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U.S. Nuclear Regulatory Commission
ATTN: Mrs. Deborah A. DeMarco
NRC/CNWRA Deputy Program Manager
Two White Flint North
Mail Stop T8A23
Washington, DC 20555

Subject: Transmittal of FY2000 CNWRA QA Audit - Letter Report
Intermediate Milestone 01402.159.020

Dear Mrs. DeMarco:

This letter transmits a copy of the CNWRA Audit 2000-1 report to you for your information, as specified in the CNWRA Operations Plans for the Repository Program. This report was provided to the CNWRA by Southwest Research Institute QA July 27, 2000.

The annual CNWRA QA audit was planned, executed, and reported in accordance with the CNWRA Quality Assurance Manual and associated Quality Assurance Procedures. Although a number of programmatic issues were identified, the audit determined that the CNWRA QA program continues to be effective. We appreciated the observation of this audit by the NRC representatives and believe the audit will improve our internal practices and procedures. As indicated in informal communications with NRC management, in-depth evaluations of and responses to the issues raised in this audit are underway.

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

Sincerely yours,

for Henry F. Garcia
Director of Administration

HFG/mp

w/o attachments:

cc: J. Linehan, B. Meehan, E. Whitt, T. Carter, L. Campbell, K. Stablein, J. Greeves, W. Reamer
CNWRA Directors
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CENTER FOR NUCLEAR WASTE

REGULATORY ANALYSES

AUDIT REPORT 2000-1

July 21, 2000

EXECUTIVE SUMMARY

The annual internal Quality Assurance (QA) audit of the Center for Nuclear Waste Regulatory Analyses (CNWRA) was conducted June 20–23, 2000. The audit team, comprised of eight technical specialists, four QA auditors, and the two audit team leaders (ATL), determined that the CNWRA QA program is being effectively implemented but a number of programmatic issues need to be addressed. The CNWRA staff was operating in accordance with the CNWRA Quality Assurance Manual (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 results of the audit, including observations and recommendations, were discussed with the CNWRA management and staff during a post-audit meeting on July 23, 2000. The Nuclear Regulatory Commission (NRC) was represented by Mr. Ted Carter, Mr. James Pearson, Mr. Robert Hermann, and Ms. Deborah DeMarco. Mr. John Linehan, Director of Program Management, Policy Development and Analyses, attended the daily management meetings and the post-audit conference. In addition, Mr. Larry Campbell, Senior QA Engineer, and Mr. King Stablein, Section Chief of the NRC Division of Waste Management, participated in the post-audit meeting by telephone.

The CNWRA staff appeared to have a good understanding of the quality system requirements and was forthright and frank in their interviews. Personnel qualifications, record control, sample control, and technical report content exhibited a high level of compliance. A number of minor discrepancies were noted and corrected during the audit. In addition, the audit team provided suggestions for consideration by the CNWRA management as a means of either avoiding potential future nonconformances or for improvement of processes.

Though the overall quality program was identified as being effective, six Corrective Action Requests (CARs) and four Nonconformance Reports (NCR) were initiated dealing with specific noncompliances which were discussed with the CNWRA management at the postaudit meeting. An additional CAR had been initiated (CAR 2000-04) but upon subsequent investigation it was rescinded and the deficiency was documented in NCR 2000-10.

1. CAR 2000-01 Procurement Planning

Not all requirements of NQA-1 [reference CQAM 2.3.1(2)] or the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Description related to procurement controls have been addressed in procedure QAP-016 or are not being complied with.

2. CAR 2000-02 Scientific Notebook Control

A number of scientific notebooks reviewed did not comply with procedure QAP-001 in that they contained omissions or discrepancies such as lack of dating of entries, crossout/initialing of corrections, use of whiteout, missing pagination, or detailed description of work.

3. CAR 2000-03 Verification of Calculations

The requirement of procedure QAP-014, 3.2, that 10% of calculations be verified and the verification documentation be contained in, referenced in, or attached to the review documentation has not been consistently complied with. Journal article (Q199911240001) for Container Life and Source Term did not receive a calculation check.

4. CAR 2000-05 Training

There was no evidence to document that consultants have been provided copies of applicable procedures to assure they are aware of their responsibilities and requirements. Also, the documentation of training of CNWRA staff does not indicate the objective or contents of the training or a review by management to determine the need for retraining, as described in the NRC Review Plan for High-Level Waste Repository QA Program Description, 2.14 C and D.

5. CAR 2000-06 Corrective Action

Effective corrective action to prevent recurrence of adverse conditions has not been taken. Deficiencies noted during the 1999 audit (procurement, CAR 99-02; software CAR 99-05) continue. Adverse trends identified during a January 2000 review by CNWRA QA related to software and scientific notebooks were not documented in CARs and similar deficiencies continue to be observed.

6. CAR 2000-07 Quality Planning

There is no documentation that all Quality Requirements Application Matrices (QRAM) were evaluated for the need for revision when Operations Plans were revised as required by procedure QAP-013, 3.1.5. Of the QRAMs for which the impact determination was made, not all three signatures required by procedure QAP-013, 3.1.6 were obtained. Also see CAR 99-01 from the 1999 audit.

7. NCR 2000-07 QRAM

The QRAM for Structural Deformation and Seismicity does not indicate that TOP-018 should be applied although the task description indicates that scientific and engineering software will be used. Reference QAP-013, 3.1.2.

8. NCR 2000-08 Drawing Control

Procedure QAP-017 does not provide requirements to include qualitative or quantitative acceptance criteria on drawings as required by CQAM, 5.3. The sequence of reviews was not always clear. Original drawings are maintained by QA rather than the Element Manager or Principal Investigator as required by the procedure.

9. NCR 2000-09 Quality Planning

The Quality Requirements Application Matrix for Container Life and Source Term (CLST) did not invoke QAP-016, "Procurement," although corrosion test samples were purchased.

10. NCR 2000-10 Software Acceptance Test

MULTIFLO acceptance testing (i.e., benchmark method) of release 1.2 was performed as documented in multiple scientific notebooks over a period of approximately two years. Testing just prior to release was performed and witnessed by QA; however, no evidence [e.g., notes in scientific notebooks, annotations on Design Verification Reports (DVR)] was available to support successful test results or QA observations.

A copy of each CAR and NCR is attached to this report.

In addition to the findings documented on the CARs and NCRs, a number of minor infractions were observed which were either corrected during the audit or judged not of a nature that would affect the quality of the work performance. These were:

- The review and overcheck of calculations for IM 20.1402.471.050 was not documented on Form TOP-3 as required by procedure.

- Supporting data for code calculation for IM 20.01402.771.030 did not appear to be available at the time of the audit.

- Some rationale for technical decisions were not stated or obvious to the reviewer (i.e., for IM 20.01402.771.030, in some cases the highest value for a variable was chosen and in other cases the average; the grouping of age sets by a method not used in the cited material was not explained; no explanation for Comment 3 of page 2 in IM 20.01402.771.905).

- In some cases it did not appear that a verification was performed to assure that reviewer comments were incorporated (i.e., in IM 20.01402.711.030 the author agreed to change "farmer" to "farmers" but this did not occur consistently).

- Some typographical errors appeared in IM 20.01402.771.030 that involved the mixing of "inhalation" and "consumption" and "breathing rate" and "consumption."

- Letter report IM 20.01402.771.040 was delivered without receiving a review in accordance with procedure QAP-002; however, there was evidence that the element manager and director did review the document.

- It did not appear that deliverable 20.8801.006.001 received an editorial review nor was it clear how the need for review was determined and documented.

- In one case, NRC guidance was accepted at face value even though it appeared questionable. In this case, the statement "more conservative of the 5th or 90th percentile" was not questioned when the normal case is to cite symmetric distributions such as "5th or 95th" or "10th or 90th" percentile.

- For Task Order 6 of the Site Decommissioning Management Plan (SDMP), the work was primarily authored by CNWRA staff; however, the summary and conclusion section of the report state, "This EA was prepared by NRC staff . . . ."

- Inconsistencies were noted in the procedure forms, revision and change numbers. Administrative Procedures (APs) are not addressed in the CNWRA document control procedure.

- Because information relevant to computer code development is spread among multiple developer notebooks, reconstruction or determination of status would be difficult.

- Software problems for Beta or released software is not tracked consistently. For example, problems related to TPA are documented in Software Change Requests (SCRs), while those related to MULTIFLO are documented in multiple scientific notebooks.

- While the CNWRA Information Management System (IMS) department maintains a list of acquired software, the QA department has no immediate knowledge of the acquisition so they can determine if the acquired software should be controlled or not. If the acquired software is used on a project, it should be added to the QRAM and QA notified when the QRAM is updated, but this does not consistently occur.

INTRODUCTION

The annual internal audit for the CNWRA was conducted June 20–23, 2000. The audit was performance-based, addressing the technical aspects of the activities conducted as well as programmatic compliance to the CQAM. The audit was conducted with an audit plan prepared by the ATL and approved by the CNWRA QA Director and CNWRA President.

The eighteen criteria contained in 10 CFR Part 50, Appendix B, were evaluated during the audit. Criterion III, "Design Control," is addressed by the "Scientific Investigation and Analysis Control" procedure. Criteria X, "Inspection;" XI, "Test Control;" and XIV, "Inspection, Test, and Operating Status" are not applicable to the CNWRA QA program because of the nature of the work performed. An evaluation of acceptability of excluding these criteria was conducted during the audit and it was agreed that the exceptions taken were appropriate.

The activities associated with seven HLW key technical issues (KTIs) and one project area were audited. The technical activities were selected by the QA Director in conjunction with the Technical Director and President of the CNWRA after review of prior audit reports and determining priority based on progress to date, time since the last audit in the general area, and the amount of work involved with each KTI. The effectiveness of programmatic controls specifically applicable to the technical activities was evaluated. A 67-page audit checklist containing 148 programmatic and 139 technical inquiries was used during the audit. In addition, a 48-page checklist based on the Nuclear Utilities Procurement Issues Committee (NUPIC)

checklist was used to evaluate the compliance of the CNWRA QA program to NQA-1 as applied to research and technical activities. The audit also included a follow-up of the four CARs initiated during the previous annual audit, CNWRA Audit 99-1. The audit process was explained to CNWRA personnel and interview schedules were established during the pre-audit meeting held on June 20, 2000.

The audit team was comprised of two co-audit team leaders (ATL), four QA auditors, four of whom are certified as a lead auditor, one as an auditor, and one as a software specialist under the Institute Nuclear QA Program and eight technical specialists who have completed a formal audit training program for technical specialists. Mr. Rodney Weber acted as both technical specialist and QA auditor for the Yucca Mountain Review Plan. Eight of the thirteen team members had participated in previous CNWRA audits. None of the team has been involved with quality or technical areas reviewed during this audit. Because of schedule conflicts, co-audit team leaders were employed for this audit. Mr. Dunavant managed the planning, coordination, and start of the audit. Mr. Trbovich took over on day two and completed the audit and presented the results at the postaudit meeting. Audit team members included:

Donald W. Dunavant, P.E. Manager, Quality Systems Technology Southwest Research Institute QA	Co-ATL and QA Auditor
Thomas C. Trbovich Staff Scientist Southwest Research Institute QA	Co-ATL and QA Auditor
Rodney M. Weber Manager Southwest Research Institute QA	QA Auditor and Technical Specialist for the Yucca Mountain Review Plan
Gerald T. Cogar Software QA Engineer Southwest Research Institute	Software QA Auditor
Robert D. Brient Lead Auditor Southwest Research Institute	QA Auditor
Sheila C. Dannelly Auditor Southwest Research Institute	QA Auditor

Steven W. Dellenback, Ph.D. Institute Scientist Southwest Research Institute	Technical Specialist
Lawrence J. Goland, P.E. Principal Engineer Southwest Research Institute	Technical Specialist
John P. Hageman, C.H.P. Radiation Safety Office Southwest Research Institute	Technical Specialist
Randy Manteufel, Ph.D., P.E. University of Texas at San Antonio	Technical Specialist
Richard A. Page, Ph.D. Institute Scientist Southwest Research Institute	Technical Specialist
Diane R. Smith, Ph.D. Trinity University	Technical Specialist
William Thomann, Ph.D. University of the Incarnate Word	Technical Specialist

The QA auditors and technical specialists worked in teams evaluating technical direction and performance as well as the QA programmatic elements applicable to their assigned KTI. The ATLs attended as many of the task discussions as practicable and reviewed the QA programmatic elements of a more general nature not specifically addressed in the technical tasks. Each of the audit team members presented their respective audit status, results, concerns, potential findings, and observations at daily team caucus meetings. Daily briefings were held with the CNWRA management to apprise them of audit results.

A post-audit meeting was held with the CNWRA staff on June 23, 2000, to summarize the audit results.

The audit team wishes to thank Bruce Mabrito, Mark Ehnstrom, and Maria Padilla who acted as escorts during the audit and provided detailed information on the status of programs, and to the CNWRA technical personnel for their cooperation in answering questions during the various interviews.

QUALITY ELEMENTS AND TECHNICAL AREAS EVALUATED

10 CFR Part 50, Appendix B Criteria		Corresponding CQAM Chapter
I	Organization	1
II	QA Program	2
N/A	Scientific 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 Processes	9
XII	Control of Measuring and Test Equipment	12
XIII	Handling, Storage, and Shipping	13
XV	Nonconformance Control	15
XVI	Corrective Action	16
XVII	Records Control	17
XVIII	Audits	18

All CNWRA CQAM chapters were addressed in this audit. The following technical areas were audited. One of the areas was non-HLW and seven were HLW-related.

Technical Areas or KTIs		Project Number
(1)	**Non-HLW**	
	Site Decommissioning Management Plan	20.08801
(2)	**HLW**	
	Container Life and Source Term	20.01402.570
	Repository Design and Thermal Mechanical Effects	20.01402.670
	Structural Deformation and Seismicity	20.01402.470
	Radionuclide Transport	20.01402.870
	Yucca Mountain Review Plan	20.01402.590
	Computer Codes TPA, V4.0 and Multiflo, V1.2	20.01402.762, 562
	Activities related to Development of the NRC HLW Regulations	20.01402.770

AUDIT RESULTS

I. CNWRA Quality Assurance Program
Donald W. Dunavant, Thomas C. Trbovich, Rodney M. Weber, Robert D. Brient, and Sheila C. Dannelly

Organization
CNWRA QAM, Section 1

Overall, the CNWRA staff interviewed exhibited knowledge of the applicable requirements of the CNWRA QA program. The QA program complies with the applicable criteria of 10 CFR Part 50, Appendix B, and is effectively implemented except as noted in the following sections.

The QA function is fully integrated in the CNWRA activities. The QA Director reports to the CNWRA President and is organizationally independent of line operations and free of conflicting responsibilities.

Discussions with senior CNWRA management indicated strong support for the QA program. No allegations of inadequate quality have been identified to the CNWRA management.

Quality Assurance Program

CNWRA QAM Section 2
QAP-005, "Quality Indoctrination and Training"
QAP-007, "Professional Personnel Qualification:
QAP-013, "Quality Planning"

Records documenting applicable training were reviewed for a significant number of personnel involved in the programs. Documentation of training to the CQAM is available. It was not clear to the auditor, however, whether this training was done one on one, through staff meetings, or through reading. Other (i.e., procedure) training appears to be done through reading and is documented on document transmittal receipts. There appears to be no objective evidence that anyone other than those on controlled distribution of documents are receiving training when appropriate. There is no evidence of assessments for need for specialized training except for those participating as technical specialists in observation audits.

Based on other auditor and technical specialist observations during this audit, it appears that more attention to training activities is needed. The 1999 audit identified a need for "refresher" training to those persons who support CNWRA activities such as consultants and other Institute employees. This refresher training should be extended to CNWRA staff as well. See CAR 2000-05.

Quality Requirements Application Matrices (QRAMs) were prepared for each KTI in the Operations (OPs) Plans, Revision 14, Change 0. At the time of the audit, Revision 14, Change 3 of the OPs Plan was in effect. Some evidence of reviews of OPs Plan changes for impact on QRAMs was available, but reviews were not consistently applied to all KTIs. This is a recurring condition because CAR 99-1 from audit CNWRA 99-1 also determined that the reviews to determine whether QRAMs need to be updated had not been performed and documented. In addition, QRAMs are prepared for the top level KTI, but not for each task in the OPS Plan as required by QAP-013 "Quality Planning." This last element is particularly important because the applicability of software and existing data controls depends, at least in part, on the potential use of the software or data in future licensing decisions. The potential use of software and/or data should be explicitly determined for individual products of the CNWRA, and that might be accomplished in quality planning at the task level.

When the OPs Plan is reviewed to determine the potential impact on the QRAMs, QAP-013 requires that the determination be approved by the Element Manager, Director of QA, and Technical Director. Documentation was available to demonstrate approval by the Director of QA in most cases, but not that of the Element Manager or Technical Director. See CAR 2000-07.

The QRAM for Structural Deformation and Seismicity incorrectly identified TOP-018 for software control as not applicable. TOP-018 should be applicable because scientific and engineering software was used extensively in this KTI. See NCR 2000-07.

Scientific Investigation and Analysis Control
CNWRA QAM, Section 3
QAP-001, "Scientific Notebook Control"
QAP-002, "Review of CNWRA Documents, Reports, and Papers"
QAP-014, "Documentation and Verification of Scientific and Engineering Calculations"
QAP-015, "Qualification of Existing Data"

Scientific Notebooks

Audit team members during their technical interviews conducted notebook reviews. In addition, a sampling of filed (closed) notebooks was conducted. As a result of observations from several of the team members, technical and programmatic, a finding in this area was issued. See CAR-2000-02 and the individual technical discussions.

Scientific notebooks, to a significant degree, document the Center's research activities. Therefore, they should provide clear cut and repeatable details of these

research activities. Over the years, notebooks have been cited for numerous minor discrepancies. As the Center activities become more complex, particularly in the area of software controls, the ability to reconstruct activities from information contained in notebooks will be a greater challenge.

Although there were multiple and varied minor programmatic discrepancies, the intent of the finding is not to cause focus on these minor issues. A higher level approach and awareness should be adopted. Managers should ensure their staffs attend to the details and address those programmatic elements that ensure documentation will allow activities to be reconstructed should that be needed. Recommendations include more involvement from the element managers. Consideration might be given to a single page checklist of key requirements to be prominently positioned in each notebook.

Document reviews are being conducted in accordance with procedural requirements for the most part; however, several discrepancies were noted. The requirement to verify 10% of calculations and that verification be documented in, referenced in, or attached to the review documentation was not consistently complied with. A journal article (Q19991124001) for Container Life and Source Term did not receive a calculation check. See CAR 2000-03. In some cases, the overcheck was not documented on the form TOP-3 as required (IM 20.01402.471.050) or was not readily available (IM 20.01402.711.030). For document IM 20.01402.711.030, not all reviewer comments were consistently incorporated. SDMP document 20.8801.006.001 did not receive an editorial review.

Instructions, Procedures, and Drawings
CQAM, Section 5

There is no evidence on the drawings nor is there definition in the procedure as to who the reviewer is and what the review consisted of. The procedure does not contain qualitative or quantitative criteria, which is a violation of 10CFR50, Appendix B, Criterion 5 and CQAM, Paragraph 5.3. Some procedure requirements are not being strictly adhered to. See NCR 2000-08.

Guidance from NRC, particularly that involving development of the Issue Resolution Status Reports and the Yucca Mountain Review Plan, should be considered as "instructions" as described in Criterion V of 10CFR50, Appendix B. This guidance prescribes the format and defines acceptance criteria for these products. The CNWRA should identify controls in procedures to assure that the current and complete NRC guidance is available to affected staff, and that obsolete guidance is removed or identified as such.

Document Control
CQAM, Section 6
QAP-008, "Document Control"

The CNWRA documents were uniquely identified by titles and document numbers as well as a master list of documents including scientific notebooks. Effectivity pages with signatures were prepared for changes. Copies were clearly identified as controlled or uncontrolled. Current and correct versions of the documents were available at the point of use. Acknowledgements of receipt of controlled documents were maintained.

Receipts for controlled copies are, for the most part, received in a timely fashion. Distribution lists are maintained. Changes or revisions to procedures are well noted.

There are inconsistencies in the use of procedure forms, revision and change numbers associated with QAPs and TOPs. These were all discussed with CNWRA document control at the time of the audit. Administrative procedures are not referenced in the CNWRA document control procedure. No objective evidence of attempts to retrieve late receipts was available. It is not always clear by whom or when changes to distribution lists are made.

Procurement Control
QAM, Section 7
QAP-016, "Procurement Control"

Based on the discrepancies noted in the CNWRA Audit 99-1 and CAR 99-2, revisions were made in September 1999 to the CNWRA Quality Assurance Manual, Section 4 and Section 7 to more clearly define the application of quality requirements in Consultant Services Contracts, Purchase Orders and Subcontracts. This also involved revisions to Administrative Procedures, AP-005, "Obtaining Subcontract Services," and AP-006, "Obtaining Consultant Services" to specify in the procurement documents the quality procedures that were to be followed and the type of quality training to be provided.

A sample of nine consultant services contracts spanning the time frame of November 1999 through April 2000 were reviewed and found to have the quality requirements indicated. However, no objective evidence could be located to determine if "any technical or QA procedures required in the performance of the consultant's work had been provided," as indicated by Section 14 of the agreement. This discrepancy has been documented in CAR-2000-05.

Overall, quality and indoctrination training packages have been signed by the consultants and were available for review. However, consideration should be given

to having refresher quality training for those consultants used for longer than one year.

Quality Procedure QAP-016, "Procurement," was also revised in November 1999 to correct deficiencies identified in CAR-99-02 and incorporate some of the requirements identified in ANSI/ASME NQA-1, 1986. However, the procedure is deficient in identifying the process of bid and supplier evaluation prior to the award of the purchase order or subcontract as required by NQA-1, Element 7, Sections 3 and 4. This discrepancy is documented in CAR-2000-01.

A review of purchase orders to Metal Samples Incorporated from March 1999 through March 2000, indicated incomplete imposition of technical and quality requirements in the procurement documents. In addition, the supplier quality evaluation performed in January 2000 evaluated the Metal Samples Incorporated quality system in accordance with ISO 9000 quality system requirements. There is no objective evidence of a review and acceptance of the evaluation as meeting the applicable requirements of 10CFR50, Appendix B by the CNWRA-QA.

A review of eight purchase orders procuring items from various organizations from February through May 2000, noted discrepancies with complete application of both technical and quality requirements. In some instances, no technical requirements were identified but the listing of quality requirements were, in fact, technical requirements. In other instances, technical requirements were incomplete with no identification of codes or standards and quality requirements either were absent or identified as "Certification Required" with no reference to quality system requirements.

The revision of QAP-016 changed the procurement process significantly. However, no formal training was provided to the CNWRA staff and this could lead to confusion in how to apply quality and technical requirements when generating purchase requisitions.

A recommendation is made to revise QAP-016 to incorporate provisions for supplier performance evaluations and the pass down of special process controls when welding, heat treating, or nondestructive testing may be involved. It may also be beneficial to segregate purchases to standard commercial off-the-shelf (COTS) where minimal quality requirements may be imposed, or special cases where complete applicable requirements of 10CFR50, Appendix B and NQA-1 would be imposed.

Identification and Control of Items, Software, and Samples
CQAM, Section 8

For the CNWRA, the identification and control of items as well as handing, storage and shipping applies primarily to samples and laboratory solutions. Controls

addressing these criteria are identified in Technical Operating Procedure TOP-012. Implementation of TOP-012 was observed in the radionuclide transport and container life lab areas.

In the radionuclide transport laboratory, several water and well cutting samples from the Nye County area were traced through their documentation. Sample identification used the DOE Sample Management Facility scheme (e.g., bar codes, etc.). The samples appeared to be adequately labeled and the documentation was complete.

The container life laboratory included specimens obtained from supplier Metal Samples as well as large sheets of stock material. Two configurations of Metal Samples specimens had markings only on an outer bag, and that number was the job number rather than the heat number (the sample custody log identification number). Proper identification numbers were applied during the audit. It was also noted that this laboratory is making sample custody entries only for the heat numbers, and not for individual specimens obtained from a heat. Lab personnel explained that the individual specimens are identified in scientific notebooks. The CNWRA should determine whether the sample custody log should be used for container lifetime specimens as is commonly used in other labs (see Recommendations).

The criterion for identification and control can also be applied to data. Currently, the traceability between CNWRA work products and their supporting documentation is general; usually only at the level of the cost accounting phase (or KTI). Without recourse to the Principal Investigators, supporting documentation in the QA record (for a specific work product) may be difficult to identify, and thus, replicating the results of the technical activities might be difficult as well. The CNWRA should establish methods that assure unambiguous traceability from the work product back to its supporting documents.

Control of Processes
CQAM, Section 9

Review of CNWRA activities indicated that these processes are subcontracted to other SwRI divisions or to outside suppliers. The controls within the CQAM appear to be sufficiently detailed to guide development of procedures or for documenting special process activities in scientific notebooks.

Inspection
CQAM, Section 10

A review was conducted of Section 10 of the CQAM against the requirements of 10CFR50, Appendix B and ASME NQA-1 related to Criterion X. Appendix B requires an inspection program to inspect activities affecting quality, independence

of inspection personnel, and references indirect control of activities by monitoring. ASME NQA-1, Supplement 10S-1, adds requirements for personnel training, planning of inspections, specifically addresses only in-process and final inspections, and mentions inservice inspections of power plants.

The CQAM limits inspections performed by CNWRA personnel to receipt inspections of procured material which is addressed in CQAM Sections 4 and 7. In-process or final inspection of processed material (e.g. machining) is delegated to SwRI and would be controlled by the SwRI *Nuclear Quality Assurance Program Manual.* For the type of work performed by the CNWRA, i.e., research and technical assistance, this exception appears reasonable and consistent.

Test Control
CQAM, Section 11

A similar review was conducted of Section 11 of the CQAM against the requirements of 10CFR50, Appendix B and ASME NQA-1 related to Criterion XI, "Test Control."

Both Appendix B and NQA-1 are written to address testing for design verification as applied to power plants and fuel reprocessing plants to assure structures, systems, and components perform satisfactorily inservice. The kind of testing performed at the CNWRA is experimental and scientific investigation in nature and is more appropriately addressed in Section 3, "Scientific Investigation and Analysis Control."

While the auditor agreed that test control as applied by the CNWRA was adequately controlled by Section 3, it was noted that in some cases, standard tests were repeated numerous times. In these instances, it would be more efficient to apply more normal test processes. The generation of a test procedure with a data sheet which could be completed repetitively with the acquired data would be less laborious than documenting each test in scientific notebooks.

Control of Measuring and Test Equipment
CQAM, Section 12

To evaluate the adequacy of the control of calibrated equipment, instrumentation used in the container life and radionuclide transport laboratories was reviewed. Equipment requiring periodic calibration is administered under the SwRI Calibration Laboratory, which is accredited by the American Association for Laboratory Accreditation to ANSI/NCSL Z540.1-1994. With the exception of returning instruments for recalibration and evaluating the impact of out-of-tolerance conditions, all calibration responsibilities have been assumed by the SwRI facility. Equipment in use was found to be properly labeled and within the calibration interval. Overdue equipment was appropriately labeled.

In the container life laboratory, potentiostats are required to have performance verifications run on six-month intervals. CNWRA staff perform these activities. Since the verifications are valid for a specific time period, labels indicating the expiration date should be applied. If desired, the SwRI Calibration Lab could place these instruments under their recall system as well.

Handling, Storage, and Shipping
CQAM, Section 13

Handling, storage, and shipping was limited to that related to samples. Samples appeared to be properly handled and stored when noted.

Inspection, Test, and Operating Status
CQAM, Section 14

Parallel to the review of Criteria X and XI, Criterion XIV was evaluated. The CQAM, Section 14, takes exception to this element as not applicable to the activities of the CNWRA, but rather, appropriate to the design, construction, and operation of nuclear power plants. Based on the determination that Criteria X and XI are appropriately excluded or covered elsewhere in the CQAM, it was determined that the exclusion of Criterion XIV was also acceptable.

Nonconformance Control
CQAM, Section 15
QAP-009, "Nonconformance Control"

Nine nonconformance reports have been initiated since audit CNWRA 99-1, most having to do with out-of-tolerance measuring and test equipment and procedural noncompliance. The requirements of QAP-009 were followed for processing and tracking, and appropriate dispositions were identified. All but one of the nonconformance reports had been followed-up and closed out at the time of the audit. The one open report has had the completion date extended to August 25, 2000.

Corrective Action
CQAM, Section 16
QAP-010, "Corrective Action"

A review of the CNWRA corrective action process was conducted with emphasis on effectivity in recognition of the deficiency documented in the previous audit, CNWRA 99-1.

In addition to the four Corrective Action requests (CARs) initiated during that audit, one additional CAR has been generated by CNWRA QA personnel. One of the

CARs from Audit 99-1 (CAR 99-4), remains open pending the implementation of corrective action.

CAR 99-1, written during audit CNWRA 99-1, indicated that the corrective action process was not being effectively implemented because no CARs other than audit findings had been written in several years. In addition, some nonconformance reports appeared to reflect significant conditions that should have been addressed as CARs. The condition identified in CAR 99-1 appears to persist based on a 1999 Trend Analysis Report prepared in January 2000 by the CNWRA QA staff. This report identified "adverse trends" in "control of purchased or developed computer codes" and in "procedural nonconformances relative to scientific notebooks." Adverse trends are clear indicators for applying the corrective action process, however, no CARs were initiated in response to these trends and similar issues were noted during this audit.

In addition, the corrective action process appears to be ineffective because of the recurring conditions identified in CARs 99-2, regarding the procurement process, and 99-5, regarding software control. Conditions similar to those identified in these CARs were identified in this audit. See CAR 2000-06.

Records Control
CQAM, Section 17
QAP-012, "Quality Assurance Records Control"

Records are readily retrievable and legible. Changes are made appropriately. Records are maintained in appropriate containers and are protected from loss or deterioration (including computer files). A new requirement in 2000 has scientific notebooks being copied and stored every six months; however, not all staff have yet complied with this new requirement

Audits
CQAM, Section 18
QAP-004, "Surveillance Control
QAP-011, "Audits"

Surveillance schedules are prepared annually. For the most part, the indicated activities have been surveyed, although sometimes a few months late. No revision to the schedule had been made, and no surveillance appears to have been scheduled specifically to follow-up on corrective action effectiveness (this was an observation from audit CNWRA 99-1 as well, see Recommendations).

The annual audit was conducted by SwRI QA staff supported by SwRI and external technical specialists. Audit scheduling and reporting was administered under the SwRI audit procedure OP-17.0-30-1. Auditor and Technical Specialist qualification and training was in order. Applicable QA program criteria have been assessed, as

have been a sample of technical activities. Audits integrate the technical and programmatic elements, and are performance based.

Conditions adverse to quality observed during the audit were documented on a CAR. Before acceptance of the proposed corrective action, the audit team leader reviewed the adequacy of the corrective action responses. While follow-up to corrective actions resulting from audits does occur, it is recommended that documentation be generated specifically addressing the effectivity of corrective action taken.

II. Technical Areas

A. Container Life and Source Term
Richard A. Page, Ph.D., Technical Specialist
Robert D. Brient, Quality Assurance Auditor

Individuals Interviewed:

N. Sridhar
G. Cragnolino
D. Dunn
B. Brossia
V. Aaron
J. Sievert

Documents Reviewed:

1. "Effects of Environmental and Metallurgical Conditions on the Passive and Localized Dissolution of Ti-0.15Pd," IM 20.01402.571.010

2. "Input to Safety Evaluation Report on Disposal Criticality Analysis Methodology Topical Report," IM 20.01402.571.005

The technical specialist and the programmatic auditor interviewed six individuals during the audit. Four of the individuals interviewed, N. Sridhar, G. A. Cragnolino, D. S. Dunn, and C. S. Brossia, were members of the CNWRA staff. The remaining two, V. D. Aaron and J. Sievert, were members of the Mechanical and Materials Division of SwRI (Division 18) staff who were actively involved in experimental work for the CLST KTI. All of the staff were very forthright in their discussions. It was evident from these discussions that the staff were well qualified for the work they were performing. It was also evident that the staff understood the importance of the job they were performing and therefore, the need for the QA program.

As part of the audit, one CNWRA laboratory (the corrosion laboratory in bldg. 57) and one Division 18 laboratory (bldg. 90) involved in CLST activities were visited.

Equipment calibrations were found to be in order. Specimen archive procedures were also examined and found to be satisfactory.

Five scientific notebooks (009, 287, 298, 328 and 366) were examined during the laboratory visits. Apart from a few minor discrepancies, the scientific notebooks were in good shape; initial entries were present and data entry was thorough. A qualified scientist should be able to reproduce the experimental results from the scientific notebook entries.

The document review files for four documents produced in the CLST KTI were examined during the audit. It was evident that each document had received a thorough review (technical and programmatic) by a qualified individual. Adequate responses were provided for all reviewer comments. One report (QA Record No. Q19991124001) involved model development and extensive calculation but did not include calculation overchecks in accordance with Procedure QAP-014. See CAR 2000-03.

One significant issue related to procurement of welded samples was identified during the audit. Welded corrosion coupons of C-22 and Ti-Pd were ordered with inadequate procurement control. Since these specimens were ordered without specifying the critical welding parameters, their pedigree is in question. Subsequent to their purchase, many of the parameters necessary to characterize the welds have been obtained. Nonetheless, post-procurement documentation should not take the place of procurement QA. Since these specimens are now reasonably well documented, they should be suitable for preliminary examinations of possible weld effects. However, because of the problems associated with the procurement of these specimens, they should not be used to generate corrosion data that will be input into predictive codes such as the TPA code.

The technical and QA programmatic assessments of quality planning, procurement, scientific notebooks, sample control, and the review process were conducted simultaneously. QRAMs identified the appropriate procedures; however, the practice is for a QRAM to cover an entire KTI rather than individual tasks or work products. No significant changes in the scopes of work have occurred since Revision 14, Change 0 of the OPs Plan. Controlled software was used to conduct numerical analyses. Laboratory activities were documented in scientific notebooks. Measuring equipment was calibrated as required. The Chemistry and Chemical Engineering Division of SwRI (Division 01) was used for some activities. Properly completed work orders were used. Division 01 and Division 18 activities were under the direct supervision of CNWRA staff. One surveillance had been conducted in the past 12 months. The QRAM for CLST did not invoke QAP-016, "Procurement," even though samples were purchased. See NCR 2000-09.

In summary, the work being performed in the CLST KTI is of very high quality. Furthermore, an effective QA system is in place. Staff who have been involved in

the system for many years have not become lax and newer staff appear to have been adequately trained and are effectively implementing the QA system.

The following recommendations are based on audit observations.

1. A qualified welding consultant should be involved in the procurement of all welded samples.

2. Instrument calibrations listed in the scientific notebooks should list the date the calibration was performed as well as the date of entry in the notebook.

B. Repository Design and Thermal Mechanical Effects
Lawrence J. Goland, P.E.; Technical Specialist
Thomas C. Trbovich, Quality Assurance Auditor

Individuals Interviewed:

D. Gute
S-M Hsuing
A. Chowdhury

Documents Reviewed:

Assessment of Mechanical Response of Drop Shields Under Repository Environment – Program Report (IM 20.01402.671.070)

The report reviewed addresses the preliminary effort taken to develop the analytical methodology using finite element analysis for determining the response of a drip shield at elevated temperatures when subjected to impact by falling rock. Impact conditions both with and without seismic ground motion were included in the analytical study. The actual phenomenon itself is very complex in nature. When impacted by the falling rock, the drip shield will undergo large displacements with the material undergoing elastic-plastic behavior. This will occur at elevated temperatures, where the drip shield material will exhibit reduced deformation and strength material properties. Also, the rock behavior at impact is complex, with the possibility of rock surface crushing and breaking. Drip shield contact with the waste package is also a possibility. All of these factors effect the behavior of the drip shield during the impact event. It is desired to model all of this behavior and interaction using the finite element method of analysis, thereby creating a tool which can be used to evaluate the final drip shield design. The final objective of this work is to improve the current drip shield / rockfall model currently being used in the SEISMO module of the NRC TPA code.

The audit began with an interview of three of the four authors of the technical report. Each author described his educational, technical, and experience background. In addition, responses to technical questions posed during the audit showed a true understanding of the subject matter. It was found that the principal

investigators (authors) were well qualified in the structural and geotechnical disciplines required for conducting the subject analyses and interpretation of results.

The subject matter presented in the report was discussed in detail. Some of the topics addressed were as follows:

1) The appropriateness and ability of the finite element code used to perform the analyses;

2) Finite element types (shell vs. solid) used;

3) Drip shield material properties at ambient and elevated temperatures, which included yield and ultimate strengths, and elastic-plastic stress-strain behavior;

4) Seismic behavior of the system and input into the analysis;

5) Boundary conditions; and

6) Validation of results from the finite element analyses.

Since this report presents the initial effort in developing the finite element analysis methodology used to determine the effects of rockfall on drip shields, the actual results (e.g., meeting acceptable stress levels) were not discussed in any great detail. At the time of the audit, the final design of the drip shield had not been finalized.

One of the more important issues discussed was Item 6, which was how the principal investigators validated the results obtained from the finite element analyses. The methods used, classical calculations and engineering experience, were presented, discussed, and found to be satisfactory.

Finally, a review of the scientific notebook was made. From a technical standpoint, it was found to be very thorough, neat (legible), and professionally done. All aspects of the analysis were documented, including supporting information about material properties and analysis results validation.

All personnel participating in this KTI were found to have the proper professional personnel qualifications in accordance with QAP-005 and had received Quality Indoctrination and Training in accord with QAP-007.

The Scientific Notebook #391, used to record results, was reviewed and, in general, found to have neat and concise entries that were easy to follow. However, discrepancies noted included the use of whiteout on page 29; single-line crossouts

of errors with no initial or date on pages 52 and 53. (See CAR 2000-02) These and other pages were reviewed by the technical author and properly corrected during the audit. The other provisions of QAP-001, "Scientific Notebook Control." were found to be satisfactory.

The Progress Report review, as required by QAP-002,"Review of CNWRA Documents, Reports, and Papers," had taken place from 5/11/2000 through 5/18/2000. All comments had been properly resolved with no discrepancies being noted. In accordance with the Quality Requirements Application Matrix (QRAM), a review of scientific calculations was to take place, in accordance with QAP-014, "Documentation and Verification of Scientific and Engineering Calculations." G. Ofoegbu conducted this review on 5/11/2000, and S. Mayer on 5/12/2000, and properly documented on the CNWRA Form TOP-3 and referenced the scientific notebook pages where calculations had been verified.

One suggestion is being made: When discussing important issues directly related to the subject matter, documenting the conversation and outcome might be beneficial for future reference. This is analogous to making a record of important telephone conversations.

C. Structural Deformation and Seismicity

Diane R. Smith, Ph.D., Technical Specialist
Robert D. Brient, Quality Assurance Auditor

Individuals Interviewed:

J. Stamatakos
M. Miklas
B. Sagar
T. Ressler

Documents Reviewed:

1) 20-1402-471-050: Extensional Relay Ramp Deformation, by D. A. Ferrill and A. P. Morris
2) 20-1402-471-040: Three-Dimensional Structural Model of the Amargosa Desert, Version 1.9: report to accompany model transfer to the Nuclear Regulatory Commission, by D. W. Sims, J. A. Stamatakos, D. A. Ferrill, H. L. McKague, D. A. Farrell, and A. Armstrong
3) 20-1402-471-020: Composite 13 Million Year Record of Extensional Faulting and Basin Growth of Crater Flat, Nevada, by J. A. Stamatakos, B. E. Hill, D. A. Ferrill, P. LaFemina, D. Sims, C. B. Connor, M. B. Gray, A. P. Morris, and C. M. Hall

During the audit on June 21, 2000, additional documents were provided, including two published articles,

Ferrill, D. A., Stamatakos, J. A., and Sims, D., 1999, Normal Fault Corrugation: Implications for Growth and Seismicity of Active Normal Faults: *Journal of Structural Geology*, v. 21, p. 1027-1038

Ferrill, D. A., Winterle, J., Wittmeyer, G., Sims, D., Colton, S., and Armstrong, A., 1999, Stressed Rock Strains Groundwater at Yucca Mountain, Nevada: *GSA Today*, v. 9, no. 5, p. 1-8

and two articles that have been submitted and accepted for publication,

Gray, M. B., Stamatakos, J. A., Evans, M. A., and Ferrill, D. A., 1999, Fault Behavior and Fault Zone Architecture in Miocene Volcanic Tuffs at Yucca Mountain, NV: *EOS, Transactions, American Geophysical Union*

Ferrill, D. A., Morris, A. P., Stamatakos, J. A., and Sims, D., in press, Crossing Conjugate Normal Faults: Invited manuscript for the American Association of Petroleum Geologists book entitled "*Recognition and Characterization of Reservoir Scale Structures*".

On June 21, the auditors (R. Brient and D. Smith) interviewed two Senior Research Scientists, Dr. John Stamatakos and Mr. Michael Miklas, who described their major activities since the 1998 audit. Later in the afternoon, Dr. Budhi Sagar (Technical Director) and Mr. Ted Kessler (student worker) were asked questions to clarify some issues.

Documents in addition to the items listed above were examined. These included:

Two professional personnel qualification files (for Dr. Mary Beth Gray and Dr. Kenneth Ridgway, both of whom are outside consultants).

Five scientific notebooks (# 099, 248, 262, 312, and 247). The notebooks belong to several different scientists (e.g., Stamatakos, Sims, Ferrill, Colton, Ridgway) and document a variety of activities, ranging from field studies to laboratory measurements and computing activities.

Three review packages, which document the technical reviews of IM 20-01402-471-833 (Ferrill et al.), IM 20-01402-471-020 (Stamatakos et al.), and IM 20-01402-471-050 (Ferrill and Morris).

Since the 1998 audit, there have been no changes in the CNWRA core staff for this KTI. The staff involved with this KTI were found to be highly qualified to carry out the research. They have many years of research experience, including academic and industrial research, as well as applied, theoretical, and experimental studies. Their respective fields of expertise are very complementary. Since the last audit, two outside consultants (M. B. Gray and K. Ridgway) have become research collaborators with CNWRA scientists. Examination of Gray's and Ridgway's personnel qualification files revealed that they are very qualified and well suited for the work that they are doing for the

CNWRA. They both have strong publication records, which include journals that are well respected within their fields of expertise. They both have diverse research interests with respect to both topic and geographic location. Both scientists have been successful in attracting research funding; in particular, Ridgway has a very strong record of external funding (e.g., from the National Science Foundation).

During the audit interview, sampling procedures were discussed. Dr. Stamatakos noted that samples collected for the purpose of paleomagnetic studies had been added to the sample custody log, otherwise he had no further sampling to report. All of these samples had been consumed during the process of paleomagnetic analysis (which is typical for this technique); thus there was no reason to visit the sample storage facility during the audit. Dr. Stamatakos discussed the sampling conducted by one of the consultants, Dr. Gray, who employed QA procedures required by the Department of Energy in collecting and maintaining her sample collection. Dr. Stamatakos pointed out that the DOE requirements are more stringent than the CNWRA's requirements, and involve bar coding of all samples, sites, and notebook entries.

In general, the scientific notebooks were found to be very well maintained documents. In the opinion of the technical specialist, a qualified individual could repeat the laboratory measurements, return to the same field location, duplicate calculations, or replicate other research activities of CNWRA staff, based on the documentation provided in the notebooks. It is noted that one of the notebooks examined was maintained by an outside consultant, but it also followed notebook control requirements (e.g., initial and in-process entries were complete and consistent with QA procedures). However, a small number of problems were observed in several of the notebooks examined. For example, some of the notebook entries include duplicated copies. Although the great majority of these entries are legible, a couple (e.g., notebook #262) were found to be difficult to read, due to poor duplication. Another problem involved a stratigraphic column (p. 10 in notebook #312) for which the descriptions are printed in very small font that is difficult to read. Another notebook (#247) was found to have entries that were not dated, nor were signatures or initials provided by the researcher and/or principal investigator, as required by QA procedures. Notebook #247 also includes a copy of an Honors Thesis, which is clipped to the back cover. It is recommended that the thesis be more securely taped into the body of the notebook or be provided electronically. Finally, it is suggested that the complete citation be provided for all sources given in notebook entries. In a couple of cases (e.g., p. 7, notebook #312) only the author and year of publication were provided, whereas it might be useful to provide all the bibliographic information.

The research conducted by this KTI's scientific staff has been effectively communicated in CNWRA reports as well as peer-reviewed journals. The latter includes the most prestigious and well-read journals that publish

structural/seismic studies (e.g., *Journal of Structural Geology*). Each of the three review packages examined were found to contain careful reviews by the appropriate CNWRA staff, and the author of the document carefully responded to each comment. One of the review packages (for IM 20-01402-471-050 by Ferrill and Morris) involved a manuscript that documented and discussed scientific calculations. A technical reviewer (Dr. Budhi Sagar) had reviewed those calculations and the review package states that the calculations were checked. However, according to item 3.2.4 in QAP-014, such verifications shall be documented on the comment resolution sheets (TOP-3 forms), which was not the case for this review package. Except for this single omission, the technical reviews for the three packages examined were found to be thorough and complete.

The technical and QA programmatic assessments of quality planning, procurement, scientific notebooks, sample control, and the review process were conducted simultaneously. The QRAM indicated that TOP-018 software controls were not applicable, however this KTI involves the extensive use of software for modeling (see NCR 2000-07). One of the reports reviewed used Earthvision software and contained a disclaimer indicating that the software was not under configuration control. No supporting documentation was available to justify Earthvision not being controlled, but the Principal Investigator indicated that the CNWRA considered this software to be more database oriented (similar to Excel) and not needing control. Quality planning at the task or work product level may have more clearly justified and documented this determination.

This KTI involves many consultants, but no subcontracted experimental or laboratory activities. Notebook control by consultants appear to be satisfactory. Some field samples collected by a consultant are controlled and stored by her as well. No attempt was made to determine the implementation of sample controls in this instance. Within the CNWRA, all recent samples had been consumed in testing, so samples control in this KTI was not assessed.

Overall, the QA system appears to be effectively and consistently applied within this KTI. The activities and qualifications of the staff of this KTI are found to be of the highest caliber. The scientific staff employs sound technical methods, maintains high standards and scientific rigor, and utilizes a wide variety of techniques and approaches. Their data and geological findings have important implications for the repository performance assessment. Their results are also important to the geologic community in general, and especially for researchers interested in the structural evolution and seismicity of the Basin and Range and other similar geologic provinces.

D. Radionuclide Transport
William F. Thomann, Ph.D., Technical Specialist
Robert D. Brient, Quality Assurance Auditor

Individuals Interviewed

E. Pearcy
D. Turner
P. Bertetti
M. Nugent

Documents Reviewed

1) Programmatic Review of Paper: *Modeling Colloid Transport for Performance Assessment*, by J.S. Contardi, D.R. Turner, and T.M. Ahn, presented at Migration >99 Conference, Lake Tahoe, California, Budhi Sagar letter to Mrs. Deborah A. DeMarco dated August 12, 1999.

2) Programmatic Review of Paper: *Uranium^{VI} Sorption Behavior on Silicate Mineral Mixtures*, by James D. Prikryl, Alka Jain, David R. Turner, and Roberto T. Pabalan, presented at Migration >99 Conference, Lake Tahoe, California, Budhi Sagar letter to Mrs. Deborah A. DeMarco dated August 12, 1999.

3) IM 01402.871.000 *Technicium-99 Chemistry in Reducing Groundwaters: Implications for the Performance of a Proposed High-level Nuclear Waste Repository at Yucca Mountain, Nevada*, by Roberto T. Pabalan, David R. Turner, and Michael P. Miklas, Jr., planned submission for publication in proceedings volume for the Materials Research Society Symposium on the Scientific Basis for Nuclear Waste Management XXIII. E.C. Pearcy letter to J. Bradbury dated December 13, 1999.

4) IM 01402.871.040 *An Archeological Site at Akrotiri, Greece, as a Natural analog for Radionuclide Transport: Implications for Validity of Performance Assessments*, by D.L. Hughson, L. Browning, W.M. Murphy, and R.T. Green, planned submission for publication in proceedings volume for the Materials Research Society Symposium on the Scientific Basis for Nuclear Waste Management XXIII. E.C. Pearcy letter to J. Bradbury dated January 21, 2000.

5) IM 01402.871.010 *Effect of Heterogeneity on Radionuclide Retardation in the Alluvial Aquifer near Yucca Mountain, Nevada* by S. Painter, V. Cvetkovic, and D.R. Turner, planned submission for publication in Ground Water. E.C. Pearcy letter to J. Bradbury dated February 28, 2000.

6) MM 0 1402.871.020 *Input to RT IRSR, Revision 2 - Letter Report*, June 20, 2000

7) IM 01402.871.000 *Thermodynamic Modeling of the Adsorption of Radionuclides on Selected Minerals. I: Cations*, by Peiming Wang, Andrzej Anderko, and David R. Turner, planned submission to Geochimica et Cosmochimica Acta, no date on paper.

8) IM 01402.871.000 *Thermodynamic Modeling of the Adsorption of Radionuclides on Selected Minerals. II: Anions*, by Peiming Wang, Andrzej Anderko, and David R. Turner, planned submission to Geochimica et Cosmochimica Acta, no date on paper.

Documents reviewed included one major milestone, three intermediate milestones, and four research papers on geochemistry and geochemical modeling. Scientific notebooks were also examined and these included two active (original), two closed (photocopies), one active (original) laboratory, and two closed (photocopies) laboratory notebooks.

A brief tour of the lab facilities in building 57 was conducted so that auditors could examine the analytical equipment and storage areas for well cuttings and well water samples collected from Nye County, Nevada. There were no on-going laboratory experiments to examine at the time of the audit but past laboratory activities included Neptunium sorption and co-precipitation experiments. One of these activities included preparation of various concentrations of Neptunium which were placed in saturated solutions of calcite to determine the extent of uptake of Neptunium in the mineral calcite and in the solution. Selected well water samples from Nye county, Nevada were analyzed in-house through Division 01 and by outside commercial laboratories (Geochron and Coastal Science Labs) for inter-element comparison of deuterium and oxygen isotopes. The audit team examined the storage locations of the Nye County water samples and well cuttings, both of which were kept in separate rooms. The six boxes of well cuttings contain rock chips in sealed plastic bags identified with SMF specimen custody receipts. The acidified well water samples are stored in a refrigerator in standard plastic bottles and these appear to be properly labeled.

Examination of the scientific notebooks reveals various minor to major deficiencies based upon the requirements described in QAP 001, "Scientific Notebook Control" (See CAR 2000-02). These include such items as missing entries of dates and/or initials of researcher, incomplete labeling of computer storage disks, incomplete descriptions of results (or meaning of) computer model runs, incomplete descriptions of computer analyses using the TPA V3.2 code that would allow another scientist to duplicate the computer run, incomplete information or poorly photocopied, closed scientific notebooks that have missing page numbers and dates for text and figures, cut-offs of portions of the text along edges of some photocopied pages, and the separation of long charts and maps into two or more unnumbered pages. The following outline consists of brief descriptions of minor

and/or major deficiencies for individual notebooks, and indicate instances in which the nature of various entries that could not be determined in the course of the audit.

Open Notebooks

CNWRA Controlled Copy 374

1. Needs an initial entry at the beginning of the notebook.
2. The description of the use of the TPA code (V3.2) is not sufficient for another researcher to reproduce the results of the computer run.
3. There are many pages of output from the run with no summary of results or conclusions of run.
4. It was not clear if entries on each page of output were the dates of the run or the dates when the output was placed in the notebook.
5. The initial date when the notebook was first issued is 10/29/99 but the computer run for sensitivity analysis is listed for 6/15/2000. There was an apparent eight month break between these two entries.
6. The CD-R has a date of 3/27/2000 on page 2 of the notebook but it was not clear if this was the date TPA files were copied onto this disk.
7. The CD-R is stored in a back pocket of the notebook but has no label with identification of its contents; the CD-R though is described in the text on pages 1 and 2 of the notebook.

CNWRA Controlled Copy 394 (originally 241) - initial date entry 6/12/2000 and last dated entry on 6/16/2000; 75 pages

1. Needs an initial entry at the beginning of the notebook
2. The ZIP disk in the back pocket of the notebook needs to be labeled with the number of the Controlled Copy 394.

CNWRA Controlled Copy 309 - laboratory notebook with initial entry of 3/18/99 and last dated entry on 6/16/2000

Scientific Notebook 309 appears to be in order although time constraints prevented the Technical Specialist from performing a detailed examination of the notebook contents. The notebook included a description of the preparation of calcite for use in Neptunium sorption experiments, and preparation of U^{232} for uranophane synthesis.

Closed Notebooks

CNWRA Controlled Copy 252 - dated from 1/3/98 to 3/3/2000; pages 1 to 228; David Turner; first entry noted; some figures and pages are not numbered (e.g., pp. 72-76)

CNWRA Controlled Copy 258 - dated from 2/4/98 to ? (no last entry date found); David Turner and Christian Null; some page numbers are missing and selected portions of the text have been cut off due to improper photocopying; no dates after page 14 are given in Appendix B - Southern Route

CNWRA Controlled Copy 365 - no name in the copy

CNWRA Controlled Copy 266 - dated from 4/21/98 to 8/5/99; David Turner, Alka Jain, James Prikryl - notebook appears in order

Despite the various shortcomings in the notebooks, all of the major and intermediate milestones for the current KTI have been successfully met and fulfill the on-going tasks described in the QRAM for RT. The personnel working on the RT program have demonstrated the highest degree of competency and professionalism in carrying out their assigned tasks from basic research to final report writing. All of the personnel are certainly highly qualified to perform the theoretical, computational, field, and laboratory work of this KTI, and all interviewed personnel conducted themselves in a professional manner by providing clear and concise answers to technical questions related to office, field, and laboratory activities, and by providing the scientific notebooks and other documents to the audit team.

The technical and QA programmatic assessments of quality planning, procurement, scientific notebooks, sample control, and the review process were conducted simultaneously. QRAMs appeared to reflect actual activities being conducted, however, are only applied at the overall KTI (rather than at the task) level. Lab staff indicated a thorough understanding of requirements; calibration of pH meters before use was well documented, solutions were properly identified, and samples were properly identified. Work product technical review comments were properly resolved and documented. Several analyses were performed by outside suppliers and other SwRI divisions. Since these were performed only for comparative information, no supplier controls were necessary.

Recommendations

It is recommended that closed copies of the scientific notebooks be carefully copied to contain all original information in proper sequence along with proper labeling of oversized charts, tables, figures, and maps. A researcher who has followed all of the requirements of QAP-001 has spent a lot of time and effort in maintaining the notebook and there should be no less than a faithful reproduction of its entire contents. If possible, make legal or ledger size photocopies of the oversized charts, tables, etc. that can be folded into the photocopied 8 ½" x 11" notebook. Computer storage disks such as ZIP disks and CD-R media should have attached labels with information about the controlled notebook number, type and version of computer code on disk (or location of where the code is stored if the code is too big to be

stored on disk), computer platform such as UNIX, LINUX, DOS, and major file types with page references that a researcher can look up in the notebook. The results of computer runs should be placed on disk instead of pasting many pages of calculated outcomes and other data that simply fill up space in the notebook. The size of the type is in some cases so small (perhaps due to photo-reducing to fit copies of data runs in a notebook) that it makes it difficult to read the data. Thus, storage of raw data and results from computer runs onto a ZIP disk, JAZ disk, or CD-R media would provide a much better way to maintain a record of all computer work.

Provide an explicit readable summary of the results from a computer calculation, computer simulation, lab experiment, field mapping, literature search, or theoretical/mathematical analysis of a geochemical system upon completion of a particular work or effort. If possible, verify part of a computer run by hand calculation, show the data and data source, equation or formula, and sources of error, and then compare the hand-calculated result with the computer-generated result. Write this information on the same page (or consecutive pages) in the notebook so the reader does not have to keeping searching for pertinent information which may be scattered throughout the notebook

Practically all of the issues discussed in this report can be corrected through better bookkeeping by adhering to the structural and organizational procedures described in QAP-001, "Scientific Notebook Control." This will allow each researcher to provide a readable, organized document that another researcher can examine and study for purpose, scope, important meaning of results, and implications for future studies.

E. Yucca Mountain Review Plan
Rodney M. Weber, Technical Specialist and Quality Assurance Auditor

Individuals Interviewed:

P. Mackin
D. Turner

Documents Reviewed:

Yucca Mountain Review Plan, Revision 0.

A discussion of the Development of the Yucca Mountain Review Plan (YMRP) was conducted with Project Manager Pat Mackin and Principal Investigator David Turner. Because the activity involved the assembly of a large number of technical inputs from inside and outside sources, a complex collaborative effort was required between the CNWRA and the NRC. Using a checklist based project management

principles and approach, the auditor conducted inquiries on the CNWRA's understanding of purpose, and its approach, management, scheduling, and communications related to this document's development. All are areas important to the successful completion of a project involving integration of inputs from multiple sources.

A review was conducted on the items delivered to date. Revision 0 of the YMRP, comprised of three deliverables (intermediate milestones), was discussed. The three sections were 1. *Preclosure*, 2. *Postclosure*, and 3. *Administrative and Other Sections*. The process was found to be highly complex and therefore dependent upon effective communication between CNWRA and NRC staff. Through weekly project meetings, daily electronic and telephonic communications, project personnel of both organizations managed the assembly of the three deliverables, all within the agreed upon schedules. A review of the files for evidence of acceptance found two deliverables having been accepted by the NRC. The third milestone was delivered on time in May, but the acceptance letter had not yet been received. There was no evidence that there are outstanding issues that would prevent acceptance. In addition, the individual inputs for all sections were sampled. Records of document reviews (QAP-002 requirements) were sampled for individual elements of six sections. All were found to be compliant to the review requirements.

In addition to the interviews conducted above, the auditor requested and was extended an invitation to the High Level Waste Management Board Meeting held telephonically between CNWRA management and NRC management. The auditor monitored discussions related to the YMRP. The meeting was conducted using a written agenda, action items were discussed, and responsibilities assigned. Using an outline prepared by Mr. Mackin, the board discussed issues related specifically to the YMRP SRM (staff requirements memorandum). Again, as a result of the discussions, recommendations were made and actions assigned.

Based on the interview process and review of records associated with this key technical area, this auditor finds that the project is being managed effectively and the required programmatic elements are satisfactorily implemented.

Recommendation: Because there are no formal meeting minutes issued as a result of weekly project meetings, a means to document and track significant action items, which occur as a result of weekly meetings and daily communications, should be considered.

F. COMPUTER CODES TPA, V4.0 AND MULTIFLO, V1.2

Steven W. Dellenback, Ph.D., Technical Specialist
Gerald T. Cogar, Software Quality Assurance Auditor

Personnel Interviewed:

S. Mohanty
G. Wittmeyer
R. Janetzke
S. Painter
B. Mabrito
R. Folck

Documents Reviewed:

TPA, V4.0
MULTIFLO, V1.2

TPA

Requirements for TPA were documented in a Software Requirements Description (SRD). Changes were documented in Software Change Reports. It was thought by the auditors that the tracking of requirements from the SRD through SCRs was difficult. They recommend that all requirements in the SRD be numbered and the number be used to track software changes in the source code, test documents, and scientific notebooks. The numbers would be present in the revision block in the header of each source file and the number would appear in the source code where modifications have occurred.

The SRD for TPA was reviewed in accordance with procedure QAP-002. A Software Development Plan (SDP) was piloted in the development of V4.0 of TPA. The use of an SDP is an enhancement in the planning process for software and can provide benefits. It was recommended by the auditors that TOP-018 be revised to provide a more useable/workable document. In addition, once an SDP is generated, periodic internal reviews should be held to assess compliance and utility of the SDP.

Development of TPA V4.0 software was documented in scientific notebooks and electronic files included in the development environment. The electronic files were archived with the release of the code. It was noted that as many as 20 developers had worked on TPA in the past, 12 in the recent past. The development activities are documented by each developer in their own scientific notebook, all of which have the same number. As a result, reconstruction of the code development activities would be difficult.

It was recommended that in cases in which multiple developers are working on code and using scientific notebooks as the principle means of documentation, a unique numbered scientific notebook be assigned to each developer. These could be breakouts of a root notebook (e.g., 170 for TPA, 170-1, 170-2, 170-n for developers 1, 2, to n). The notebook should clearly identify the portion of the code being worked on with a summary at the end describing activities covered by the notebook and a cross-reference maintained between the notebooks.

TPA V4.0 code from multiple developers is controlled and integrated by a single developer. Acceptance criteria for integration is undocumented and informally controlled; code is not accepted unless it will compile without warnings and error free. Code developed by the integrator is not independently reviewed. Source code reviews are not planned or documented. Verification testing is performed once code is integrated. Verification consists of domain experts (i.e., research scientists) exercising the code to verify computational features produce the desired result; thus assuming the code functions correctly. Verification testing was seen as a means of conducting code reviews since TOP-018 was not specific as to the requirement for 'source' code reviews.

It is recommended that TOP-018 be modified to require a source code review by someone other than the developer to assure that the software documentation requirements of TOP-018 are being implemented. This review will need to be performed by someone skilled in the implementation language and TOP-018. The QA review currently being performed is not detailed enough to verify TOP-018 compliance.

The Design Verification Review (DVR) report for TPA V4.0 indicated acceptance tests for the target platforms was conducted.

TPA V4.0 Acceptance Testing was governed by the project's SDP. Acceptance testing of changes was documented on SCRs. The project"s SDP indicated that overall TPA acceptance testing would be performed to ensure correctness of the screen output and the *.RES files. No evidence in scientific notebooks, quality records, or developer/EM interviews indicate acceptance test requirements were performed.

The DVR for TPA V4.0 indicated installation tests for the target platforms was conducted and results were consistent. The EM's signature on the DVR was used to determine results were reasonably expected.

TPA computer code uses an automated version control system for controlling versions of the code.

Software problems for Beta and released software are not tracked consistently. Software problems (versus requirements) for TPA code is documented on SCRs. Traceability of reported problems is not evident.

DVRs were completed for TPA software under configuration control.

Software Release Notices (SRNs) were part of quality records for TPA computer codes.

A Software Validation Test Plan (SVTP) for TPA V4.0 has not been developed.

MULTIFLO

The SRDs for MULTIFLO were reviewed in accordance with procedure QAP-002 and complied with the requirements of TOP-018. The SRD was used in lieu of an SDP for MULTIFLO.

Software development activities for MULTIFLO was documented in scientific notebooks and electronic files included in the development environment. These electronic files were also archived with the release of code. A single developer develops MULTIFLO code with the assistance of a subcontracted technical consultant. Development related to MULTIFLO code is documented in a single scientific notebook. The method used to verify correct operation of the code is documented in the scientific notebook relevant to the specialized area being verified (i.e., KTI specific).

MULTIFLO code was informally reviewed when received from the subcontracted consultant. Documentation of the reviews was inconsistent. The SwRI developer/integrator's code was not independently reviewed. Benchmark and regression testing was performed. Correct results assume the computational code is correct.

It was noted by the auditors much of the source code in both TPA and MULTIFLO has been developed over a number of years by a variety of scientists. The style and structure widely varies. This greatly complicates the software maintenance efforts. It is recommended that the CNWRA establish a set of guidelines as to how future code changes will occur. While much of the existing code is not compliant, to the current version of TOP-018, it is recommended that any time a change/addition is made to a file in the future the contents of the file be brought up to TOP-018 compliance. This is not a recommendation to retrofit all of the source code, rather, it is a recommendation to update code as it is "opened" for modification with the goal of having all of the code "cleaned up" within the next five years. It is also recommended that the scientists implementing software utilize some of the software coding techniques prevalent in the industry to make the source code more readable and

maintainable (e.g. do not leave in comment out sections of source code w/o significant explanations, utilize variables to establish "debug levels" so that debug code is not routinely commented out in production versions). In support of this recommendation, TOP-018 (Section 5.5.2) should be modified to replace the word "should" with "shall." Having guidelines which are "optional" does not fit with the overall goal of TOP-018.

MULTIFLO testing began in 1998 and continued until release of the code in March 2000. The approach to testing was based on benchmarking existing code against known results. These benchmarking activities were documented over the 1998-2000 timeframe and covered many scientific notebooks . Although cross references between and entries within them were evident, the traceability of testing activities was difficult, cumbersome, and time consuming to follow. A single benchmark test for overall MULTIFLO acceptability was developed and its successful execution witnessed by QA prior to the release of MULTIFLO V1.2. No record in the notebooks or quality records could be found as to witnessing and success/failure of the benchmark test. See NCR 2000-10.

The DVR for MULTIFLO indicated installation tests for the target platforms was conducted and results were consistent. The EM's signature on the DVR was used to determine results were reasonably expected.

It was recommended by the auditors that the CNWRA adapt TOP-018 to include the configuration management and change control processes/procedures in NUREG/BR-0167 or ISO/IEC 12207, Sec 6.0, or ASME NQA-1a-1994, Sec 5. To facilitate and standardize configuration management and control of source code it is recommended that TOP-018 adopt and require the use of a formal source code control system.

The basis for software engineering and development is the software development life cycle. A definitive life cycle provides the frame of reference, adds structure to software engineering and development, provides the checkpoints to verify development of quality software. The life cycle makes software engineering and development engineering traceable, provides a framework for planning, and a means of controlling development activities. TOP-018 does not embrace the idea of a software life cycle. The concept of a software life cycle is an industry standard that has no domain boundaries, (i.e., applies to scientific, mechanical, chemical, electrical, nuclear). It is recommended that TOP-018 be modified to include CNWRA's concept of a software life cycle. That computer code development activities be planned, controlled, and traceable to this life cycle.

It was noted that while the CNWRA/IMS directorate maintains a list of acquired software, CNWRA QA is not notified when software is acquired so that a determination can be made whether the software should or should not be controlled by the CNWRA Quality System. If the QRAM were updated when the decision to

use new, acquired software was made, QA would be alerted during QRAM review and approval but QRAMs are not consistently updated as tasks progress.

A random inspection of software under configuration control revealed that the Software Summary Form (SSF) was being completed. TOP-018, paragraph 5.7.2 requires a technical description for each software item placed under configuration control. It gives the developer several options for documenting the technical description. However, the SSF does not require identification of which option was chosen. It is recommended that an item be added to the SSF that identifies where the developer documented the software technical description.

DVRs were completed for MULTIFLO software under configuration control. The DVR provides a checklist of relevant compliance items required by TOP-018. No objective evidence was provided or referenced to support the decision process for the answers chosen. Questions with "Yes" answers checked should provide references to surveillance reports, QA inspection results, and/or scientific notebooks (e.g., volume, page, owner, date), as supporting evidence.

SRNs were part of quality records for MULTIFLO computer codes. TOP-018, 5.9.2 (Software Release) requests the software developer to report, with the new SRN, any expected deviations from past verification and benchmark data. The SRN does not have provisions for documenting these deviations. It is recommended that an item be added to the SRN that identifies where the developer will identify deviations or to state that no deviations was expected.

Periodic inspection of QA records and released software maintained on a server should be performed to validate the version controlled is the released version.

TOP-018 requires 'Installation Test Documentation' be made a permanent part of QA records but does not require 'Installation Test Documentation' to be written. It is recommended that CNWRA amend TOP-018 to require an installation manual, version description document, and validation test results. The installation manual and version description document can be combined into a single electronic document and included on the CD or floppy as a "Readme" file or individual text/word processor document referenced by the DVR. The installation instructions should be a step by step procedure that explains to the user how to install the software even if that software is maintained on a local CNWRA server. The version description document identifies various files comprising a software release, file dependencies, known errors/problems, and operating system/hardware requirements for execution of the software. Test procedures, input, and output files, and expected results can also be identified in the version description document. Enough test detail should be included such that anyone needing to verify the integrity of the delivered software can duplicate the test and test results and validate that the software is performing as expected. Electronic documentation like the version description document and software validation procedure should be

delivered with the software and/or maintained on the network server providing the software.

Several scientific notebooks were reviewed during the software portion of the CNWRA audit. It was noted from several of the notebooks that the time, (e.g., days and weeks), needed to run computer code models was lengthy. In some cases after lengthy runs, no results or wrong results were observed. In another case it was reported that system acceptance testing for TPA code could not be performed because of the dynamic dimensions/complexity and execution time required to completely test the code. The complexity of the licensing process and the dependence on computer codes to generate timely and accurate modeling results would seem to indicate that performance enhancements of computer code (specifically TPA and Multiflo) and upgrades to computing platforms and operating systems may be needed. It is recommended that CNWRA perform an assessment of overall computing code (i.e., Multiflo and TPA, and others that may not have been reviewed during the audit) performance and determine if enhancements to computer code performance and/or upgrades to computer platforms and operating systems are needed.

G. Site Decommissioning Management Plan
Randall D. Manteufel, Ph.D., P.E., Technical Specialist
Donald W. Dunavant, Quality Assurance Auditor

Individuals Interviewed:

P. LaPlante (by phone)
J. Weldy
J. Russell (by phone)

Documents Reviewed:

1) Deliverable 20.08801.002.008: "Input to a Request for Additional Information Based on Reviews of the U.S. Army Decommissioning Plan and Risk Assessment Reports for the Jefferson Proving Ground Site" under Task Order 2

2) Deliverables: 20-8801-006-001: "Adequacy of Methods and Schedules for Decontamination and Dismantlement: Molycorp, Inc. (York); 20-8801-006-003: "Radiation Survey Plan Review Report: Molycorp—York;" and 20-8801-006-005: "ALARA Review Report: Molycorp—York" under Task Order 6

3) "Technical Assistance for Reviewing Licensee Submittals Concerning Decommissioning" under Task Order 7, where the draft NUREG entitled "Re-evaluation of the Indoor Resuspension Factor for the Screening Analysis of the Building Occupancy Scenario for NRC's License Termination Rule" and comments by Duane Schmidt (NRC) were reviewed

Both P. LaPlante and J. Weldy stated that the work conducted in the SDMP area did not require the use of scientific notebooks (QAP-001), or scientific and engineering calculations (QAP-014). This was found to be appropriate because the activities consisted of reviewing and commenting on reports provided to CNWRA. No consultants or subcontractors were used in the SDMP area. It was found that the CNWRA deliverables transmitted to the NRC were reviewed according to QAP-002. However, one deliverable (20.08801.006) lacked editorial review and it was not clear how the determination of need for reviews is established.

Work in each of the three task order areas were reviewed as follows:

Task Order 2:

The CNWRA deliverable under Task Order 2 provided input to a request for additional information from the U.S. Army for decommissioning the Jefferson Proving Ground site. The report was prepared by P. LaPlante and J. Russell and consists of 15 comments on the decommissioning plan and 14 comments on the risk assessment report (both Los Alamos reports). The report states that NRC staff technical comments have been edited and combine with CNWRA comments in the deliverable. Although this is efficient, it is unclear who did what.

Only two CNWRA technical staff performed this review, and provided expertise in the areas of performance assessment and radiological health. The review could have benefited from additional staff with expertise in hydrology and geochemistry, because the most significant recommendation of the report was for additional groundwater radiological monitoring. Because this was a joint effort, the NRC staff may have provided additional expertise in hydrology and geochemistry. However, this is unclear from the report.

It is suggested that the concentration of U-234 in depleted uranium (DU) be reevaluated. The author explained that trace amounts of U-235, Tc, and Pu (due to processing techniques) might be important in radiological risk assessment. It appears that U-234 may also be of concern. It appears that the Los Alamos risk assessment report included U-234 and Th-230 in the RESRAD calculations as well as U-238D with daughters.

It is suggested that CNWRA staff clarify the rationale that supports NRC guidelines, when necessary. In the report, it is stated that the "more conservative of the 5^{th} and 90^{th} percentile...." This appears as a typographical error. One would expect a symmetric use of percentiles, such as 10^{th} and 90^{th} or 5^{th} and 95^{th} percentiles. When asked if this was a typographical error, it was stated that "no, those percentages were taken from NRC guidelines." When asked to explain the rationale behind the guidelines, it was stated that the guidelines had not been questioned and no explanation was available.

Task Order 6:

The CNWRA deliverable under Task Order 6 was combined into a single NRC report, and a copy of this report was sent to NRC on July 7, 1999. The contribution of CNRWA staff was found to be unclear. The transmittal letter from J. Russell states that "We are the primary authors of the report" yet the report does not mention or describe CNWRA participation. The summary and conclusions section of the report states "This EA was prepared by the NRC staff..." The text of the deliverable only acknowledges NRC staff contributions.

In the recommended license condition section of the report, additional groundwater radiological monitoring is suggested for a number of nuclides. However, Th-230 is not listed. On page 13 of the report, Th-230 is cited as having slightly elevated levels in the groundwater, hence the omission of Th-230 appears to be an oversight. The author provided a reasonable explanation that Th-230 is a daughter of U-234 and produces Ra-226 (both were recommended for monitoring) and that Th-230 will be included in gross alpha measurements (also recommended).

Task Order 7:

Under Task Order 7, a balanced and comprehensive team of CNWRA experts was organized. This team included experts in radiological health, nuclear engineering, applied statistics, and performance assessment. The CNWRA team performed a thorough review of the draft NUREG and associated documents. A literature search was conducted, and additional literature was identified as being relevant and the impact of the literature was clearly summarized. The report was well written, although some comments assumed the reader has a thorough understanding of the draft NUREG. For example, on page 3-5 of the report the statement that "the first ANOVA test should have 12 and 234 degrees of freedom, not 18 and 12" is not fully justified.

It was found that the CNWRA staff adhered to CNWRA QA procedures under stringent deadlines. The CNWRA received a request for proposal on March 14, 2000 and provided a final letter report on April 17, 2000. In the interim, a cost proposal was sent to NRC, the QRAM was completed, the technical report was prepared, and both technical and programmatic reviews were performed according to QAP-002. The CNWRA staff are to be commended for producing a quality document within the sponsors' time constraints.

H. Activities Related to Development of the NRC High-Level Waste Regulations

John P. Hageman, C. H. P., Technical Specialist
Rodney M. Weber, Quality Assurance Auditor

Individuals Interviewed:

G. Wittmeyer
P. LaPlante
M. Smith

Documents Reviewed:

(1) Intermediate Milestone Report "Information and Analyses to Support the NRC on Proposed 10 CFR Part 63, Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, NV" (IM 01402.771.030);

(2) Intermediate Milestone Report, "Improvements to Approach for Modeling Dose (IM 01402.771.040); and

(3) Intermediate Milestone Report, "Comments on the Proposed EPA Standard 40 CFR Part 197, Environmental Radiation Protection Standards for Yucca Mountain, NV" (IM 01402.771.905).

The CNWRA staff interviewed fully demonstrated the necessary technical expertise required to prepare or review the three referenced reports. There were no major findings related to these reports, however there were a few specific observations.

The degree of technical review for properly providing adequate citations and references were inconsistent among the three reports, as noted by the differences required by CNWRA Form QAP-12-4, when used, and by the absence of several references for IM 01402.771.905.

Supporting data from code calculations for IM 01402.771.030 did not appear to be available at the time of this audit, which may have been inconsistent with CNWRA procedures.

The rationale was not stated or obvious for some of the technical decisions presented in these reports. For example in IM 01402.771.030, in some cases the "highest" value for a variable was chosen, while in other cases an "average" value was chosen, without adequate explanation; also, the grouping of the age sets by a method not used in the cited material was not explained in the report. The age group "embryo/fetus" was not included, even though it could receive the same dose

as an adult, while no explanation is given as to why this age group was excluded. Also, the rationale was not stated for several comments in IM 01402.771.905, just one example is given in Comment 3 of page 2 of the report.

There appears to be a lack of verification by the technical and programmatic reviewers to assure that those comments "accepted" by the author were indeed incorporated into the final report. One example is where the author agreed to change "farmer" to "farmers" and this change was not made throughout IM 01402.771.030. Other agreed to changes may not have been made; however, this is difficult to discern since the marked-up draft copies are not available.

Typographical errors appeared in the final report, IM 01402.771.030, which caused confusion. For example, errors related to the incorrect mixing of "inhalation" and "consumption" and "breathing rate" and "consumption" of radionuclides (used for dose calculations) on page 2-2 (paragraph 3, line 8) and page 2-4 (paragraph 1, line 10) of the report.

RECOMMENDATIONS

During the course of the audit, the audit team made a number of recommendations that they felt would either prevent a future noncompliance or provide an opportunity for improvement of the process. While these suggestions are contained in each area individually, they are reported here as a group for ease of assimilaton and better perspective. These suggestions are presented for CNWRA consideration and no response is required.

- A welding expert should be involved in the procurement of welded samples.

- Instrument calibrations listed in scientific notebooks should list the date of the calibration, not just the date of entry into the notebook.

- For projects such as the Yucca Mountain Review Plan in which much of the direction and guidance results from weekly project meetings and daily communications, a means to document and track significant action items should be considered.

- For sources cited in scientific notebooks, a complete reference should be provided, not just a year of publication and author.

- Quality planning and QRAM generation at the Key Technical Issue (KTI) level may be too general to adequately address all quality and procedural requirements. Better planning might result if QRAMs were generated on a Task Order level.

- Conversations discussing important issues related to a subject matter should be documented for future reference.

- The readability, and therefore usefulness, of scientific notebooks could be enhanced by taking such precautions as:

  - copying oversized charts or tables fullsize and folding them rather than using reduced copies in which edges are lost or the print is unreadable
  - carefully labelling computer disks with information as to the scientific notebook number, type and version of code contained (or reference to location if code is too large to store on disk), computer platform and major file types with page references
  - using computer disks when possible instead of pasting many pages of output and data into the notebook.

- Provide an explicit, readable summary of the results from a computer calculation, simulation, experiment, field mapping, literature search, or theoretical/mathematical analysis upon completion of the work.

- The CNWRA should identify controls in procedures to assure that the current and complete NRC guidance, especially for the Issue Resolution Status Reports and for the Yucca Mountain Review plan, is available to affected staff, and that obsolete guidance is removed or identified as such.

- CLST metallic samples are tracked in the Sample Custody Log only at the level of the heat. Individual specimens or groups of similar specimens cut from the original heat are not documented in the Sample Custody Log, rather they are documented in Scientific Notebooks *when tested* (not when the specimen is prepared). Other KTIs apply the Sample Custody Log to all levels of sample/subsample. Clarification should be provided when the Sample Custody Log must be used.

- CLST potentiostats should be labeled to indicate the status of the performance verification (e.g., calibration) that is currently valid for 6 months.

- CNWRA work products should be explicitly traceable to the supporting documentation QA records (e.g., scientific notebooks). Currently, most work products are traceable at the level of the cost accounting phase number that typically involve a large number of individual activities. Identification of the specific supporting documentation for a work product

is not readily accomplished without recourse to the author and contributing staff.

- Surveillance should be scheduled to determine whether corrective action has been effective. The surveillance should be planned around three months after the CAR close-out date to allow sufficient time for complete implementation.

Code development in general, and TOP-018 in particular, have been the subject of continual review. Both as a result of previous audits and the efforts of CNWRA staff, significant improvements have been made in the code development process and no deficiencies in the code audited this year were observed. In the spirit of continuous process improvement, and recognizing the increasing dependency on computer codes and their sophistication, the following suggestions are offered for consideration.

- Tracking requirements [from either the Software Requirements Description (SRD) or SCRs] is difficult. It is recommended that all requirements identified in the SRD be numbered (SCR is already numbered). This numbering should be used to track the software change in the source code, test documents, and the scientific notebooks. The number should be present in the revision block in the header of each source file and the number should appear in the source code when the software modification occurred.

- While the specific requirements of TOP-018 [with respect to Software Development Plans (SDPs)] were achieved, it was observed that the SDPs were thought by some of the staff to be of little value to the software implementers. It is recommended that the discussion of SDPs in TOP-018 be revised to provide a more workable/usable document. Inherent with this recommendation is that once an SDP is developed and approved, a project should hold periodic internal reviews to assess how compliance to the SDP is being met.

- In cases where multiple developers are working on computer code and the scientific notebook is the principal means of documenting the progress of code development, the EM should assign a unique notebook number to each developer. The unique number could be a breakout (e.g., 170 for TPA, 170-1, 170-2, 170-n for developers 1, 2, to n). The notebook should clearly identify the portion of the code being worked on. A summary of activities covered by the notebook should be at the end. Clear, concise, and accurate cross-references between notebooks should be made.

- TOP-018 should be modified to require a source code review (by someone other than the developer) to assure that the software documentation requirement of TOP-018 are being implemented. This review will need to be performed by someone skilled in the implementation language and TOP-018. The QA review currently being performed is not detailed enough to verify TOP-018 compliance.

- Much of the source code in both TPA and MULTIFLO has been developed over a number of years by a variety of scientists. One of the shortcomings of the existing code is that the style and structure widely varies. This greatly complicates the software maintenance efforts. It is recommended that the CNWRA establish a set of guidelines as to how future code changes will occur. Because much of the existing code is not TOP-018 compliant, it is recommended that *any* time a change/addition is made to a file in the future the contents of the file be brought up to compliance with the most current revision of TOP-018. This is *not* a recommendation to retrofit all of the source code, rather, it is a recommendation to update code as it is "opened" for modification with the goal of having all of the code "cleaned up" within the next five years. It is also recommended that the scientists implementing software utilize some of the software coding techniques prevalent in the industry to make the source code more readable and maintainable (e.g., do not leave in comment-out sections of source code without significant explanations, utilize variables to establish "debug levels" so that debug code is not routinely commented out in production versions).

- TOP-018 (section 5.5.2) should be modified to replace the word "should" with "shall." Having guidelines that are "optional" does not fit with the overall goal of TOP-018.

- Adapt TOP-018 to include the configuration management and change control processes/procedures in NUREG/BR-0167 or ISO/IEC 12207, Section 6.0, or ASME NQA-1a-1994, Section 5. To facilitate and standardize configuration management and control of source code, it is recommended that TOP-018 adopt and require the use of a formal source code control system.

- The basis for software engineering and development is the software development life cycle. A definitive life cycle provides the frame of reference, adds structure to software engineering and development, provides the checkpoints to verify development of quality software. The life cycle makes software engineering and development engineering traceable, provides a framework for planning, and a means of controlling development activities. TOP-018 does not embrace the idea of a software life cycle. The concept of a software life cycle is an industry

standard that has no domain boundaries, (i.e., applies to scientific, mechanical, chemical, electrical, nuclear). It is recommended that TOP-018 be modified to include CNWRA's concept of a software life cycle and that computer code development activities be planned, controlled, and traceable to this life cycle.

- TOP-018, paragraph 5.7.2, requires a technical description for each software item placed under configuration control. It gives the developer several options for documenting the technical description. However, the Software Summary Form (SSF) does not require identification of which option was chosen. Recommend adding an item to the SSF that identifies where the developer documented the software technical description.

- The Design Verification Report (DVR) provides a checklist of relevant compliance items required by TOP-018. No objective evidence was provided or referenced to support the decision process for the answers chosen. Questions with "Yes" answers checked should provide references to surveillance reports, QA inspection results, and/or scientific notebooks (e.g., volume, page, owner, date), as supporting evidence.

- TOP-018, paragraph 5.9.2, (Software Release) requests the software developer to report, with the new Software Release Notice (SRN), any expected deviations from past verification and benchmark data. The SRN does not have provisions for documenting these deviations. Recommend adding an item to the SRN that identifies where the developer will identify deviations or to state that no deviations is expected.

- CNWRA should require, by amending TOP-018 and requiring as part of quality records, an installation manual, version description document, and validation test results. The installation manual and version description document can be combined into a single electronic document and included on the CD or floppy as a "readme" file or individual test/word processor document referenced by the DVR. The installation instructions should be a step-by-step procedure that explains to the user how to install the software, even if that software is maintained on a local CNWRA server. The version description document identifies various files comprising a software release, file dependencies, known errors/problems, and operating system/hardware requirements for execution of the software. Test procedures, input, and output files, and expected results can also be identified in the version description document. Enough test detail should be included such that anyone needing to verify the integrity of the delivered software can duplicate the test and test results and validate that the software is performing as

expected. Electronic documentation, like the version description document and software validation procedure, should be delivered with the software and/or maintained on the network server providing the software.

- Several scientific notebooks were reviewed during the software portion of the CNWRA audit. It was noted from several of the notebooks that the time (e.g., days and weeks), needed to run computer code models was lengthy. In some cases, after lengthy runs, no results or wrong results were observed. In another case, it was reported that System Acceptance Testing for TPA code could not be performed because of the dynamic dimensions/complexity and execution time required to completely test the code. The complexity of the licensing process and the dependence on computer codes to generate timely and accurate modeling results would seem to indicate that performance enhancements of computer code (specifically TPA and MULTIFLO) and upgrades to computing platforms and operating systems may be needed. It is recommended that CNWRA perform an assessment of overall computing code (e.g., MULTIFLO and TPA, others that may not have been reviewed during the audit) performance and determine if enhancements to computer code performance and/or upgrades to computer platforms and operating systems are needed.

PERSONNEL CONTACTED

Personnel Contacted	Attended Pre-Audit Conference	Contacted During Audit	Attended Post-Audit Conference
V. Aaron		√	
T. Ahn	√		
R. Ard			√
P. Bertetti		√	√
R. Brient	√		√
S. Brossia		√	√
L. Browning		√	
L. Campbell			√ *
T. Carter	√		√
R. Cherrington			√
A. Chowdhury		√	√
G. Cogar	√		√
G. Cragnolino	√	√	√
S. Dannelly	√		√
D. Daruwalla			√
B. Dasgupta			√
S. Dellenback	√		√
D. DeMarco	√		√
D. Dunavant	√		
D. Dunn	√	√	√
M. Ehnstrom	√	√	√
R. Folck	√	√	√
A. Galloway		√	
H. Garcia	√		
L. Goland	√		√
C. Greene	√		
D. Gute		√	√
J. Hageman	√		
B. Hermann	√		
A. Holt	√		√
S. Hsuing	√	√	√
D. Hughson		√	

* by telephone

R. Janetzke		√	
T. Kessler		√	
P. LaPlante		√	
J. Linehan			√
B. Mabrito	√	√	√
P. Mackin	√	√	
P. Maldonado			√
R. Manteufel	√		√
S. Mayer			√
M. Miklas	√	√	√
O. Moghissi			√
S. Mohanty		√	√
M. Nugent		√	
G. Ofoegbu			√
R. Pabalan	√		
M. Padilla		√	√
R. Page	√		√
S. Painter		√	√
W. Patrick	√		√
E. Pearcy	√	√	√
J. Pearson	√		√
O. Pensado			√
J. Russell		√	√
B. Sagar	√	√	√
P. Seely		√	
J. Sievert		√	
D. Smith	√		√
M. Smith		√	√
N. Sridhar		√	√
K. Stablein			√ *
J. Stamatakos		√	√
W. Thomann	√		√
T. Trbovich	√		√
D. Turner	√	√	√
R. Weber	√		√
J. Weldy		√	
G. Wittmeyer	√	√	√
L. Yang			√

* by telephone

REVIEWED:

Richard A. Page, Ph.D. — July 20, 2000 (Date)

Lawrence Goland, P.E. — July 20, 2000 (Date)

Diane R. Smith, Ph.D. — 21 July 00 (Date)

Randall Manteufel, Ph.D. — 21 July 00 (Date)

Steven W. Dellenback, Ph.D. — 7/20/00 (Date)

William G. Thomann, Ph.D. — 21 July 00 (Date)

John P. Hageman, C.H.P. — 7-20-2000 (Date)

Gerald T. Cogar — 7.20.2000 (Date)

Rodney M. Weber — 21 July 00 (Date)

Robert D. Brient — 7/20/2000 (Date)

Sheila C. Dannelly — July 20, 2000 (Date)

APPROVED:

Donald W. Dunavant, Co-Audit Team Leader — Date: 21 July 00

Thomas C. Trbovich, Co-Audit Team Leader — Date: 7/21/00

Bruce Mabrito, Director — Date: 7/21/2000
Quality Assurance
Center for Nuclear Waste Regulatory Analyses

[s:\doc\audits\CNWRA-2000\00-1CNWRAFinalRpt.doc]

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-01 **Associated AR, SR, NCR No:** Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Not all requirements of NQA-1 [reference CQAM 2.3.1(2)] or the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions related to procurement controls have been addressed in procedure QAP-016 or are not being complied with. See attached.

Initiated by: D. W. Dunavant **Date:** 06/03/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

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:**

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Attachment to CNWRA CAR 2000-01

(Paraphrased) NQA-1, Supplement 4S-1, 2.3, requirement that procurement documents shall require that the supplier have a documented quality assurance evaluation prior to award.

NQA-1, Supplement 7S-1, 3.1, selection of suppliers shall be based on an evaluation prior to award.

Review Plan for HLW Repository QA Program Description, 4.1, requires procedures to assure applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents are prepared, reviewed, and approved to confirm that these requirements have been correctly carried out.

Review Plan for HLW Repository QA Program Description, 4.2, requires procurement documents to specify that suppliers are to provide an acceptable QA program commensurate with the scope, complexity, and safety of the activity.

Review Plan for HLW Repository QA Program Description, 4.3, requires that organizational responsibilities are described for...(5) review and concurrence of supplier QA program before initiation of activities affected by the program.

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-02 Associated AR, SR, NCR No: Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Contrary to the requirements of QAP-001, a number of scientific notebooks reviewed contained omissions or discrepancies such as lack of entry dates, crossout/initial of corrections, use of whiteout, pagination, or detailed description of work.

Initiated by: D. W. Dunavant DWD **Date** 06/30/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

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:**

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-03 Associated AR, SR, NCR No: Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

The QAP-014, 3.2 requirement that 10% of calculations be verified and the verification be documented in, referenced in, or attached to the review documentation has not been consistently complied with. The journal article (Q199911240001) for Container Life, Source Term did not receive a calculation check.

Initiated by: D. W. Dunavant DWD **Date** 06/30/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

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:**

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-04 Associated AR, SR, NCR No: Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY: Software Control

Not all requirements of TOP-018 are being complied with, such as: para 5.5.2, changes/modifications to MULTIFLO are not being updated to be compliant; para 5.5.5, the requirement for code review is not being determined by the Element Manager; para 5.6.2, acceptance testing for MULTIFLO/TPA has not been formally documented.

Initiated by: D.W. Dunavant DWD Date: 06/30/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

1) Extent of Condition: UPON FURTHER INTERVIEWS WITH EM & PI IT WAS AGREED THAT THE FIRST TWO DEFICIENCIES CITED WERE BEING COMPLIED WITH. THIS CAR IS RESCINDED AND THE THIRD ITEM IS BEING DOCUMENTED ON CNWRA NCR 2000-10.

2) Root Cause: DW Dunavant
Audit Team Leader
9/10/00

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:

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-05 **Associated AR, SR, NCR No:** Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

There is no evidence to document that consultants have been provided copies of applicable procedures to assure they are aware of their responsibilities and requirements. Also, the documentation of training of CNWRA staff does not indicate the objective or contents of the training or a review by management to determine the need for retraining, as described in the NRC Review Plan for HLW Repository QA Program Descriptions, 2.14 C and D.

Initiated by: Donald W. Dunavant **Date** 06/30/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

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:**

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-06 Associated AR, SR, NCR No: Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY: Corrective Action

Effective corrective action to prevent recurrence of adverse conditions has not been taken. Deficiencies noted during the 1999 audit (procurement, CAR 99-02; software, CAR 99-05) continue. Adverse trends identified during a January 2000 review related to software and scientific notebooks were not addressed in CARs, and similar deficiencies continue to be observed.

Initiated by: D.W. Dunavant DWD Date: 06/30/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

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:

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No: 2000-07 Associated AR, SR, NCR No: Audit 2000-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY: Quality Planning

There is no documentation that all QRAMs are evaluated for need for revision when Operations Plans are revised as required by QAP-013, 3.1.5. Of the ones for which the impact determination was made, not all three signatures required by QAP-013, 3.1.6 were available. Also see CAR 99-01 from the 1999 audit.

Initiated by: D.W. Dunavant DWD Date: 06/30/00

PART B: PROPOSED ACTION

Responsible Individual:
Response Due:

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:

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
NONCONFORMANCE REPORT

Project No. 20.01402.471 **NCR No.** 2000-07

PART 1: DESCRIPTION OF NONCONFORMANCE

The QRAM for Structural Deformation and Seismicity does not indicate that TOP-018 should be applied, although the task description indicates that scientific and engineering software will be used. Reference QAP-013, 3.1.2.

Initiated by: D.W. Dunavant **Date:** 6/30/00
Action Required by: Larry McKague

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

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:**

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B. Sagar, H. Garcia

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
NONCONFORMANCE REPORT

Project No. 20.01402.159 NCR No. 2000-08

PART 1: DESCRIPTION OF NONCONFORMANCE: Drawing Control

QAP-017 does not provide requirements to include qualitative or quantitative acceptance criteria on drawings as required by CQAM 5.3. The sequence of reviews is not always clear. Original drawings are maintained by QA rather than the PI or EM as required by the procedure.

Initiated by: D.W. Dunavant Date: 6/30/00
Action Required by: B. Mabrito

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

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:**

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
NONCONFORMANCE REPORT

Project No. 20.01402.571 NCR No. 2000-09

PART 1: DESCRIPTION OF NONCONFORMANCE: Quality Planning

The Quality Requirements Application Matrix for Container Life, Source Term did not invoke QAP-016, "Procurement," although corrosion test samples were being purchased.

Initiated by: D.W. Dunavant DWD **Date:** 6/30/00
Action Required by: N. Sridhar

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

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:**

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B. Sagar, H. Garcia

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
NONCONFORMANCE REPORT

Project No. 20.01402.562 **NCR No.** 2000-10

PART 1: DESCRIPTION OF NONCONFORMANCE

MULTIFLO acceptance testing (i.e., benchmark method) of V1.2 was performed as documented in multiple scientific notebooks over a period of approximately two years. Testing just prior to release was performed and witnessed by QA; however, no evidence (e.g., notes in scientific notebooks, annotations on Design Verification Report) was available to support successful test results or QA observations.

Initiated by: Donald W. Dunavant **Date:** 07/10/2000

Action Required by: Gordon Wittmeyer

PART 2: PROPOSED DISPOSITION AND CORRECTIVE ACTION

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:**

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