

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT OA-95-09
OF THE
U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT YM-ARP-95-9
OF THE
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT'S
MANAGEMENT AND OPERATING CONTRACTOR
Las Vegas, Nevada
July 24-28, 1995

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1.0 INTRODUCTION

During July 24-28, 1995, members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) and technical staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) performance-based audit of Office of Civilian Radioactive Waste Management's Management and Operating Contractor (M&O) processes relative to the control of waste package design. The audit, YM-ARP-95-16, was conducted at the M&O offices in Las Vegas, Nevada. The audit evaluated the effectiveness of the M&O waste package design processes and M&O adherence to quality assurance (QA) program requirements. The waste package design effort is presently in the conceptual stage.

The State of Nevada also participated as an observer of this audit.

The objectives of the audit were to determine whether the M&O QA Program implementation in waste package design meets the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and associated M&O implementing procedures.

The NRC staff's objective was to gain confidence that the M&O and YMQAD are properly implementing the requirements of their QA programs in accordance with the QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

This report addresses the effectiveness of the YMQAD audit and the adequacy of implementation of QA controls in the audited area of the M&O waste package design program.

2.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that YMQAD audit YMP-ARP-95-16 of the M&O was useful and effective. The audit was well organized, and it was conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA and technical disciplines, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team findings. While the audit team rated M&O compliance with two of its procedures as marginal, its overall finding was that the audit showed satisfactory M&O performance. Two new procedures (AP-16.1Q, "Performance/Deficiency Reporting," and AP-16.2Q, "Corrective Action and Stop Work") were used in judging deficiencies noted by the audit team during this audit. No significant deficiencies were found. However, discrepancies were noted which resulted in the issuance of three preliminary Discrepancy Reports (DRs) and one preliminary Performance Report (PR). In addition, ten recommendations were made for M&O management consideration. The above items were discussed at the closing meeting held on July 28, 1995.

3.0 AUDIT PARTICIPANTS

3.1 NRC

Kien Chang	Technical Observer	
John G. Spraul	Observer	
Thomas C. Trbovich	Observer	Center for Nuclear Waste Regulatory Analysis

3.2 DOE/YMQAD

Stephen R. Maslar	Audit Team Leader (ATL)	Quality Assurance Technical Support Services (QATSS)/CER Corporation
John R. Matras	Auditor (ATL in Training)	QATSS/Science Applications International Corporation (SAIC)
Marc J. Meyer	Auditor	QATSS/CER Corporation
Paul A. Cloke	Technical Specialist	SAIC

3.3 State of Nevada

Susan W. Zimmerman Observer

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This YMQAD audit of the M&O was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program," and QAAP 16.1, "Corrective Action." The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

Since the last DOE audit observed by the NRC staff, DOE has introduced two new procedures as noted in Section 2.0, above. These two procedures (AP-16.1Q, "Performance/Deficiency Reporting," and AP-16.2Q, "Corrective Action and Stop Work") supersede QAP 16.1, "Corrective Action," and QAP 16.2, "Stop Work." AP-16.1Q includes two new levels of deficiency reporting while AP-16.2Q narrows the concept of Corrective Action Requests (CARs). The two new levels of deficiency reporting are:

- Performance Report (PR) - A document used to report a performance condition in an activity or associated documentation where only remedial actions or minor improvements are necessary to meet minimum requirements.
- Deficiency Report (DR) - A document used to report a nonsignificant deficiency in activities, associated documentation, or procedures that requires remedial and investigative actions, as a minimum.

CARs are now used only for significant deficiencies such as a deficiency requiring immediate notification to the NRC, a significant failure or breakdown in QA program implementation, an adverse quality trend, or a significant discrepancy between the final design as approved and released for implementation and the design documents.

4.1 Scope of the Audit

The following technical documents concern the waste package to be used for underground storage of radioactive waste. They were reviewed by the DOE audit team prior to the audit and formed the basis for most of the technical questions in the audit checklist:

- Analysis of Degradation Due to Water and Gases in MPC (Multi-Purpose Canister), BB0000000-01717-0200-00005, Revision 00, March 28, 1995.
- Report on Preliminary Selection of Waste Package Materials, BB0000000-01717-5705-00007, Revision 00, June 13, 1995.
- Initial Waste Package Probabilistic Criticality Analysis: Uncanistered Fuel (TBV 059-WPD), B00000000-01717-2200-00079, Revision 00, April 14, 1995.
- Initial Waste Package Probabilistic Criticality Analysis: Multi-Purpose Canister with Disposal Container (TBV-060-WPD), B00000000-01717-2200-00080, Revision 00, April 14, 1995.

The principal key technical uncertainties associated with the audit are listed below. They are all associated with Section 5.2, "Assessment of Compliance with the Design Criteria for the Waste Package and its Components," of the License Application Review Plan (NUREG-1323).

- Prediction of Thermomechanical Effects on the Waste Package and the Engineered Barrier System (EBS).
- Prediction of Environmental Effects on the Waste Package and the EBS.
- Prediction of Criticality Events in Waste Packages.
- Extrapolation of Short-Term Laboratory and Prototype Test Results to Predict Long-Term Performance of Waste Packages and the EBS.

4.2 Conduct of the Audit

The audit was performed in a professional manner, and the audit team was well prepared. This was a performance based audit for which the flow chart (next page) was developed. The flow chart identifies the critical design process steps, objectives of the review, and measurement criteria. The flow chart, technical documents, and M&O quality procedures were the basis for checklist development. The auditors followed the prepared checklists, asking additional questions as necessary to ensure understanding of the design controls by M&O personnel.

The audit team divided into subteams, with two audit team members each, to conduct the evaluations. There was good discussion during the daily audit team caucus meetings, and M&O management was kept aware of the audit progress through the daily morning meetings. NRC staff was present at these meetings.

PROCESS STEP	OBJECTIVE	MEASUREMENT CRITERIA
Waste Package Design Input Control	Design inputs are identified, documented, specified, and approved and changes are controlled.	QAP 3.5, "Development of Technical Documents."
Waste Package Design Process	Design work is prescribed and documented, design documents are adequate, appropriate standards are approved including changes, and design documents contain sufficient detail.	Technical Document Preparation Plan and QAP 3.5, "Development of Technical Documents." Use of trained and qualified personnel per QAP 2-1, "Indoctrination and Training."
Waste Package Design Analyses	Design Analyses are planned controlled, and documented.	QAP 3.9, "Design Analysis."
Waste Package Design Verification	Design verifications and reviews are performed and documented.	QAP 3.1, "Technical Document and Milestones Review."
Waste Package Design Interface Control	Design interfaces are identified and coordinated, responsibilities are assigned, and transfer of information is controlled and documented.	QAP 3.12, "Transmittal of Design Input" and QAP 17.1, "Record Source Responsibilities for Inclusionary Records."
Identifying QA Controls for Waste Package Design	The applicable controls for quality affecting work are documented and applied.	QAP 2.0, "Control of Activities."

4.3 Examination of Technical Areas and QA Controls

The technical portion of the audit focused on the checklist questions related to the documents listed in Section 4.1 above. The checklist questions stemming from these four M&O documents could be traced directly to the reports. Topics of the more general QA programmatic type checklist questions related to waste package design were also discussed. The nature of the questions by the technical specialist demonstrated a detailed review of the technical documents prior to the audit and a general knowledge of the waste package design process.

At the time of the audit, the advanced conceptual design of the waste package was being completed. The next milestone activity, preliminary design, was being initiated. Some advanced conceptual design analyses (for example, waste package failure analysis and thermal analysis) do not satisfy QARD requirements for graded QA to ensure "that designs (from conceptual through final) are defined, controlled, and verified." A preliminary DR was discussed at the post-audit conference reflecting this deficiency. The same DR reported

that some analyses had been completed for the waste package transporter without QA controls, even though the QA classification of the transporter had not yet been determined (See Section 4.7.2). It appeared that M&O management had not estimated (and had not planned for) the work required to up-grade the advanced conceptual design work for the preliminary design, and the required up-grade may delay the waste package design schedule.

For waste package design, OCRWM is following the strategy of continuing development and analytical work on a selected set of candidate waste package materials (that is, carbon steels UNS-G10200, ASTM A516, ASTM A27; copper nickel alloy UNS C71500 70% of Cu 30% Ni; and Alloy 825). The final choice of material will not be made until the time of prototype construction or at the time of submittal of the license application for the waste package design. The M&O indicated that none of the currently available performance data (for example, corrosion and material specification) on the candidate materials will be used for licensing. The M&O plans to obtain data of tests of only up to 5 years real time to address long term failure analyses at the time of licensing. Validation of waste package performance is expected to continue during initial repository operation. The prediction of long term waste package performance will be difficult using only the relatively short term test results that will be available at the time of licensing.

In addition to the documents listed in Section 4.1 and referenced above, numerous other documents were examined during the audit. Examples include:

- Technical Document Preparation Plan For the Waste Package Conceptual Design Report, BBA000000-01717-4600-00004, Rev. 00, January 13, 1995.
- Analysis of MPC Weight, Dimensional Envelope, and Configuration Requirements, BB0000000-01717-0200-00003, Rev. 00.
- Methods for Waste Package Probabilistic Criticality Analysis (for Information Only).
- Memorandum on Compensatory External Review Work Instruction.

The audit of each document was quite thorough.

The audit team audited activities related to the preparation of documents on waste package design, design analyses, design verification, and design interface control. Detailed discussions of the following were observed:

- Calculation of water vapor pressure and density involving linear interpolation and conversions of temperature and pressure units (Report on "Analysis of Degradation Due to Water and Gases in MPC" and the two reports on "Waste Package Probabilistic Criticality Analysis").
- The subject of data acquisition (Report on "Analysis of Degradation Due to Water and Gases in MPC").
- The application of empirical relationships (The two reports on "Waste Package Probabilistic Criticality Analysis").

During the review of calculations in the reports, the audit team noted that calculations were not always included, even though the reports provided the basic data and described how the calculations were performed. A reported calculated value was also found to be in error. QAP 3.9, "Design Analysis," requires that the calculations be shown, and a second preliminary DR was generated as a result (See Section 4.7.1). The M&O did not provide objective evidence to the audit team that the design checking process met all the QAP 3.9 requirements for design checks, and this resulted in the third (and final) preliminary DR (See Section 4.7.1).

This portion of the audit provided satisfactory demonstration/evaluation of the adequacy of M&O's QA program in waste package design and the acceptability of the advanced conceptual design of the waste package.

4.4 Audit Team Qualifications and Independence

The qualifications of the ATL and auditors were found to be acceptable in that the ATL and each auditor met the requirements of QAP 18.1, "Qualification of Audit Personnel." The background of the Technical Specialist was well-suited to conduct the evaluation of waste package design processes.

The audit team members did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence. The audit team was well qualified in the QA and technical disciplines, and the assignments and checklist items were adequately described in the audit plan.

The audit team members were prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The Audit Plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, the performance based audit flow chart, and the audit checklist.

4.5 Review of Previous Correction Actions

The audit team verified that previous commitments made to establish a Product Checking Group and Office of Product Integrity within the M&O organization in response to the NRC to DOE letter of October 13, 1994, were continuing. These organizations had performed reviews on several waste package design documents and activities.

4.6 NRC Staff Findings and Recommendations

The audit was conducted in a professional manner, and the audit team adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the M&O QA program as applied to the design of the waste package. While the audit team rated M&O compliance with two of its procedures as marginal, its overall finding was that the audit showed satisfactory M&O performance.

The NRC staff assessed the audit as being effective and agreed with the audit team's findings and recommendations. The NRC staff did not observe any deficiencies in the audit process.

M&O personnel were very cooperative with the audit team and observers. Escorts were provided from the M&O QA organization that set up meetings with various M&O Engineering personnel, retrieved necessary documents, and provided copies when requested by the auditors. This aided in the conduct of a smooth and efficient audit.

Copies of technical documents reviewed by the DOE audit team prior to the audit and used in the preparation of the audit checklists were not provided with the audit plan to NRC observers for review prior to the audit. However, when asked, the ATL supplied copies of requested documents to the NRC prior to the audit. The NRC staff recommends that technical documents be provided with the audit plan on future performance based audits of this type.

4.7 Summary of YMOAD Audit Findings

At the closing meeting, held July 28, 1995, the ATL in Training discussed the following deficiencies and recommendations with M&O personnel.

4.7.1 CARs - None.

4.7.2 DRs

- None of the design analyses that result from the waste package advanced conceptual design will be subject to QARD requirements based on statements in M&O QAP 2.0 Evaluation Forms. These same forms are being use for waste package preliminary designs. This is in conflict with the QARD Paragraphs 2.7.3.F and 3.1.
- Three technical documents provided basic data and described how calculations were performed, but they did not include an actual copy of the calculations. This was not in accordance with the provisions of QAP 3.9 Revision 5 Attachment I, Item 7, which requires a complete presentation of the design analysis including calculations.
- Four technical documents were identified where no objective evidence could be located that the QAP 3.9 checking functions had been properly performed. These involved lack of initialing of check copies, calculation checks, and use of appropriate checklists.

4.7.3 PR - The Fiscal Year 1995 Lawrence Livermore National Lab (LLNL) Statement of Work assigns LLNL responsibility for waste package design thermal analyses and for establishing criteria for selecting materials, evaluating materials, and recommending materials for the waste package. The LLNL QARD Matrix states that Section 3, "Design Controls," is not applicable.

Work performed by LLNL at the request of the M&O is reviewed by the M&O using LLNL procedures. The authority assigned to individuals conducting such reviews and procedures used are not identified in M&O implementing documents.

4.7.4 Recommendations

- The Product Integrity Group performed an "external" review of the "Report on Preliminary Selection of Waste Package Materials (BBA000000-01717-5705-00007)". The results of this review are reported in M&O Performance Report LVMO-95-P-001. This review was defined to be a non-QA activity; not required to comply with the QARD. It was recommended that Product Integrity Group reviews of quality affecting work be performed as a QA activity complying with the QARD.
- "Internal" reviews of the "Report on Preliminary Selection of Waste Package Materials" missed a number of deficiencies of QAP 3.5 based on M&O Performance Report LVMO-95-P-001 (see above). Based on discussions with two of the reviewers, the reason for this may have been a lack of time and confusion on how "TBVs" (items or activities that are "to be verified") need to be documented. It was recommended that "TBV" requirements and other factors that may have contributed to the conditions described in M&O Performance Report LVMO-95-P-001 be clarified. M&O management should ensure that reviewers have sufficient time to perform their reviews and are provided with appropriate training and the necessary supporting information.
- TBVs 059 and 060-WPD pertain to information and assumptions in the two reports on Waste Package Probabilistic Criticality Analysis, B00000000-01717-220-079 and -080, respectively. The TBVs cover all information and assumptions needed to calculate the probability of criticality as a function of time. Five categories of information and assumptions are identified. However, much of the information in these categories is contained in references provided in the analyses that are not considered design input. According to QAP 3.9, only design inputs need to be identified and tracked as TBVs. Thus either the reports are asking for more than QAP 3.9 requires or not all of the inputs have been identified in Section 4 of the analyses.

It was recommended that 1) assumptions and inputs that require qualification or verification be asterisked, 2) both analyses be reviewed to make certain all design inputs have been identified, 3) QAP 3.9 and other procedures be reviewed to determine whether the practice of identifying all unqualified inputs in a document with a single TBV is a practice that should be limited to conceptual design and other early phases of design. Such blanket use of TBVs during later design phases is of concern.

- It was difficult to ascertain whether work identified on QAP 2.9 evaluation forms was completed work, ongoing work, or future work. It was recommended that the relationship between described work and scheduled activities be identified by, for example, citing milestone numbers and, if necessary, estimated start and completion dates.

Responsible managers are sharing QAP 2.9 evaluation forms signed by only one responsible manager. Thus, it was not readily apparent that work on the form will be performed by a number of different organizations. It was

recommended that each responsible manager sign the QAP 2.0 evaluation form, complete separate QAP 2.9 evaluation forms, or identify on the QAP 2.0 evaluation form the lead organization and other participating organizations.

Not all activities related to a Q-List item need to be subject to the QARD. However, due to the way Part II of the QAP 2.0 evaluation form is structured, a "yes" response to "is the activity related to an item in the WAST/MGDS Q-List?" makes the activity subject to the QARD. It was recommended that Part II of the QAP 2.0 evaluation form be revised.

It was sometimes difficult to understand the applicability of QAPs listed in Part III of the QAP 2.0 evaluation form based on the description of the activity in Part I. For example, Part I may read "Evaluate information furnished by supplier" and Part III may read, "QAPs 3.1, 3.2, 3.5, and 6.1." Thus it was not certain whether all four QAPs must be implemented or only one of the four. It was recommended that a list of products resulting from the activity be itemized in Part I and that Part III identify QAPs and options, if applicable. If the relationship between products and QAPs cannot be clearly defined because of the number of different products involved, it was recommended that the products be divided into lower-level tasks and defined on separate QAP 2.0 evaluation forms.

- LLNL is responsible for long-term testing of waste package materials including defining test environment. The required test environment is documented in LLNL plans that are not subject to LLNL or M&O design control. It was recommended that QARD requirements for these tests, their environment, and the test plans be investigated further and consideration be given to placing these items under M&O design controls prior to the start of the material testing program.
- It was recommended that more care be exercised in obtaining definitive published data and in restricting the application of empirical relationships to ranges where they have been shown to apply. One instance of inadequate care was found for each of these points:
 1. The "Analysis of Degradation Due to Water and Gases in MPC" involves the vapor pressure of the azeotrope (at about 68% HNO_3) in the nitric acid-water system. Data for 90% HNO_3 were used to estimate the vapor pressure. Existing literature data should have been obtained. These data show the estimate to be high by a factor of nearly 3.5. This is still conservative, so there is no impact on the conclusions.
 2. The two reports on Waste Package Probabilistic Criticality Analysis, B00000000-01717-220-079 and -080, state: "This equation (Equation 6) is representative of experimental data for moderate temperatures (up to about 350°K). However, Equation 6 was used for calculations at 839°K; well outside its range of applicability. At the higher temperature and presumably relatively low pressure the water will be a low density steam as contrasted to the water at a density close to 1 gm/cm³ of which the equation is representative. No data appear to exist to indicate that the same equation applies for these conditions. However, calculations

conducted during the audit showed that there is no impact on the conclusions given in the reports.

- In view of the usage of a high estimate of the vapor pressure of the azeotrope in the water-nitric acid system noted above, it was recommended that the potential impact of nitrogen be reevaluated. This might include consideration of the potential for nitrogen gases to dissolve in thin surface films of water (for example in mono- or di-molecular layers) as well as corrosion by nitrous acid, which should also be present as a consequence of nitrogen oxides dissolving in water.
- The "Analysis of Degradation Due to Water and Gases in MPC" cites requirements in the MPC subsystem Design Procurement Specification. One of these requirements is that the residual water content of the MPC interior be less than 0.25 volume percent. This requirement is subject to at least three different interpretations. The audit team recommended that the specification be rewritten such that there is only one interpretation, if feasible. Whereas this has no impact on the present document because all three interpretations were considered, it could significantly reduce any future effort on the topic of the present document or a related question.
- In Section 4.3.2 of "Analysis of Degradation Due to Water and Gases in MPC," a statement is made to the effect that a fill pressure greater than 152 kPa could lead to excessive internal pressure. However, neither the value of this excessive internal pressure nor its basis is stated. It was recommended that at some point during the design process such a pressure be determined and included in a suitable document.
- Discussion indicated that the potential for water leakage through pin holes (failures) in the zircaloy cladding of fuel rods was significantly greater in the past than at present. Possibly this source of water would exceed the permissible limit. It was recommended that this possibility be carefully evaluated in respect to criticality and, if necessary, older fuel rods be segregated from newer ones and be handled in a different manner so as to remove the water before emplacement in a repository.