U. S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT OAR-00-02

OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION

AUDIT M&O-ARP-00-001

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM

MANAGEMENT AND OPERATING CONTRACTOR

Kenneth R Hooks 01/21/00
Ken Hooks
Uranium Recovery and Low-Level Waste Branch
Division of Waste Management

Charles A Greene 1/21/00
Charles Greene
High-Level Waste and Performance Assessment Branch
Division of Waste Management

T.C. Trbovich 1/19/00
Thomas Trbovich
Center for Nuclear Waste Regulatory Analyses

Darrell Dunn 1/19/00
Darrell Dunn
Center for Nuclear Waste Regulatory Analyses

Reviewed and Approved by:

King Stablein 02/02/00
N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste and Performance Assessment Branch
Division of Waste Management

Enclosure

1.0 INTRODUCTION

Staff and consultants of the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD), limited scope, performance based audit of the Waste Package Process Model Report (PMR) at the Management & Operating Contractor (M&O) facilities. The audit, M&O-ARP-00-001, was conducted on November 8-12, 1999, for work being performed at the facilities in Las Vegas, Nevada and involved the review of selected Analysis Model Reports (AMRs) prepared by the Lawrence Livermore National Laboratory (LLNL).

The objective of this audit by YMQAD was to evaluate the implementation of the OCRWM program requirements and the technical activities associated with development of the Waste Package AMRs.

The NRC staff objective was to gain confidence that the M&O and OQA are properly implementing the provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD) and the requirements contained in Subpart G, Quality Assurance, to Part 60, of Title 10 of the Code of Federal Regulations (10CFR Part 60). Because of the anticipated DOE submittal of the Site Recommendation (SR) in November 2000, the following observation activities were emphasized: (1) confirming that data, software, and models supporting SR are properly qualified; and (2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-001 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was qualified in their respective disciplines, and its assignments and checklist items were adequately described in the audit plan.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. However, the selected AMRs were still in the revision process and the associated software, data, and model packages had not been qualified, verified or validated, therefore no packages were reviewed by the audit team or NRC staff. One deficiency was identified during the audit. Thirty-four recommendations were offered by the audit team during the closing meeting as improvements or enhancements to the AMR development process and to the QA program procedures. The NRC staff agrees with the audit team's conclusion and recommendations. The NRC staff determined that this audit was effective, that the QA program implementation was adequate and the recommendations should prevent future discrepancies in the AMR/PMR development process.

3.0 AUDIT PARTICIPANTS

3.1 NRC

Thomas Trbovich	Observer (Team Leader- CNWRA)
Charles Greene	Observer (Technical Specialist)
Ken Hooks	Observer (QA Specialist - NRC Task Force Member)
Darrell Dunn	Observer (Technical Specialist - CNWRA)

3.2 DOE Audit Team

Emily Jensen	Audit Team Leader (ATL)	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Kristi Hodges	Auditor	OQA/QATSS
Victor Barish	Auditor	OQA/QATSS
Richard Powe	Auditor	OQA/QATSS
Robert Hartstern	Auditor	OQA/QATSS
Frank Wong	Technical Specialist	Management and Technical Services (MTS)
Robert Fish	Technical Specialist	MTS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "*Performance/Deficiency Reporting.*" The NRC staff's observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989 (Draft).

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes supporting the development of the Waste Package AMRs. The audit included review of the QA program procedures directly associated with preparation of the AMRs which included:

- AP-2.13Q "Technical Product Development Planning"
- AP-SI.1Q "Software Management"
- AP-3.15Q "Managing Technical Product Inputs"
- AP-SIII.2Q "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data"
- AP-3.10Q "Analysis and Models"
- AP-2.14Q "Review of Technical Products"
- AP-SIII.3Q "Submittal and Incorporation of Data to the Technical Data Management System (TDMS)"
- AP-3.11Q "Technical Reports"
- AP-2.15Q "Work Package Planning Summaries"
- AP-SIII.1Q "Scientific Notebooks"

The following AMRs supporting the Waste Package PMR were evaluated by the audit team:

- Analysis of Mechanisms for Early Waste Package Failure (ANL-EBS-MD-000023, Rev 00)
- General Corrosion and Localized Corrosion of the Waste Package Outer Barrier (ANL-EBS-MD-000003, Rev 00C Draft)
- Aging and Phase Stability of the Waste Package Outer Barrier (ANL-EBS-MD-000002, Rev 00C Draft)
- Environment on the Surface of the Drip Shield and Waste Package Outer Barrier (ANL-EBS-MD-000001, Rev 00B Draft)

The critical process steps examined in relationship to accomplishing the performance based aspect of this assessment included the following:

- Planning
- Resources
- Inputs to Analysis and Models
- Development and Documentation of Analysis and Models
- Validation of Models
- Use of Software or Models
- Documentation Check and Review
- Approvals
- Analysis or Model Revisions or Change
- Verification and Qualification of Data
- Submittal of Data and Models to the Technical Data Management System (TDMS)

4.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team was prepared and demonstrated a sound knowledge of the M&O organization and DOE QA programs. The LLNL Principal Investigators (PIs) for the selected AMRs were brought to the M&O offices to be interviewed by the audit team members. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. For each AMR, LLNL staff was present at the Nevada office for one day and contacted at LLNL by telephone for the remainder of the audit to resolve open items or questions. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate the ongoing activities and implementation of the QA program even though it was very early in the Waste Package AMR development process. QA audits at this stage of the AMR process development are crucial. Relatively minor corrections made at this point will result in a better quality product; however, delaying corrections to problems found by such an audit until the models are complete may result in non-qualifiable models and wasted effort.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning to discuss the current audit status and preliminary findings or recommendations.

4.3 Audit Team Qualification and Independence

The qualifications of the Audit Team Leader and audit team members were found to be acceptable in that they each met the requirements of OCRWM QAP 18.1, "Auditor Qualification," as checked by the NRC Observation Audit Lead. The audit team OCRWM members did not have prior responsibility for performing the activities they audited. In addition, training, education and experience records for audit team members were reviewed and found acceptable.

The audit team members were prepared in the areas they were assigned to audit and were knowledgeable of applicable procedures. The checklist was adequately formulated and covered the subject matter well.

4.4 Examination of Programmatic Quality Requirements

Programmatic audit activities were conducted in accordance with the OCRWM QA Audit Plan for Audit M&O-ARP-00-001. The auditors reviewed documents identified in the audit plan and used checklists as a basis for inquiries. In addition, related documentation supporting report conclusions was reviewed to verify data source and status of qualification. Personnel directly responsible for document products or appropriate representatives with sufficient levels of knowledge were interviewed by the auditors. The checklists used were effective and additional inquiries were made beyond specific checklist items, when appropriate. The NRC observers were briefed on audit conduct procedures, including the inquiry process and method for raising concerns. The NRC observers were given ample opportunity to review documents, ask questions and provide comments.

The NRC observers found that the requirements of QA Procedure 18.2 were implemented in an effective and satisfactory manner. These planning and implementation activities were accomplished and observed by the NRC observers as follows:

(1) distribution of a quality assurance audit plan, M&O-ARP-00-001;
(2) development of a performance based audit checklist;
(3) coordination and communications with all team members;
(4) conduct of an introductory pre-audit kickoff meeting with the audit team and observers;
(5) conduct of a kickoff meeting with M&O personnel including high level waste management;
(6) daily caucus meetings held for the audit team and observers;
(7) daily management status meetings held for M&O management; and
(8) conduct of a post audit meeting with M&O management, audit team members and NRC observers.

In addition, implementation of corrective measures were evaluated on the significant deficiencies documented in existing Corrective Action Requests (CARs) that could impact the AMR development process. The following is a status of the CARs as a result of the evaluation:

CAR LVMO-99-C-001

The assessment of procedures AP-3.10Q, Revision 1, ICN 1, "Analysis and Models," was found to be satisfactory in addressing the traceability and technical adequacy of data. There was one recommendation regarding the checking process; however, there is no adverse impact on the

AMRs/PMR based on this recommendation to this point. Additional verification of implementation is required in order to adequately assess the effectiveness of the AP-3.10Q development and checking process of the AMRs/PMR. This CAR remains open.

CAR LVMO-98-C-002

AP-3.15Q, Data or Technical Information Confirmation Checklists continue to be completed. Two checklists, addressing a total of 10 data tracking numbers used as inputs to AMR ANL-EBS-MD-000023, were reviewed during the audit. Problems are still occurring during the completion of the checklists with respect to the transparency of conclusions and accuracy. However, positive steps are being taken to address these issues. This CAR remains open.

CAR LVMO-98-C-006

Additional corrective actions are necessary to address deficiencies identified during the audit. Although recent changes to AP-SI.1Q, Revision 2, ICN 1, "Software Management," authorized use of unqualified software while in the process of being qualified, specific requirements found in AP-SI.1Q (Section 5.12) were not implemented for software associated with the audited AMRs. In addition, instances of inadequate documentation to support verification for software macros and routines were identified during the audit. The results of this audit are included in the unsatisfactory verification documented as part of the OQA Phase 3 verification of the CAR Management Plan. This CAR remains open.

CAR LVMO-98-C-010

The remaining CAR-010, corrective action, i.e., generation of "family trees," a general schematic of AMRs that are inputs to the TSPA, were found to be adequate; however, there was not sufficient implementation of AP-3.10Q, Revision 1, ICN 1, "Analyses and Models," in regard to model validation. Therefore, additional verification of implementation is required in order to adequately assess the effectiveness of the model process. This CAR remains open.

4.5 Examination of Technical Activities

The work supporting these AMRs was conducted at LLNL. The four AMRs audited are indicated in Section 4.1.

4.5.1 NRC Observation Team Technical Specialists General Comments

Technical specialists on the YMQAD audit team were competent and independent. Appropriate programmatic and technical questions were asked by the DOE auditors and technical specialists. The technical specialists had sufficient knowledge of technical issues associated with the Analysis of Mechanisms for Early Waste Package Failure and Environment on the Surface of the Drip Shield and Waste Package Outer Barrier AMRs. However, some lack of understanding of a few significant technical issues associated with the General Corrosion and Localized Corrosion of Waste Package Outer Barrier and the Aging and Phase Stability of Waste Package Outer Barrier AMRs was noted.

The audit identified that confusion existed on which procedures to follow to ensure QA compliance. Demonstrated difficulty was noted in executing the new QA procedures

implemented program-wide in June of 1999. This may be due to lack of training or incentive to follow new procedures.

Theoretically, a very effective database and system is in place for documenting all inputs, codes and models; however, confusion of PIs and Administrators about entering the correct documents in the proper databases was evident during the audit.

These AMRs had gone through quite extensive review and checking, yet were still plagued by editing errors such as referring to the wrong section due to the addition/deletion of sections. None of the AMRs exhibited a model in a form near enough to completion for final presentation. The DOE technical specialists inquired about the model for each of the AMRs. With the exception of the Analysis of Mechanisms for Early Waste Package Failure, which is largely based on the probability of human error, all of the AMR authors indicated that the model development was incomplete. In several cases, the AMR authors indicated that additional data had been collected for the development of the models. This additional data was not included in the version of the AMR under review since this would slow the review process.

It is apparent in many cases that the output or result from one AMR is needed for input to another AMR, yet work on the AMRs is progressing in parallel, not waiting for the necessary input, but rather making assumptions that can later be modified. For example, the output of the Environment on the Surface of the Drip Shield and Waste Package Outer Barrier AMR should feed into the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR in order to calculate corrosion rates and assess the possibility for localized corrosion. Because the experimental work on the Environment on the Surface of the Drip Shield and Waste Package Outer Barrier AMR was initiated within the last year, long term corrosion tests were performed in a range of environments that were assumed to be possible at the waste package and drip shield surfaces.

Several technical comments brought up by the observers during the audit were similar to those previously brought to the attention of the PIs during interactions with the DOE. Those comments did not appear to have been addressed in these AMRs. The most important examples of such comments are: (1) The deposition of SiO_2 and corrosion products on specimens from the Long Term Corrosion Test Facility (LTCTF); (2) The effect of welding and thermal treatments on the corrosion resistance of Alloy 22; and (3) The inconsistent use of critical potentials for the initiation of localized corrosion.

In the first example, DOE acknowledged during the July 7, 1999, Appendix 7 meeting at LLNL that there was deposition of corrosion products and SiO_2 on the test specimens of Alloy 22 from the LTCTF. The validity of the weight loss measurements was questioned by NRC at that time. The response from DOE was that the cumulative distribution curve (Figure 23 in the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR) probably should be shifted to the right so that there are no specimens with a weight gain. The NRC believes this is not a defensible approach if there is no information regarding the rate of SiO_2 deposition. Another recommendation by NRC to DOE regarding the LTCTF tests prior to and at the time of the Appendix 7 meeting was the measurement of the corrosion potential of the specimens. Although this would have taken little additional effort to accomplish, measurement of the corrosion potentials was never performed in the LTCTF by DOE.

The second example refers to NRC recommendations to DOE regarding the effect of container fabrication and welding on the corrosion resistance of Alloy 22, also discussed in the July 7, 1999, Appendix 7 meeting. These NRC comments were also expressed to the DOE at the DOE Waste Package Degradation Modeling and Abstraction Workshop (April 20-21, 1999, Las Vegas, NV). The machining of specimens from the container mockups was discussed and CNWRA staff indicated that the CNWRA would like to have a section of the container mockup with a section of the weld to support NRC staff evaluation of DOE conclusions. CNWRA staff also discussed the effect of welding with LLNL staff at the 1998 Materials Research Society (MRS) meeting (Boston, MA) and indicated that NRC was interested in the corrosion resistance of the welded alloy. LLNL staff have done some interesting microstructural characterization studies on both welded and thermally aged specimens; however, the effect of welding on the corrosion resistance has not been addressed by DOE.

The third example of DOE not addressing NRC staff comments involves DOE's inconsistent use of critical potentials for the initiation of localized corrosion. There are inconsistencies in the interpretation of critical potentials from one chapter to the next in the 1998 Engineered Materials Characterization report (edited by McCright). The NRC and the CNWRA have consistently used the repassivation potential, and from circa 1994, the crevice corrosion repassivation potential. The NRC and CNWRA have published numerous reports, conference papers and journal papers indicating this is a valid approach and that one can easily get crevice corrosion at potentials below the pit initiation potential in a period of days or weeks. DOE's reluctance to use a consistent criteria for initiation of localized corrosion is a weakness in their evaluation of waste package degradation.

Conducting the audit in Las Vegas of activities at LLNL provided some logistical difficulties, but overall the audit was effective. Once database management comes up to speed, logistical problems should be eliminated.

4.5.2 Specific Technical Comments

Technical questions, comments, and concerns from the NRC observers are summarized in this section.

Analysis of Mechanisms for Early Waste Package Failure - ANL-EBS-MD-000023 Rev 00.

A question was asked if there was any alternative text or opposing authority to Swain and Guttmann (A.D. Swain and H.E. Guttman, NUREG/CR-1278, Handbook of Reliability Analysis with Emphasis on Nuclear Plant Applications, August 1983), since all of the probability numbers come from this handbook. For example, Swain and Guttmann is used as the sole reference for the probability of a worker performing a task incorrectly and then missing his mistake on self-check as well as the probability of an independent inspector missing a mistake or defect in the construction of an engineered repository system. The PI indicated that Swain and Guttman was the only source of the probability data used in this AMR and the text is the industry/discipline standard as well as a NUREG.

In answering a question from the NRC technical specialist, the PI indicated base metal flaws such as voids, stringers, inclusions and rolling laps were considered in this AMR. These flaws were considered to occur at a frequency of 10 times less than the frequency of flaws in the welds.

These base metal flaws were considered to occur due to temporary welds and subsequent grinding out on plate during processing.

The data from E. Siegman's report (Draft of AMR "Initial Condition of Cladding", ANL-EBS-MD-000048, Rev. 00, part of upcoming OQA audit of Waste Form AMRs) was considered and the present AMR was developed using this data. One additional question regarding the failure rates published in Timmins (P.F. Timmins,"Solutions to Equipment Failures ",1999, Materials Park, Ohio, ASM International) was not asked since it seemed like the author had considered a sufficient cross section and number of reports from industrial manufacturing processes. The annealing time for the fabricated Alloy 22 container was stated as 24 hours. The PI indicated that this did not mean that the container would be at temperature for 24 hours. The text in this section of the AMR will be reviewed and corrected and/or clarified.

General Corrosion and Localized Corrosion of Waste Package Outer Barrier - ANL-EBS-MD-000003 Rev 00C (Draft).

LLNL indicated that localized dry oxidation of the waste package outer barrier was not considered but indicated that this phenomena would be considered in future versions of the AMR since the Ni-Cr-Mo alloys tend to suffer grain boundary attack rather than general corrosion under dry oxidation conditions.

In response to a question from the NRC audit observation team, LLNL indicated test specimens are identified and tracked by a Metals Samples, Incorporated lot number. In addition, each sample is stamped with a unique number than can be traced to a Metals Samples lot number which has also had composition chemistry verified by an independent qualified laboratory. The Metals Samples procedure for assigning individual heats from the manufacturer unique lot numbers was audited. This traceability is maintained on a master spread sheet in Excel at LLNL that was not available in the database (Record Information System - RIS web). Hard copies are maintained as supplements to scientific notebooks which should also be in the database on the RIS web. The traceability of randomly selected samples from the AMR was not transparent and the documentation was not in the RIS web.

The basis for selecting the critical potential (E_{crit}) for the initiation of localized corrosion was questioned by the NRC audit observation team. LLNL indicated that since some cyclic polarization tests did not result in a repassivation potential, the breakdown potential is used for all samples and environments. There exists disagreement between NRC/CNWRA and LLNL on selection of the critical potential.

Critical potentials listed in this AMR are pitting corrosion repassivation potentials reported by Gruss et al. (K.A. Gruss, G.A. Cragnolino, D.S. Dunn, and N. Sridhar, "Repassivation Potential for Localized Corrosion of Alloys 625 and C22 in Simulated Repository Environments", Proceedings of Corrosion 98, March 22-27, 1998, San Diego, California, 149/1 to 149/15, Houston, Texas: NACE International) using a lead-in-pencil specimen geometry. Since Alloy 22 is resistant to pitting corrosion, the use of pitting corrosion repassivation potentials to predict the onset of localized corrosion does not appear to be conservative. Crevice corrosion has been identified in the AMR as the most probable localized corrosion mode for the container. It was also noted that the repassivation potential measurements with welded specimens were not reported, although it is recognized that welding may increase the localized corrosion susceptibility

of Alloy 22. Future versions of the AMR will consider both crevice corrosion and the effects of welds.

The effect of sulfate reducing bacteria on Stress Corrosion Cracking (SCC) of Alloy 22 will be considered in future AMRs. Nickel alloys are known to be susceptible to SCC in sulfide environments. In addition to SCC, questions were raised regarding the Alloy 22 corrosion rate in solutions inoculated with bacteria. While the weight loss of the specimen indicated the corrosion rate increased by a factor of 2, analyses of the corrosion products in solutions suggests preferential dissolution of Cr and Mo. Since these alloying additions are largely responsible for the localized corrosion resistance of Alloy 22, the long term effects of preferential dissolution may be much more severe than a 2x increase in the corrosion rate. The PI of this AMR suggested that the microbial induced corrosion data in the AMR was preliminary and that additional investigations are underway to further investigate the effect of microbes on the corrosion rate of Alloy 22.

Questions were raised on how the results of the Atomic Force Microscopy (AFM) examination of the Alloy 22 samples exposed for one year will be used to predict the performance of the waste package outer barrier. At the present time, the AFM work is relatively new and the knowledge that can be obtained by the examination of long term test specimens is not known. DOE stated that one possibility may be to determine if a silica layer will deposit on the waste package surface and form a protective covering.

There is a concern about validity of LTCTF weight loss measurements due to deposition of SiO_2 that could not be removed prior to final weight measurement. The deposition of silica on the specimens would alter the weight loss of the specimens. Corrosion rate calculations that do not properly consider the effect of silica deposition would under predict the actual corrosion rate. LLNL indicated that additional AFM studies are being conducted using lithography masks to measure metal volume loss and presumably, though not specifically mentioned, volume of SiO_2 deposited on LTCTF coupons.

Aging and Phase Stability of Waste Package Outer Barrier - ANL-EBS-MD-000002 Rev 00C (Draft).

Overall a concern was expressed about qualifying samples and procedures or specimens received from Haynes International. The long term thermal aging tests of several heats of Alloy 22 were performed by the research and development section of Haynes International. Efforts to qualify the data obtained from these material heats are ongoing. There is an overall concern about qualifying software used for calculations, e.g., THERMOCALC, used to determine phase stability for Ni-Cr-Mo alloy at low temperatures and long times.

A concern was raised about range of chemical composition of Alloy 22 allowed by ASTM specification and effect of extremes in chemistry still within specification on phase stability. The AMR author responded that these effects can be captured by data in the literature and by studying other alloys such as Alloy 59 and Alloy 686. There is general disagreement on this issue between NRC/CNWRA staff and authors of this AMR. The statement in this AMR that compositional variations of Alloy 22 within the limits of ASTM B575 are not expected to have a significant effect on the phase stability of the alloy based on a number of alloy heats examined, was not justified. The compositions of the heats had not been verified and examination of the entire range of tungsten, cobalt, and iron compositions to determine the effects of these alloying

elements/contaminants on the phase stability of the alloy were not performed. It was also noted that the composition specification of the Alloy 22 welds, performed by an independent, qualified, chemical analysis vendor, indicated a maximum molybdenum concentration of 4.5 weight percent. The specification for Alloy 22 weldments may be detrimental to the thermal stability of the alloy, however, this was not examined.

Environment on the Surface of the Drip Shield and Waste Package Outer Barrier - ANL-EBS-MD-000001 Rev 00B (Draft).

The author was asked by the NRC technical specialist if temporal variations in chemical composition of the water percolating through heated tuff, were considered. This may be significant if mineral sites in the tuff become saturated with ions from the simulated well J-13 water. The response was that this had not been considered but acknowledgment was made that future versions of the AMR would need to address this issue.

The parallel development of the AMR was a cause for concern since the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR is based on the results of tests using Basic Simulated Water (BSW) for input, yet BSW is not considered in this AMR. As a result, there appears to be a disconnect between this AMR and the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR. It was indicated by LLNL that discrepancies arising from some of the assumptions necessary for the parallel development of these AMRs will need to be resolved.

4.6 NRC Staff Findings

The NRC staff has determined that OQA Audit M&O-ARP-00-001 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented. The audit team performed a good review considering the early stage of development that was evident with the selected AMRs. However, one deficiency and thirty-four recommendations were identified by the audit team to improve the AMRs and associated quality program procedures. The NRC staff agrees with the audit team conclusion and recommendations. The NRC staff determined that this audit was effective and that the QA program implementation was adequate.

4.6.1 Audit Observer Inquiries

No NRC observer inquiries were initiated during the audit. A potential inquiry dealing with corrosion metal sample certification traceability was resolved with receipt of the hardcopy of certifications by the NRC staff.

4.6.2 NRC Summary Comments

The following comments were made at the closing meeting by the NRC Audit Observation lead:

1. The audit team has conducted an effective, performance based in-process review of the Waste Package AMR development process.

2. The issuance of the new procedures from the Process Validation and Reengineering (PVAR) process appears to have created confusion, misinterpretation and lack of coordination, thus creating implementation difficulties especially in database management and To Be Determined/To Be Verified (TBD/TBV) clearing process.

3. Additional self assessments of the AMR/PMR process prior to outside reviews would be beneficial. The results of the one self assessment performed had not resulted in any corrective measures prior to this audit.

4. The AMR/PMR development process, the data/model TBD/TBV clearing process and software qualification process appear to be conducted as separate entities when all these processes are interrelated and should come together before SR and License Application.

5. The comments discussed in 4.5.1 of this report have been made to PIs previously by the NRC staff on reports included as a basis of the AMRs at Technical Exchange meetings. However, the comments apparently have not been addressed.