:**

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
ELEMENT MANAGERS

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

NONCONFORMANCE REPORT

Project No. 20.01402.158 NCR No. 2001-14

PART 1: DESCRIPTION OF NONCONFORMANCE

1. Inspection status was not indicated on purchased goods after receipt inspection as required by CQAM 14.4.2.
2. Implementing procedure addressing receipt inspection (QAP-016) does not address inspection status identification.

Initiated by: Robert Brient RBS **Date:** 8/24/2001

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION : H. Garcia/B. Mabrito
Response 9/10/2001

Disposition:

Basis of Disposition:

Action to correct nonconformance:

Target date for completion: _____

Proposed by: _____ **Date:** _____

PART 3: APPROVAL

Element Manager: _____ **Date:** _____

Director of QA: _____ **Date:** _____

Comments/Instructions:

PART 4: CLOSE OUT

Comments:

Verified by: **Date:**

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
ELEMENT MANAGERS

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

NONCONFORMANCE REPORT

Project No. 20.01402.158 **NCR No.** 2001-15

PART 1: DESCRIPTION OF NONCONFORMANCE

1. No documentation could be located for the quality affecting activities of a former employee/consultant.
2. The assigned scientific notebook was not used.
3. Bi-annual capture of documentation was not accomplished.

Initiated by: Robert Brient RBB **Date:** 8/24/2001

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION : L. McKague
Response 9/10/2001

Disposition:

Basis of Disposition:

Action to correct nonconformance:

Target date for completion: _____

Proposed by: **Date:**

PART 3: APPROVAL

Element Manager: _____ **Date:** _____

Director of QA: _____ **Date:** _____

Comments/Instructions:

PART 4: CLOSE OUT

Comments:

Verified by: **Date:**

Distribution:
Original-CNWRA/QA DIRECTOR QA Records
ORIGINATOR
ELEMENT MANAGERS