

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE
FISCAL YEAR 2004 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QUALITY ASSURANCE AUDIT 2004-1

OBSERVATION AUDIT REPORT NO. OAR-04-03-CNWRA

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ENCLOSURE

1.0 INTRODUCTION

On June 8-11, 2004, U.S. Nuclear Regulatory Commission (NRC) staff from the Office of Nuclear Material Safety and Safeguards (observers) observed the Fiscal Year 2004 Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance (QA) Audit 2004-1. QA and technical Staff from Southwest Research Institute (SwRI) and the University of The Incarnate Word (auditors) performed this risk-informed, performance-based audit at the CNWRA facilities in San Antonio, Texas.

The CNWRA provides technical support to NRC staff under contract NRC-02-02-012. Under this contract, CNWRA is required to meet the QA requirements specified in 10 CFR Part 63 as implemented by the CNWRA QA Program. The objectives of this CNWRA audit were to determine whether the CNWRA QA Program meets the applicable requirements of 10 CFR Part 63, and if it is effectively implemented. The objective of the NRC staff's observation of the CNWRA audit were to evaluate the adequacy of the CNWRA audit process and the effectiveness of the CNWRA QA Program implementation in meeting the QA requirements of 10 CFR Part 63. This report presents a summary of the conduct of the CNWRA QA audit and the NRC staff's audit observations, conclusions, and recommendations regarding the adequacy of the CNWRA audit and the effectiveness of the CNWRA QA Program implementation.

2.0 MANAGEMENT SUMMARY

The observers evaluated the CNWRA audit process and the CNWRA QA Program implementation through: (1) observation of, and discussions with, the auditors; (2) observations of interviews with CNWRA Element Managers and technical staff; (3) review of objective evidence such as the audit plan, the audit checklist, technical documentation, and Scientific Notebooks; and (4) observation of laboratory activities.

The CNWRA Audit Team Leader adequately described the audit schedule and individual assignments in the audit plan and associated audit documentation, made available audit checklists to the auditors, and was effective in providing guidance and leadership to the auditors throughout the audit. The observers determined that the Audit Team Leader and auditors were qualified: technical specialists were qualified in their individual areas of technical expertise and the QA auditors were qualified in the CNWRA QA Program requirements. The auditors were thorough, effective, and performed in a professional manner.

The observers determined that CNWRA Audit 2004-1 achieved its purpose of evaluating the implementation of the QA Program controls regarding programmatic and technical activities. The observers determined that the audit was effective in determining CNWRA staff compliance with procedural controls in the areas examined and that the CNWRA QA Program controls are being adequately implemented. The observers also determined that the technical adequacy of the work products and procedures was satisfactory but is subject to continuing in-depth evaluation by NRC technical staff. The observers agree with the auditors' findings that, overall, the CNWRA QA Program controls are being adequately implemented in the areas that were evaluated, except for the identified nonconformances.

During the audit, the auditors identified eight nonconformances as described in Section 9.10 below. The auditors determined that the nonconformances identified during the audit are

unlikely to have adverse impacts on CNWRA technical products. The auditors also made 13 recommendations to improve implementation of the QA Program as described in Section 9.11 below. The Audit Team Leader provided appropriate opportunities for the observers to provide comments and ask questions throughout the conduct of the audit. The auditors and observers discussed the findings with CNWRA management during daily debriefs and at the post-audit meeting.

The observers believed that the CNWRA audit was thorough and effective; however, several specific comments for more effective future audits are presented in Section 10 below.

3.0 PARTICIPANTS

CNWRA staffed the audit team with qualified QA auditors and technical specialists who were trained in auditing techniques. The auditors were independent of the activities and technical areas being audited. Sub-teams comprising a technical specialist and a QA auditor performed the audit of each technical activity.

3.1 AUDIT TEAM MEMBERS

Don Dunavant	Team Leader	SwRI
Mary Ann Clark	Technical Specialist	SwRI
James Dante	Technical Specialist	SwRI
Lawrence Goland	Technical Specialist	SwRI
Christopher Hobson	QA Auditor	SwRI
Robert Morgan	Technical Specialist	SwRI
Ashley Smith	QA Auditor	SwRI
William Thomann	Technical Specialist	University of The Incarnate Word
Rodney Weber	QA Auditor	SwRI
Waring Worsham	Technical Specialist	SwRI

3.2 NRC OBSERVATION TEAM MEMBERS

Thomas Matula	Team Leader
Keith Compton	Technical Specialist
Frank Jacobs	QA Specialist
Yong Kim	Technical Specialist
Bret Leslie	Technical Specialist
Wilkins Smith	QA Specialist

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under contract NRC-02-02-012. In performing work for NRC under this contract, CNWRA is required to meet the QA requirements specified in 10 CFR Part 63 as implemented by the CNWRA QA Program. The CNWRA QA Program requires that, at a minimum, the CNWRA shall be audited on an annual basis. The CNWRA conducted the Fiscal Year 2004 CNWRA QA Audit 2004-1 to satisfy the requirement for an annual audit. Under the provisions of contract NRC-02-02-012 NRC elected to observe the conduct of the CNWRA QA audit to determine the adequacy of the CNWRA audit process

and the effectiveness of the CNWRA QA Program implementation in meeting the QA requirements of 10 CFR Part 63. The auditors performed the audit in accordance with CNWRA QA Procedure (QAP)-011, "Audits." NRC staff observed the CNWRA QA audit in accordance with Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The CNWRA QA Program audit was risk-informed and performance-based. CNWRA risk-informed its selection of the technical topics for the audit based on the time since the previous audit of the areas and the importance of the activity, particularly in regard to risk insights. The audit was performance-based in that the auditors reviewed completed technical products to determine compliance with CNWRA QA control processes and procedures. The auditors reviewed selected QA Program elements to determine compliance with applicable procedures. The QA Program elements and technical products reviewed by the auditors are identified in Sections 8.0 and 9.0 below, respectively.

6.0 CONDUCT AND TIMING OF THE AUDIT

The observers determined that, overall, the auditors achieved the purpose of the CNWRA Audit 2004-1. The auditors were thorough, effective, and performed in a professional manner. In general the observers believe the timing of this annual CNWRA QA audit was appropriate. However, during this audit the auditors reviewed nine technical products and 18 QA Program elements in less than three days. The observers recommend that additional time be allowed to perform future audits of this size to assure that comprehensive reviews are performed.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The CNWRA audit team was composed of an Audit Team Leader, technical specialists, and QA auditors who were qualified in accordance with the CNWRA QA manual. The observers found the qualifications of the Audit Team Leader and the audit team members to be acceptable in that each met the requirements of SwRI Procedure No. IQS-OP-623, "Certification of auditors." The auditors had no involvement with, or responsibility for, performing any of the activities they audited.

8.0 EXAMINATION OF QA ELEMENTS

The auditors evaluated the QA programmatic elements listed in Table 1 below in light of their application to technical activities:

Table 1
QA Programmatic Elements Evaluated

<u>QA Programmatic Elements</u>	<u>CNWRA QA Manual Chapter</u>
Organization	1
QA Program	2
Design Control	*
Scientific Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Drawings, and Procedures	5
Document Control	6
Control of Purchased Material	7
Identification and Control of Items	8
Control of Special Processes	9
Inspection	10
Test Control	11
Control of Measuring and Test Equipment	12
Handling, Storage, and Shipping	13
Inspection Test and Operating Status	14
Nonconformance Control	15
Corrective Action	16
Records Control	17
Audits	18

* Design-related activities are not performed by the CNWRA, therefore, Design Control requirements are not applicable.

The auditors reviewed the QA Programmatic elements concurrent with their review of technical activities described in Sections 9.1 through 9.9 below. The auditors' findings and recommendations are presented in Sections 9.10 and 9.11 below below, respectively. The auditors reviewed documentation related to the applicable QA procedures and interviewed a representative sample of CNWRA personnel to determine the effectiveness of implementing procedures and processes.

9.0 EXAMINATION OF TECHNICAL ACTIVITIES

The CNWRA Technical Director and QA Director determined the technical and programmatic areas selected for audit and the CNWRA President approved them. The determination was made based on the level of activity, technical risks involved, programmatic risks involved, and the time since each area had last been audited.

The auditors used a performance-based approach to evaluate the effectiveness of the QA Program in ensuring product quality. They used direct evaluation of selected activities, assessment of products, and evaluations of product development processes. The performance-based approach was implemented by using sub-teams of QA auditors and technical specialists who evaluated activities from their individual perspectives, and evaluated implementation of procedures and plans associated with product development. The auditors evaluated the technical activities listed in Table 2 below:

Table 2
Technical Activities Evaluated

Unsaturated and Saturated Flow Under Isothermal Conditions
Igneous Activity
Container Life and Source Term
Repository Design and Thermal-Mechanical Effects
Total System Performance Assessment Integration
Fuel Cycle Safety and Safeguards Projects
Spent Fuel Project Office
Decommissioning
Licensing Support Network

For each of the technical activities evaluated, the auditors confirmed the presence of required documentation supporting the processes involved and compliance to procedural requirements. The auditors assessed implementation of QA procedures by reviewing applicable Scientific Notebooks and other documents. The auditors assessed the control of the Scientific Notebooks and the information in the Scientific Notebooks that was used to document and validate scientific and engineering calculations. The auditors determined that research activities reviewed in each of the Scientific Notebooks audited were well documented.

Technical specialists evaluated the qualification of involved technical personnel, rigorousness of the science or engineering involved, and thoroughness of supporting documentation. The auditors reviewed training, education, and experience records for personnel who conducted scientific studies to ensure compliance with individual position requirements. The auditors determined that the records for personnel performing work in each of the technical activities audited were in compliance with their individual position descriptions.

Based on review of selected technical products produced in the period since the last audit in May 2003, the auditors created checklists specific to each technical activity and a general checklist addressing the QA programmatic requirements. The observers noted that the checklists for each of the technical activities audited were significantly different in format and technical content. The observers also noted that the checklists for the QA Programmatic elements audited were not at the level of detail or organization that would assure that a comprehensive evaluation of all important aspects is performed. The observers believed that the CNWRA audit was thorough and effective; however, a more formal approach to developing checklists for future audits would produce better tools to assure effective audits.

During the audit, the auditors identified eight nonconformances and made 13 recommendations to improve the QA Program implementation. The nonconformances and recommendations are presented in Sections 9.10 and 9.11 below, respectively.

9.1 Unsaturated and Saturated Flow Under Isothermal Conditions

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed three reports: (1) "Review of DOE Response to Agreements USFIC.4.06, SDS.3.02, and RT.3.06"; (2) "Geophysical Interpretations of Hydrostatigraphy in

the Forty Mile Wash Area”; and (3) “Results from Bishop Tuff Permeability Studies on Faulted NonWelded Tuffs.”

The observers identified that CNWRA technical staff turned in Scientific Notebooks to the QA Records Department on an annual basis as required by QAP-001, “Scientific Notebook Control.” However, QAP-012, “Quality Assurance Records Control,” requires Scientific Notebooks to be turned in each 6 months. CNWRA issued a nonconformance (Reference NCR 2004-12 in Section 9.10 below) and revised QAP-012 during the audit to reflect actual practice and the requirements of QAP-001 to turn in Scientific Notebooks an annual basis.

The observers agree with the auditors’ findings in this technical activity.

9.2 Igneous Activity

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed three reports: (1) “Review of DOE Documents Pertaining to Additional Information Needed for Igneous Activity KTI”; (2) “Examination of Effects of Geologic Features on Thermally Induced Stress at Yucca Mountain”; and (3) “First Order Conceptual Model for Fluvial Remobilization of Tephra Along Forty Mile Wash.”

The auditors focused on a review of the above listed technical reports, ensuring the quality of samples and laboratory equipment, and on software development. The audit team found that the QA Program implementation has been fully effective in developing the reports and that the program has been effective in carrying out technical activities such as field work, literature research, computational analysis, and presentation of results and conclusions. The auditors also reviewed control of samples collected during fieldwork and found no deficiencies.

The auditors had no findings in this technical activity. The observers agree with the auditors’ findings in this technical activity.

9.3 Container Life and Source Term

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed two reports: (1) “Natural Analogs of HLW Container Material – Experimental Evaluation of Josephinite”; and (2) “Effects of Fabrication Processes on Material Stability – Characterization and Corrosion.” The audit team found that the test methods used for the program were accepted practices and appropriately used. It also found that the CNWRA had a cohesive and well thought-out plan and performed a thorough examination.

However, the audit team identified two nonconformances during the audit of this technical activity. The first nonconformance, which was contrary to the requirements of QAP-016, “Procurement,” regarding not identifying weld material used on corrosion samples (Reference NCR 2004-10 in Section 9.10 below). The second nonconformance, which was first identified by the observers, was regarding three metal samples found in the laboratory having no identification markings to provide traceability as required by TOP-012, “Identification and Control of Samples and Chemical Reagents and Standards” (Reference NCR 2004-13 in Section 9.10 below). CNWRA immediately marked and subsequently discarded the samples during the audit.

The observers agree with the auditors' findings in this technical activity.

9.4 Repository Design and Thermal Mechanical Effects

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed three reports: (1) "Assessment of Subsurface Transporter Safety System for the Proposed Repository at Yucca Mountain"; (2) "The Effects of Fabrication Processes on the Mechanical Properties of Waste Packages"; and (3) "Preclosure Safety Assessment Tool Development and Progress Report." The auditors found that the products in this technical activity were acceptable and identified no problems.

The observers agree with the auditors' findings in this technical activity.

9.5 Total System Performance Assessment Integration

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed the report "A Plan for Risk Analysis by the Total System Performance Assessment Integration Key Technical Issue."

The auditors found that the QA Program was very effective to aid in preparation and delivery of high quality deliverables. The auditors reviewed training and qualification records and found no deficiencies. Several good practices were noted, including the fact that an integrated team worked effectively with the Total Performance Analysis (TPA) code to bring together the knowledge from the other technical activities.

The observers inquired about the method used for determining which version of the TPA 5.0 code was applicable for use in analyses. As a result of this inquiry, the auditors examined the process for controlling the use of versions of the TPA code and the associated input databases to ensure any appropriate limitations of the current version of the code were known to code users. As a result, the auditors developed one recommendation regarding the use and control of alpha and beta versions of the TPA code.

The auditors also reviewed the Master Software List to identify software to be audited. The auditors found that the Master Software List was not up to date: the Software Release Notice (SRN) date field was sometimes informally used by the library staff for recording comments. The audit team recommended that the Master Software List should be maintained up-to-date and if the SRN date field is used for comments, the use should be explained in the legend.

The auditors identified no nonconformances in this technical activity. The observers agree with the auditors' findings in this technical activity.

9.6 Fuel Cycle Safety and Safeguards Projects

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed the report "Construction Application Safety Evaluation Report."

The auditors reviewed this report for technical support for the Mixed Oxide (MOX) fuel fabrication facility construction authorization reviews. This task involved limited technical

activity to update the Safety Evaluation Report (SER) for seismic, geological, and geotechnical issues. No calculations were required and no scientific notebook inputs were made on this task. The auditors verified that CNWRA controlled the SER in accordance with the applicable CNWRA technical operating procedures.

The audit team found that the QA Program implementation was effective and the QA Program was adequate. No nonconformance or recommendation was made by the audit team in this area. The observers agree with the auditors' findings in this technical activity.

9.7 Spent Fuel Project Office Projects

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed the reports "Diablo Canyon Independent Spent Fuel Storage - Installation Safety Evaluation Report." The audit team found that the reports were well prepared and high quality.

During the review of the Diablo Canyon Independent Spent Fuel Storage Installation SER, the auditors identified a nonconformance in that calculations were referenced in the report and not documented in Scientific Notebooks contrary to the requirements of QAP-014, "Documentation of Scientific and Engineering Calculations" (Reference NCR 2004-11 in Section 9.10 below). The auditors recommended that QAP-014 be revised to allow mechanisms other than the scientific notebooks for documenting calculations.

The auditors identified two additional nonconformances, which were corrected during the audit. The first nonconformance was that Form QAP-011 "Professional Qualification and Training Record," for one CNWRA manager was not reviewed annually as required by QAP-007, "Professional Personnel Qualification" (Reference NCR 2004-14 in Section 9.10 below). The training record form was reviewed and signed by the cognizant supervisor during the audit. The second nonconformance was in regard to Scientific Notebook protocol such as not initialing and dating corrections as required by QAP-001, "Scientific Notebook Control" (Reference NCR 2004-15 in Section 9.10 below)

The observers agree with the auditors' findings in this technical activity.

9.8 Decommissioning

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed the report "Review Comments on IAEA Documents for Consideration at the Waste Standards Safety Committee Meeting 16 Milestone."

After the auditors completed their interviews in this technical activity, the observers inquired whether the CNWRA Form AP-6, "Document Review and Transmittal Form," which implements QAP-002, "Review of CNWRA Documents," for the report was appropriately initiated by the responsible Element Manager. As a result of the observers' inquiry, the auditors determined that an inappropriate person had initiated the document review. When questioned, the person who inappropriately initiated the Form-AP-6 stated that he knew he was not the appropriate Element Manager to initiate the Form AP-6 but did so to expedite the review process. Further, he stated that he had inappropriately initiated the Form AP-6 to expedite the review process on a number

of other occasions. In addition, the observers pointed out that CNWRA QA staff had signed the subject Form AP-6 indicating the document review had been verified for compliance with QAP-002. The auditors characterized the fact that an inappropriate person initiated the Form AP-6 as a minor nonconformance (Reference NCR-2004-08 in Section 9.10 below).

The observers agree with the auditors' findings in this technical activity.

9.9 Licensing Support Network (LSN)

For this technical activity, the auditors interviewed the responsible Element Manager and scientific staff and reviewed two reports: (1) "Procedure for Scanning and Continuous Provision of Documents in the Licensing Support Network"; and (2) "Summary Completion Report." Interviews were also conducted with the records specialist and the administrative lead for scanning and CD preparation. The auditors reviewed CNWRA planning and management, and NRC regulatory and contractual requirements for the organization, copying, and transmittal of documents. CNWRA utilized its Electronic Laboratory Facility (ELF) document tracking and records control system to enter and control the documents. The auditors verified implementation of, and compliance with, requirements for unique document identifiers assigned by the ELF, recording and tracking of entry into the ELF system, transmittal, and acceptance by NRC, and document search and retrievability using the ELF system. The auditors also verified inclusion of scientific instrument calibration records, technical reports, and QA records in the ELF and transmittal to NRC.

The auditors reviewed training and qualification records for personnel responsible for LSN support activities and found that contrary to the requirements of QAP-005, "Quality Indoctrination and Training," certain SwRI Publication personnel performing CNWRA activities under LSN had not received QA Program indoctrination (Reference NCR-2004-09 in Section 9.10 below).

The observers agree with the auditors' findings in this technical activity.

9.10 Nonconformances

The auditors identified eight nonconformances during the audit. The auditors stated that CNWRA personnel corrected four of the nonconformances during the audit and that these nonconformances would be documented in the CNWRA audit report, but not on Nonconformance Reports (NCRs). The observers questioned this practice. First, the CNWRA QA Program requires that all nonconformances with QA procedures be documented on NCRs. Second, if not formally documented on NCRs, the nonconformances would not be entered into the nonconformance data base and the data would not be available for trending as part of the CNWRA corrective action process. As a result of the observers' inquiry, the CNWRA Director of QA had the nonconformances that were corrected during the audit documented on NCRs.

The four open NCRs follow:

- Contrary to QAP-002, "Review of CNWRA Documents," the Document Review and Transmittal Form for the "Review Comments on IAEA Documents for Consideration at the Waste Standards Safety Committee Meeting 16 Milestone" was initiated by

someone other than the responsible Element Manager. No delegation of authority was documented for that person to sign for the responsible Element Manager. Reference NCR-2004-08.

- Contrary to the requirements of QAP-005, "Quality Indoctrination and Training," 3.1.1, SwRI Publication personnel performing CNWRA activities under LSN had not received QA Program indoctrination. Reference NCR-2004-09.
- Contrary to TOP-012, "Identification and Control of Samples and Chemical Reagents and Standards," the identification of weld material used by supplier, Roben Manufacturing, for fabrication of CNWRA corrosion samples was not identified on weld operation documentation. Reference NCR 2004-10.
- Calculations in support of the Diablo Canyon safety analysis review were either referenced in the report and not documented in the Scientific Notebook or not documented in the report contrary to the requirements of QAP-014, "Documentation of Scientific and Engineering Calculations," which require that calculations be documented in a scientific notebook. Reference NCR 2004-11.

The four closed NCRs are:

- CNWRA technical staff turned in Scientific Notebooks to the QA Records Department on an annual basis as required by QAP-001, "Scientific Notebook Control." However, QAP-012, "Quality Assurance Records Control," requires Scientific Notebooks to be turned in each 6 months. CNWRA revised QAP-012 during the audit to reflect actual practice and the requirements of QAP-001 to turn in Scientific Notebooks an annual basis. Reference NCR 2004-12.
- The observers noted three metal samples in the laboratory with no markings to provide traceability as required by TOP-012, "Identification and Control of Samples and Chemical Reagents and Standards." CNWRA laboratory personnel marked the samples and disposed them when the discrepancy was noted. Reference NCR 2004-13.
- The responsible CNWRA manager did not perform the annual Form QAP-11, "Professional Personnel Qualification and Training Record," for one manager as required by QAP-007, "Professional Personnel Qualification." The cognizant supervisor reviewed and signed the form during the audit. Reference NCR 2004-14.
- The auditors noted several minor deficiencies in Scientific Notebook protocol, as defined in QAP-001, "Scientific Notebook Control," such as not initialing and dating corrections. CNWRA corrected the identified problems during the audit. Reference NCR 2004-15.

9.11 Auditors' Recommendations

During the course of the audit activities, the auditors made 13 recommendations which might prevent a future nonconformance or will support continuous improvement of the CNWRA program. These recommendations are:

- The software development process should include clear provisions for indicating potential restrictions on the use of developed software. This is a clarification of bullet number one under Section 9.3 Recommendations, of the Center's July 9, 2004 Quality Assurance Audit Report of the Center for Nuclear Waste Regulatory Analyses; CNWRA Audit 2004-1.
- Staff should be reminded to refer to the online Master Software List on G-drive to encourage consistency of reference to software titles.
- The Master Software List should be maintained up-to-date and if the SRN date field is used for comments, the use should be explained in the legend.
- There is no date on Form QAP-11-1 indicating when it was issued to a staff member so that the 30-day response time could be easily tracked. The only date present is when the manager assigns training topics. This may lead to staff performing associated quality-affecting or safety activities before completion of required training. Adding an issue date to the form or using an automated system is recommended.
- QAP-012, "QA Records Control," requires annual validation of QA records while in practice the validation occurs upon entry into LSN. The QAP should be updated to reflect actual practice.
- The file of "ReDos" of errors in accessing LSN deliveries should be periodically reviewed for trends or common causes to reduce future errors.
- Revise QAP-014, "Documentation and Verification of Scientific and Engineering Calculations," to allow mechanisms other than the Scientific Notebooks for documenting calculations.
- Promote the use of cross-referencing between Scientific Notebooks and in associated reports, which support a particular activity.
- Form QAP-012 should be revised to reflect that the location of the example of calculation verification may be referenced in the form rather than attached to the form as stated.
- In light of the possibility that some documents might not list the authors or contributors, the instructions to reviewers should clearly list all authors and contributors such that reviewers can be assigned who are independent of the persons performing the work.
- Evaluate if refresher Indoctrination should be given to long-time staff that were indoctrinated in the QA Program years ago since the CNWRA QA Program has been revised several times.
- Ongoing testing for the CLST is addressing uncertainties associated with the critical localized corrosion parameters. It is recommended that inclusion of this uncertainty data into appropriate models be verified upon completion of the testing. It was also recommended that a minimum of two replicate anodic cyclic polarization scans be run to

ensure reproducibility under each condition tested unless other techniques are used to verify the data.

- Follow-up to assure that the pressure transducers from the Healy-Shaw Cell at Bristol University are returned to SwRI for calibration before any quality-affecting data are generated.

10.0 NRC STAFF FINDINGS

The CNWRA Audit Team Leader adequately described the audit schedule and individual assignments in the audit plan and associated audit documentation, made available audit checklists to the auditors, and was effective in providing guidance and leadership to the auditors throughout the audit. The observers determined that the Audit Team Leader and auditors were qualified: technical specialists were qualified in their individual areas of technical expertise and the QA auditors were qualified in the CNWRA QA Program requirements. The auditors were thorough, effective, and performed in a professional manner.

The observers determined that CNWRA Audit 2004-1 achieved its purpose of evaluating the implementation of the QA Program controls regarding programmatic and technical activities. The observers determined that the audit was effective in determining CNWRA staff compliance with procedural controls in the areas examined and that the CNWRA QA Program controls are being adequately implemented. The observers also determined that the technical adequacy of the work products and procedures was satisfactory but is subject to continuing in-depth evaluation by NRC technical staff. The observers agree with the auditors' findings that, overall, the CNWRA QA Program controls are being adequately implemented in the areas that were evaluated, except for the identified nonconformances.

During the audit, the auditors identified eight nonconformances as described in Section 9.10 above. The auditors determined that the nonconformances identified during the audit are unlikely to have adverse impacts on CNWRA technical products. The auditors also made 13 recommendations to improve implementation of the QA Program as described in Section 9.11 above. The Audit Team Leader provided appropriate opportunities to the observers to provide comments and ask questions throughout the conduct of the audit. The auditors and observers discussed the findings with CNWRA management during daily debriefs and at the post-audit meeting.

The observers believed that the CNWRA audit was thorough and effective; however, specific comments for more effective future audits are presented as follows:

- CNWRA should review audit reports from several previous years and document all nonconformances that were corrected during those audits on NCRs and enter the associated information in the nonconformance data base. Based upon the addition of nonconformance data, CNWRA should consider performing a trend analysis.
- The nonconformances identified by the auditors could generally be attributed to inattention to detail. The observers recommend that CNWRA place additional emphasis in this area.

- **During this audit the auditors reviewed nine technical products and 18 QA Program elements in less than three days. The observers recommend that additional time be allowed to perform future audits of this size to assure that comprehensive reviews are performed.**
- **The observers noted that the checklists for each of the technical activities audited were significantly different in format and technical content. The observers also noted that the checklists for the QA Programmatic elements audited were not at the level of detail or organization that would assure that a comprehensive evaluation of all important aspects is performed. The observers believed that the CNWRA audit was thorough and effective; however, a more formal approach to developing checklists for future audits would produce better tools to assure effective audits.**