

1.0 INTRODUCTION

On June 26-30, 2006, U.S. Nuclear Regulatory Commission (NRC) staff from the Office of Nuclear Material Safety and Safeguards (observers) observed the Fiscal Year 2006 Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance (QA) Audit 2006-1. QA and technical Staff from Southwest Research Institute (SwRI), the University of The Incarnate Word, and the University of Texas San Antonio (auditors) conducted this performance-based audit at the CNWRA facilities in San Antonio, Texas.

The CNWRA provides technical support to NRC staff under NRC Contract NRC-02-02-012. Under this contract, CNWRA is required to meet the QA requirements specified in Title 10 Code of Federal Regulation Part 63, Subpart G, "Quality Assurance"; CNWRA Geosciences and Engineering Division Quality Assurance (QA) Manual; and the American National Standards Institute/American Society of Mechanical Engineers NQA-1, as implemented by the CNWRA QA Program. The objectives of this CNWRA audit were to evaluate the performance adequacy of the CNWRA audit process and to determine whether the CNWRA QA Program meets the applicable requirements of Part 63, and if the QA Program is being effectively implemented. The objectives of the NRC staff's observation of the CNWRA audit were to evaluate the performance adequacy of the CNWRA audit process and the effectiveness of the CNWRA QA Program implementation in meeting the QA requirements mandated by contract and as specified in 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 and evaluation of objective evidence such as the audit plan, audit checklists, technical documentation, and scientific notebooks; and (4) observation of laboratory activities and practices.

The CNWRA Audit Team Leader adequately described the audit schedule and individual assignments presented in the audit plan and associated documentation, and made available the audit checklists used by the auditors. Implementation of the Audit Plan was effective in providing guidance and leadership to the auditors throughout the audit investigative process. The observers determined, by review of objective evidence and observation of performance during the audit, that the Audit Team Leader and auditors were qualified, that the technical specialists were qualified in their individual areas of technical expertise, and that the QA auditors were qualified in the CNWRA QA Program requirements. The auditors were thorough, effective, and performed the audit investigative process in a professional manner.

The observers determined that CNWRA Audit 2006-1 achieved its purpose and performance objective of evaluating the implementation of the QA Program controls for QA 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 implemented adequately. Based on the activities and

documents observed, the observers also determined that the technical adequacy of the work products and procedures used to govern and control work was satisfactory. The observers agreed with the auditors' conclusions that, overall, the CNWRA QA Program controls were being implemented adequately in the technical areas that were evaluated, except for the minor nonconformances identified in this report.

During the audit, the auditors identified two minor nonconformances, two minor nonconformances corrected during the course of the audit, and two good practices. The auditors determined that the minor nonconformances identified during the audit are unlikely to have an adverse impact on quality or delivery of CNWRA technical products. The auditors also made 15 recommendations to improve implementation of the QA Program. The auditors and audit team leader provided appropriate opportunities, to the observers, for providing comments and asking questions throughout the audit process, and during daily caucuses.

Based on review and evaluation of the CNWRA audit, the observers concluded that the audit was comprehensive, thorough, and effective, and that the CNWRA QA Program controls are adequate and effectively implemented. The NRC observers made five recommendations presented in Section 10 below that should be evaluated in terms of improving the CNWRA QA Program controls or the overall efficiency and effectiveness of future audits. The NRC observers also recommended that NRC staff consider improving the directions and guidance provided to CNWRA for evaluating activity planning and documentation needs, for use in future CNWRA activities.

3.0 PARTICIPANTS

The selection and composition of the CNWRA audit team were based on technical competence and understanding of the areas being evaluated. The audit teams were comprised of qualified auditors and technical specialists trained in auditing techniques. The auditors who performed reviews of technical data were independent of the activities and technical areas being audited. The audit of each technical activity was performed using audit teams, which were comprised of a technical specialist and a QA auditor.

3.1 CNWRA Audit Team Members

Tom Trbovich	Team Leader	SwRI
Rodney Weber	QA Auditor	SwRI
Christopher Hobson	QA Auditor	SwRI
Joerg Gerhardus	QA Auditor	SwRI
Robert Morgan	Technical Specialist, Software,	SwRI
Alexander Bernado	Technical Specialist, Engineering Analysis	
Dr. Robert Mason	Technical Specialist, Statistical Analysis,	SwRI
Dr. William Thomann	Technical Specialist, Geology, University of The Incarnate Word	
James Dante	Technical Specialist, Material Science,	SwRI
Dr. Alan Dutton	Technical Specialist, Aqueous Geochemistry; Hydrogeology, Univeristy of Texas, San Antonio	

3.2 NRC Observation Team Members

Wilkins Smith	Team Leader
Eugene Peters	Technical Specialist, High-Level Waste Repository Safety
Deborah DeMarco	Program Management Specialist, High-Level Waste Repository Safety
Bret Leslie	Technical Specialist, High-Level Waste Repository Safety
Mahendra Shah	Technical Specialist, High-Level Waste Repository Safety
Paul Bell	Quality Assurance Specialist, Fuel Cycle Safety and Safeguards
James Pearson	Quality Assurance Specialist, Spent Fuel Project Office

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contract NRC-02-02-012. In performing work for NRC under this contract, CNWRA must meet the QA requirements specified in Part 63, Subpart G, and implemented in accordance with the CNWRA QA Program. The CNWRA QA Program requires that, at a minimum, the CNWRA be audited on an annual basis. The CNWRA conducted the Fiscal Year 2006 CNWRA QA Program Audit 2006-01 to satisfy the requirement of an annual audit. Under the provisions of NRC Contract NRC-02-02-012, NRC elected to observe the conduct of the CNWRA QA audit to determine the performance adequacy of the CNWRA audit process and the effectiveness of the CNWRA QA Program implementation in meeting the QA requirements of Part 63. The auditors performed the audit in accordance with CNWRA QA Procedure (QAP)-011, "Audits," and SwRI Procedure No. IQS-WI-821-1, "Audit Conduct." NRC staff observed and conducted the CNWRA QA audit in accordance with NRC Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The scope of the CNWRA QA Program audit was based on programmatic and technical insights gained through the evaluation of geosciences, engineering analysis, judgment, and performance history used to formulate risk-informed and performance-based decisions. The CNWRA's risk-informed approach and its selection of the technical topics for this audit were based on the performance history of the technical insights gained 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 initiated an incremental approach of their review and analysis of completed technical products, to determine compliance with CNWRA QA controls, processes, and procedures. The auditors reviewed select QA Program elements to determine risk insights, calculable parameters for evaluation, and 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 NRC observers determined that, overall, the auditors' plan, purpose, scope, and objectives of CNWRA Audit 2006-1 were achieved. The auditors were thorough, effective, and performed in a professional manner. In general, the observers believe the timing, length, and application of resources to complete this annual CNWRA QA audit were appropriate for the current level

and type of activities. Should the CNWRA's work load and diverse activities significantly change, additional time may need to be allocated to perform future audits, to assure that comprehensive reviews are performed.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The CNWRA audit team composition included 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 auditors to be acceptable in that each met the requirements of SwRI Procedure No. IQS-OP-623, "Certification of Auditors", or IQS-WI-622-1, "Qualification of Audit and Surveillance Personnel".

The observers also reviewed the documentation of the qualifications of the audit team technical specialists. The documentation review determined that they met all the qualifications, through training and experience, for their positions as identified in CNWRA procedure QAP-011, "Audits." The auditors and technical specialists had no involvement with, nor responsibility for, performing any of the activities they audited.

8.0 EXAMINATION OF QA ELEMENTS

8.1 QA Programmatic Elements

The auditors evaluated the QA programmatic elements listed in Table 1 below:

Table 1
QA Programmatic Elements Evaluated

<u>QA Programmatic Elements</u>	<u>CNWRA QA Manual Chapter</u>
Organization	1
QA Program	2
Scientific/Engineering Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Procedures, and Drawings	5
Document Control	6
Procurement	7
Identification and Control of Items, Software, and Samples	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

The auditors reviewed and evaluated material and documentation related to the applicable QA procedures and interviewed various CNWRA personnel to determine the effectiveness of implementing procedures and technical processes. The auditors identified two minor nonconformances, two minor nonconformances corrected during the audit, two good practices, and 15 recommendations, as described below:

8.2 Minor Nonconformances

CNWRA Procedure QAP-001, *Scientific Notebook Control*, Section 3.4.1, requires that each initial and in-process entry to be signed and dated by the authorized individual. Three electronic notebooks were noted as not in compliance with this requirement.

The identification of the training completion date is not always indicated on Form QAP-11-1, *Procedure Identification and Training Record*. The indoctrination and Training Tracker (ITT) system automatically identifies a 10-day completion requirement.

8.3 Minor Nonconformances Corrected During the Audit

CNWRA Procedure QAP-001, *Scientific Notebook Control*, requires identification of the notebook number on each page. Scientific notebook 612-E did not meet this requirement.

One Form QAP-12-1, "Geosciences Engineering Division Instructions to Technical Reviewers," was not complete.

8.4 Good Practices

Radionuclide Release and Solubility Limits:

The use of *Mathematica*™ software enables proficient capture of traceable calculations, data, graphics, and reports, used in combination with scientific notebooks, and its use supports work enhancement, productivity, and improved capability for meeting quality requirements.

Programmatic QA:

Corrective Actions and nonconformances issued during the last year, and verification of implementation were detailed, thorough, and resulted in significant improvements.

8.5 Audit Recommendations

Total-system Performance Assessment (TPA):

- Informal TPA code reviews should be documented.
- Procedures and processes should be clarified regarding the use of acceptance tests for minor Software Change Report testing, versus tests conducted just before a major software release.
- Technical Operating Procedure 018 is geared to the development life cycle (or for acquired code) and should be revised to include provisions for maintenance and modification-oriented work.

- Quarterly Software QA surveillances are performed by an outside consultant and are brief in detail. QA surveillances should include more detail on the results of each surveillance.
- Technical Operating Procedure (TOP) 018 uses language left over from the former paper-based report era. TOP-018 should be revised to remove reference to the former paper-based process, and updated to reflect electronic reporting.
- Technical Operating Procedure 018, Section 5.7.6, and the associated form should be revised to indicate that the code custodian performs QA reviews or checks, rather than QA verification, which implies more rigorous requirements.

Climate and Infiltration:

- A process of proof reading or fact checking of entries of raw data in a database, whether from literature searches or other sources should be documented.

Preclosure Safety Evaluations:

- The process for determining the qualifications of a technical reviewer should be more rigorous.

Degradation of Engineered Barriers:

- Polarization curve technique should be adjusted to ensure comparability to exposure tests.
- A process should be defined for adding deionized water to test liquid and condenser, to maintain constant values.
- There should be a determination of the root cause to explain the discrepancy, between the CNWRA and the U.S. Department of Energy (DOE) test conditions and test results regarding the corrosion potential-data.
- Since the actual eutonic composition cannot be calculated, one of the following should occur:
 - Experimentally determine eutonic composition such that solution composition is most aggressive, or;
 - Use average values of composition derived from the National Atmospheric Deposition Program data to achieve realistic compositions.

Waste Incidental to Reprocessing:

- References should be provided in Request for Additional Information (RAI) letters, to DOE, to substantiate comments.
- Mechanisms should be developed for tracking the incorporation and closure of NRC

comments when informal submittals of documents are made, on multiple occasions, for regulatory tasks, such as development of a Standard Review Plan.

Programmatic QA:

- CNWRA Procedure QAP-008, "Document Control," should be revised to reflect the replacement of the Master Document List with the ITT system reports.

Documents and records are distributed and controlled in the CNWRA electronic document control center. The document control program is robust, and allows ready access and ease of document retrieval. The observers also determined that the technical adequacy of the work products and procedures was satisfactory. However, continued technical adequacy of work products is contingent upon continuing in-depth evaluation of future work products and deliverables by NRC technical staff.

The NRC QA Audit observers agreed with the auditors' issuance of nonconformances, noted good practices, and audit recommendations. The observers also noted that the auditors reviewed and verified that appropriate actions and documentation for all nonconformances and recommendations from the 2005 CNWRA audit had been completed.

9.0 EXAMINATION OF TECHNICAL ACTIVITIES

The selection of technical activities to be evaluated during the CNWRA QA Program audit was based on programmatic and technical insights gained from the QA Director, and CNWRA management. Performance histories for these technical activities were used to formulate risk-informed and performance-based decision-making and were captured in the audit planning and implementation process. Therefore, the CNWRA risk-informed approach and its selection of technical topics for this audit were based on the performance history of the technical insights gained since the previous audit of various programmatic and technical areas, and the importance of the activity, particularly regarding technical and programmatic risk insights.

The auditors used a performance-based approach to evaluate the effectiveness of the QA Program in ensuring product quality. The audit included by direct evaluation of selected activities, assessment of products, calculable parameters for evaluation, and evaluations of the product development processes. The performance-based approach was implemented by using sub-teams of QA auditors and technical specialists who evaluated activities based on their experience, technical expertise, education, and familiarity with the subject matter. The audit sub-teams individual perspectives were used to evaluate the implementation of procedural, QA, and regulatory requirements, as well as plans associated with product development. The auditors evaluated technical activities listed in Table 2, below:

Table 2
Technical Activities Evaluated

TPA Code Development
Site Characterization - Yucca Mountain
Radionuclide Release Rates and Solubility Limits
Climate and Infiltration
Degradation of Engineered Barriers
Preclosure Safety Evaluation
Methodology and Overall System Performance
Waste Incidental to Reprocessing

For each of the technical activities evaluated, the auditors evaluated and analyzed documentation supporting the engineering and scientific processes and compliance with procedural requirements. The assessment process included the review of QA implementing procedures and an evaluation of corresponding Scientific Notebooks and other documents supporting the technical activities reviewed. The auditors assessed the controls imposed on Scientific Notebooks, data collection, and the information contained in the Scientific Notebooks that was used to document and validate scientific and engineering calculations. The auditors concluded that research activities annotated in each of the Scientific Notebooks audited were documented thoroughly with the exception of the minor nonconformances identified in Section 8.

Technical specialists evaluated the qualifications of technical personnel. A rigorous review of the scientific, technical, or engineering methodologies included a thorough review of supporting documentation. The audit process included the review of training, education, and experience records attesting to personnel who conducted scientific studies, to ensure compliance with individual position descriptions. The auditors' conclusions 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 2005, the auditors developed and used checklists specific to each technical activity audited and developed and used a general checklist addressing the associated QA programmatic requirements. The observers noted that overall, the checklists for the both the QA program and technical elements audited had improved from prior audits, and showed the consistency and level of detail necessary to ensure that a comprehensive evaluation of all important aspects. The observers did identify to the audit team that one particular checklist needed improvement and greater detail. The observers noted that the CNWRA should continue to emphasize use of audit checklists that contain the appropriate level of detail.

The specific technical area audit activities that the observers witnessed are discussed in Sections 9.1 through 9.8 below.

9.1 TPA Code Development

This comprehensive technical activity was evaluated by the auditors through personal interviews, with cognizant element managers and technical support staff, to determine the methodology used for TPA Code Development and overall system performance. The technical task also included the review and evaluation of Total System Performance Assessment and Integration,

which consisted of code development, model abstraction, description of models, and computational approaches. The auditors, element manager, and technical staff reviewed: (1) TPA 5.1, *Draft Software Requirements Description for Total-System Performance Assessment Version 5.1 Code* (application, development, and testing methodologies); (2) Software Requirements Description (SRD) for the *Total-System Performance Assessment Version 5.1 Code, (Task 354.610)*; (3) Comparison of TOP-018 and Scientific Notebooks with QAP-001, *Scientific Notebook Control*, and QAP-014, *Documentation and Verification of Scientific and Engineering Calculations*.

The auditors identified one minor repetitive nonconformance that was similar to NCR-2005-04, regarding scientific notebooks. Additionally, conclusions derived by the auditors and observations made by NRC observers were included in the auditors' roll-up of nonconformances and recommendations identified in Section 8.

The NRC observers agree with the programmatic and technical discrepancies noted by the auditors. All recommendations and minor nonconformances will be reviewed and evaluated for implementation of corrective actions and as follow-up actions, during observation of the next scheduled audit.

9.2 Evaluation of Site Characterization

The auditors reviewed and assessed the following CNWRA products: "*Summary and Analysis of Subsurface Fracture Data from the Topopah Spring Tuff Upper Lithophysal, Middle Nonlithophysal, Lower Lithophysal, and Lower Nonlithophysal Zones at Yucca Mountain, Nevada*"; "*Yucca Mountain Field Trip Guide*"; and "*Evaluation of Yucca Mountain Neotectonics Related to Earthquakes and Volcanic Hazard Assessments*". The review focused on the processes of data import and manipulation. There were several problems identified during the original document review cycle for the Subsurface Fracture Data report. Typographical errors noted during the review had been recorded and corrected, but the document management system records were unclear as to whether the corrected version was archived in the permanent records. The audit team confirmed that the correct version of the report constituted the final permanent copy. The audit team also assessed whether data processing and visualization software used in these analyses was managed correctly.

The audit team concluded, and the observer team concurred, that the analyses were robust and well-documented, allowing reproduction of calculations and results, if necessary.

The observers noted that acceptable auditing techniques were applied in this area and agreed with the auditors' conclusions.

9.3 Climate and Infiltration

The audit team reviewed "*Literature Review and Analysis: Climate and Infiltration*"; "*Implementation of the Climate and Infiltration Abstractions in the Goldsim TSPA-SR Code*"; and a journal article to be submitted for publication – "*Combined Effects of the Southern Oscillation Index and Pacific Decadal Oscillation on a Stochastic Daily Precipitation Model*", prepared by a CNWRA consultant.

The audit focused on programmatic elements, such as the role of subcontracted consultants, as

well as the technical development and content of the publications. This audit was enhanced by having a combination of QA specialist and subject-matter experts performing the audit of this area. The subject-matter auditor pursued technically-relevant matters in a QA context and solicited input on the utility and applicability of various procedural QA requirements on the various types of scientific endeavors the CNWRA is pursuing. In particular, the auditors considered the role and QA processes as they affect work performed by external consultants. The auditors identified no procedural nor technical deficiencies.

The observers agreed with the auditors' conclusions in this area.

9.4 Radionuclide Release and Solubility Limits

The auditors reviewed "*Effect of Kinetic Limitations on Colloid-Facilitated Radionuclide Transport at the Field Scale*", a paper submitted for publication in a conference proceeding. This paper was jointly authored by a CNWRA Principal investigator and an external collaborator.

This audit activity also focused on programmatic and technical elements, such as the role of scientific software (*Mathematica*[™]), as well as the technical development and content of the publications. The audit in this area was enhanced by having a combination of QA specialist and subject-matter experts form the audit team. The subject-matter auditor pursued technically relevant matter in a QA context and solicited input on the utility and applicability of various procedural QA requirements on the various types of scientific endeavors the CNWRA is pursuing.

The auditors noted one good practice related to using *Mathematica*[™] for all aspects of technical work, observing that the same platform used by the Principal Investigator for scientific calculations, maintenance of a Scientific Notebook, and report production facilitated information retrieval and minimized transfer of data between other platforms. The auditors identified no procedural nor technical deficiencies in this area.

The observers agreed with the auditors' conclusions in this area.

9.5 Preclosure Safety Evaluation

For this part of the audit, the auditors selected the calculation on the assessment of structural robustness against aircraft impact, prepared by P.A. Cox, J. Mathis, and A. Ghosh, in August, 1995. The observers noted that the auditors had applied acceptable auditing techniques and posed appropriate questions regarding the calculations. The auditors raised issues regarding verification and validation of the computer codes *BlastX*[™], and *LS-DYNA*[™], clarity of the presentations, and qualifications of the reviewer of the calculation, all of which were resolved during the audit.

The NRC observers noted that NRC staff had reviewed this calculation and had provided significant comments, which the auditors were not aware of during the initial audit review of this calculation. The NRC observers noted that the auditors would have benefitted from these review comments and the use and availability of these comments would have made the audit process more complete, informed, and comprehensive. The observers recommended that the results of NRC staff review of CNWRA products should be included as a part of the QA records for the products, and thus would be readily available to the auditors in future audits. The observers also

recommended that the training and background material for the auditors and technical specialists be reviewed. The addition of more contextual information on the CNWRA programs, including regulatory requirements and terminology, could improve the efficiency and effectiveness of the audit activities.

The observers noted that acceptable auditing techniques were applied during the evaluation of the Preclosure Safety Evaluation area. The observers also noted that one checklist for this area was not as well-prepared as some of the other checklists. Some of the checklist items reflected a preference to personal approaches to the subject area and the associated processes, rather than determining if the work had been performed acceptably and performed according to the required procedural processes.

The NRC observers agreed with the auditors' conclusions and recommendations in this area.

9.6 Degradation of Engineered Barriers

For this part of the audit, the auditors had selected the report, prepared in December 2005, on the experiments to determine corrosion of Alloy 22 in concentrated Nitrate and Chloride salt environment at elevated temperatures, varying from 150E C to 170E C. The NRC observers noted that the auditors were thorough in their audit and used acceptable auditing techniques.

During the visit to the laboratory as a follow-up to the report discussed earlier, the observers noted that the CNWRA staff performing the corrosion experiments were very knowledgeable and that the Scientific Notebooks documenting the experiments were impressive. This corrosion testing began some years ago and is controlled and it is documented by the Scientific Notebooks, as specified in the CNWRA QA Manual. A formal test plan or test procedure was not prepared for the work being performed. The observers noted that, before performing major analytical or experimental tasks, adequate planning documents should be prepared for review by the appropriate CNWRA staff and/or NRC staff, to assure an adequate understanding of the goals, objectives, and conditions of the experiments. The observers recommended that the NRC staff and CNWRA management review their current practices and processes, as well as new operations, directions, or guidance, to determine the appropriate methods to control and document specific activities. These methods should be flexible, to be applied appropriately, based on the nature and complexity of the activity, and, in some cases, may require a CNWRA or NRC approved plan for the test or analysis, before the work being performed.

The observers noted that the laboratories visited during the audit appeared to be clean, acceptably organized, and equipped for the on-going work activities.

The observers agreed with the auditors' conclusions in this area.

9.7 Methodology and Overall System Performance

The audit team reviewed a preliminary document, "*A Potential Strategy for Conducting a Review of Scenario Analysis and Identification of Events with Probabilities Greater Than 10^{-8} Per Year.*" Much of this portion of the audit focused on the status of this document as preliminary, how a preliminary document relates to on-going strategies, and whether and when the document should be considered final. The auditors also discussed, with CNWRA and NRC staffs the roles of joint authorship and how QA processes were implemented.

The auditors identified no procedural nor technical deficiencies.

The observers agreed with the auditors' conclusions in this area.

9.8 Waste Incidental to Reprocessing

The audit team undertook a performance-based audit of two deliverables, *Input to a Request for Additional Information for Technical Assistance in Evaluating Section 3116 of the National Defense Authorization Act Determination of Tanks 18 and 19 at the Savannah River Site* and *Input to a Request for Additional Information for Technical Assistance in Evaluating a Waste Determination Methodology for Closure of High-Level Waste Tanks at Idaho National Laboratory*. In addition a programmatic audit was conducted of the CNWRA efforts on *Standard Review Plan Development*. For the two milestone reports, the auditors focused on the development process of the reports. By following the development process of the milestone reports, the auditors were able to address both technical and programmatic aspects of the CNWRA work. Similarly, the programmatic audit focused on the development process of the CNWRA efforts on the review plan development. The result was an adequate audit, which allowed the auditors to evaluate the effectiveness of the CNWRA QA program implementation. Overall, the auditors identified no procedural nor technical deficiencies, but identified two audit recommendations.

The NRC observers noted that the auditors were not aware of all the milestones where the CNWRA conducted work in this program element, because the auditors rely solely on the CNWRA Operations Plan to determine the products to audit. However, the Table 3 of CNWRA Program Manager's Periodic Report (PMPR) on Activities of the CNWRA for Nuclear Waste Regulatory Analyses, which is transmitted for each program period, can add or delete milestones from the CNWRA's Operations Plan, whose changes are not reflected in the current Operations Plan. The observers recommended that auditors be provided with copies of the PMPR, for the relevant periods, to prepare and conduct their audits. This will better inform the auditors of the scope of activities the CNWRA has conducted, supporting each milestone audited, and will ensure that milestones that have been added via the PMPR are potentially within the scope of the audit.

The NRC observers agreed with the auditors' conclusions.

10.0 NRC STAFF FINDINGS/CONCLUSIONS

The auditors identified four minor nonconformances as described in Sections 8.2 and 8.3 above. The auditors determined that the nonconformances identified during the audit are unlikely to have an adverse impact upon quality or delivery of CNWRA technical products. The auditors noted two good practices as discussed in Section 8.4 above. The auditors also made 15 recommendations to improve implementation of the QA Program as described in Section 8.5 above. The Audit Team Leader provided ample opportunities to the observers to provide comments and ask questions throughout the audit process. The auditors and observers discussed potential findings with CNWRA management during daily caucuses, audit debriefs, and at the post-audit conference.

The NRC observers concluded that the CNWRA Audit Team Leader adequately planned and implemented the audit by assigning individual tasks and review of associated audit

documentation, to the audit team. Audit checklists used by the auditors were comprehensive and effective in providing guidance and leadership to the auditors and technical specialist.

The NRC observers also concluded the audit process was well planned, thorough, effective, and performed in a professional manner. The observers determined that CNWRA Audit 2006-1 achieved its purpose and its objective of evaluating the implementation of QA Program controls regarding the integration and implementation of programmatic and technical activities. NRC observers determined that the CNWRA audit was effective in reviewing, evaluating, and determining risks and the associated compliance with procedural requirements in the areas controlled by QA program requirements. NRC observers agreed with the auditors's conclusions and recommendations that the CNWRA QA Program controls are being implemented adequately in the areas that were evaluated, except for the minor nonconformances identified.

Specific comments and recommendations for more effective future audits or QA Program implementation are presented as follows:

- C The CNWRA formed a working group that addressed the observation made, during the 2004 Internal QA Audit on the attention to detail, and prepared a report with recommendations. A second group was convened to provide a "reality check" of the recommendations, identify the best of the recommendations, and suggest plausible methods for implementing the recommendations. The observers recommend the continued implementation of recommendations and actions from these reports.
- NRC observers recommended that the results of NRC staff review of CNWRA products should be included as a part of the QA records for the products, and, thus, would be readily available to the auditors in future audits.
- The performance and project knowledge of the auditors and technical specialists could be enhanced during audit planning by providing them with an information package containing regulatory requirements, technical issues, and terminology commonly used on the project. The observers recommend that the information package contain information that focus on improving the flow of information used in the audit process, by the addition of more contextual information regarding CNWRA programs, regulatory requirements, and terminology. This recommendation will improve the efficiency and effectiveness of audit activities.
- The observers noted that, before performing major analytical or experimental tasks, adequate planning documents should be prepared for review by the appropriate CNWRA staff and NRC staff, to assure an adequate understanding and documentation of the goals, objectives, and conditions of the experiments. The observers recommended that the NRC staff and CNWRA management review their current practices and processes, as well as new activities, directions, or guidance, to determine the appropriate methods to control and document specific activities. These methods should be flexible, to be applied appropriately, based on the nature and complexity of the activity, and, in some cases, may require a CNWRA or NRC approved plan for the test or analysis before the commencement of work.
- The observers recommended that auditors be provided copies of the PMPR . The PMPR should highlight relevant activities and milestones covered during the program period. This will better inform the auditors and technical specialists of the scope of activities the CNWRA has conducted, by providing objective evidence supporting each milestone audited, which will help to ensure that milestones and technical activities that have been added via the PMPR are potentially within the scope of the audit.