

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT

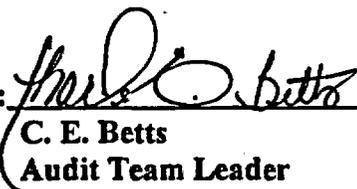
OF THE

**CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR**

CHARLOTTE, NORTH CAROLINA, NOVEMBER 11-14, 1996

VIENNA, VIRGINIA, NOVEMBER 21-22, 1996

AUDIT NUMBER MO-ARP-97-04

Prepared by: 
C. E. Betts
Audit Team Leader
Office of Quality Assurance

Date: 12/18/96

Approved by: 
Donald G. Horton
Director
Office of Quality Assurance

Date: 12/19/96

Enclosure

1.0 EXECUTIVE SUMMARY

As a result of Performance-Based Quality Assurance (QA) Audit MO-ARP-97-04, the audit team determined that the Civilian Radioactive Waste Management System Management & Operating Contractor (CRWMS M&O) is satisfactorily implementing adequate and effective QA process controls for analyses and technical documents in support of the Interim Storage Facility (ISF) Topical Safety Analyses Report (TSAR) generic design. The CRWMS M&O process controls examined during this audit were found to be in accordance with the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5. In addition, overall adequacy of and compliance to selected CRWMS M&O implementing procedures were found to be satisfactory.

The audit team identified one deficiency during the audit that was identical to conditions adverse to quality documented in existing OCRWM Deficiency Report (DR) YM-96-D-101. This deficiency will be addressed and corrected as part of the corrective action to DR YM-96-D-101. Details of this deficiency are described in Section 5.5.2. There were two deficiencies identified by the audit team that were corrected prior to the postaudit meeting. These two conditions are described in Section 5.5.4 of this report. Additionally, there were seven recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy and effectiveness of the CRWMS M&O controls for development of ISF TSAR generic design. The audit was intended to determine the degree to which the resultant products meet the program requirements and management commitments and expectations, as well as to determine whether the CRWMS M&O completed the work in accordance with implementing documents that address pertinent sections of the QARD.

The process/activities/end-products were evaluated during the audit, in accordance with the approved audit plan.

PROCESS/ACTIVITY/END-PRODUCT

Analyses and technical documents developed in support of the ISF TSAR generic design were selected for evaluation from Work Breakdown Structure (WBS) 3.1.3.3, ISF Design.

The performance-based evaluation of process effectiveness and product acceptability was based upon:

1. Classification of Permanent Items
2. Establishing Design Basis
3. Development of Technical Documents
4. Review and Approval of ISF Design/Technical Documents

TECHNICAL AREAS

The audit included a technical evaluation of process effectiveness and product acceptability. Details of the technical evaluation are included in Section 5.4.

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, their assigned areas of responsibility, and observers:

Name/Title/Organization

QA Program Elements/Requirements Technical Areas, Processes, Activities or End-products

Charlotte, North Carolina

C. E. Betts/Audit Team Leader/
Office of Quality Assurance (OQA)
Dan Tunney/Auditor/OQA
Ram Murthy/Observer/OQA

Process Steps 3 and 4
Process Steps 1 and 2

Vienna, Virginia

C. E. Betts/Audit Team Leader/OQA
Lester Wagner/Auditor/OQA
Ram Murthy/Observer/OQA

Process Steps 3 and 4
Process Steps 1 and 2

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

Preaudit meetings were held at the CRWMS M&O offices in Charlotte, North Carolina, on November 11, 1996 and Vienna, Virginia, on November 21, 1996. Daily debriefing and coordination meetings were held to discuss audit status. The audit was concluded with a

postaudit meeting held at CRWMS M&O offices in Charlotte, North Carolina, on November 14, 1996 and Vienna, Virginia, on November 22, 1996. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, the CRWMS M&O process controls are effectively being implemented for areas identified in the scope of this audit. The process controls for analyses and technical documents in support of ISF TSAR generic design were found to be effective.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation along with identification of the objective evidence reviewed. The checklists are maintained as QA Records.

5.4 Technical Activities

The following analyses and technical documents in support of the ISF Topical Safety Analysis Report (TSAR) generic design were in the process of development:

- classification analyses
- configuration item descriptions
- ISF design inputs
- accident analyses
- discipline design criteria
- configuration item design criteria
- nuclear analyses
- supporting analysis.

A sample of three classification analyses for configuration items (i.e, transfer facility, storage, and auxiliary) were evaluated. These analyses considered whether the following designations were applicable:

- Classification 1 - Important to Radiological Safety
- Classification 3 - Important Radioactive Waste Control
- Classification 4 - Important to Fire Protection
- Classification 5 - Important to Potential Interaction
- Classification 6 - Important to Physical Protection of Facility and Materials
- Classification 7 - Important to Occupational Radiological Exposure.

QA Classification 2 - "Important to Waste Isolation," was not assessed in these analyses since this applies only to the Mined Geologic Disposal Systems. The classifications of the subsystems (e.g. fire protection is a subsystem of auxiliary systems) within the configuration items were also determined. The audited organization suggested that the process for documenting the classification of subsystems be simplified. See Recommendation CR2 for details.

In addition to the classification analyses, a sample of six analyses included as part of the design basis were also evaluated. This included the following:

- Dual-Purpose Spent Nuclear Fuel (SNF) Transportation and Storage Systems Interface Information for the ISF
- Identification of ISF Design Basis Events
- ISF TSAR Structural Design Criteria
- ISF TSAR Fire Protection Systems Design Criteria
- ISF TSAR Transfer Facility Design Criteria
- ISF TSAR Storage Design Criteria.

With the exception of a deficiency which was corrected during the audit (see Section 5.5.4, C2), the analyses included appropriate documentation of purpose, method, assumptions, design input, and references. A recommendation regarding the level of detail of references was provided to the audited organization. See Recommendation CR3 for details. Also provided, was a recommendation regarding the elimination of the use of the term "Qualified: No" when referring to Draft reference documents identified as To Be Verified (TBV). See Recommendation CR1 for details.

TBV and To Be Determined (TBD) information were identified on analyses and were being tracked informally in Charlotte. However, at Vienna the above was being formally tracked in accordance with VLP-3-2, "TBD and TBV Monitoring."

See Recommendation VR1. A formal system for tracking these is not required at this time since these analyses are preliminary and are not used to support design output to be issued for procurement, fabrication, or construction.

5.5 Summary of Deficiencies

The audit team identified one deficiency during the audit for which a DR had already been issued under a previous OCRWM Surveillance Report, YM-SR-96-026. Therefore, an additional DR was not issued. Two additional deficiencies were identified and corrected prior to the postaudit meeting.

Synopses of the deficiency documented as a DR and those corrected during the audit are detailed below.

5.5.1 Corrective Action Requests (CAR)

There were no CARs identified as a result of this audit.

5.5.2 Deficiency Reports (DR)

Charlotte, North Carolina

Existing OCRWM DR YM-96-D-101

QARD, Revision 5, Section 2.2.10, states, in part: "Mandatory comments resulting from the review shall be documented and resolved before approving the document," and Section 5.2.2 states, in part: "Implementing documents shall include the following information as appropriate to the work to be performed:... Methods for demonstrating that the work was performed as required..." Contrary to the above: CRWMS M&O Quality Administrative Procedures (QAP)-3-8, "Specifications," QAP-3-9, "Design Analysis," and QAP-3-10, "Engineering Drawings," do not specify a method to identify which review comments are designated "mandatory" by the reviewer and do not specify a method to document resolutions of "mandatory" comments.

5.5.3 Performance Reports (PR)

There were no PRs identified as a result of this audit.

5.5.4 Deficiencies Corrected During the Audit

Deficiencies considered isolated in nature and only requiring remedial action may be corrected during the audit. The following deficiencies were identified and corrected during the audit:

Charlotte, North Carolina

- C1 QAP-3-9, Revision 6, Section 5.3.3D states that the reviewer shall ensure that the reviewer's comments are legible. Initial and date as the reviewer on the design analysis cover sheet if an individual design review copy for each reviewer is provided. Contrary to the above, this was not done for those design review comments generated by Rob Garrett and R. G. Eble on the QA Classification of the ISF Auxiliary Systems - Revision 00E. The auditor verified that the Design Analysis cover sheets for the above analyses had been initialed and dated as required prior to completion of the audit.**
- C2 QAP-3-9, Revision 6, Attachment I, Section 4.3, States in part, "Those assumptions requiring confirmation as the design proceeds shall be identified in this section, along with section numbers where they have been used. For frequently used assumptions, the comment "used throughout" may be substituted instead of individual references." Contrary to the above requirement, the following draft analyses identified the QA Classification of Subsystems as assumptions that required confirmation, but did not include a reference to where these assumptions were used:**
- A. CCC000000-01717-0200-00003, Revision 00B, ISF TSAR - Storage Design Criteria.**
 - B. CCB000000-01717-0200-00002, Revision 00C, ISF TSAR - Transfer Facility Design Criteria.**

Auditor verified that QA classifications of subsystems have been determined and these are no longer being considered assumptions. During the review of the above analyses, comments were generated by the mechanical and electrical systems organization to remove these assumptions.

5.5.5 Follow-up of Previously Identified CARs

This section was not applicable, as there were no previously issued CARs identified that would require follow-up.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by the CRWMS M&O management.

Charlotte, North Carolina

- CR1 The reference sections of two analyses use both designations "TBV" and "Qualified: No" to flag documents in draft stages (e.g., ISF Design Requirements Document). It was recommended that the term "Qualified: No" be removed from future revisions unless specifically referring to documents which use design parameters based on unqualified data. See Sections 3.12, 3.13, and Attachment 1, Section 4.1 of QAP-3-9, Revision 6, "Design Analysis" for discussions of the terms "Qualified Data" and "Unqualified Data".
- CR2 The QA Classification Analysis for the ISF Transfer Facility and ISF Storage Facility classified 19 and 9 subsystems respectively. Classification checklist for storage (six pages) were completed for both overall systems and associated subsystems. Results of checklist evaluations have been consolidated in tables. It was recommended that QAP-2-3, "Classification of Permanent Items" be revised to allow the use of one checklist when results of subsystem classification are presented in tables.
- CR3 References to Code of Federal Regulations (CFR) requirements are not provided to a consistent level of detail. For example, Section 7.2.3.2 of CCC000000-01717-0200-00003, Revision 00B, ISF TSAR - "Storage Design Criteria," includes three references to 10CFR Part 72 without referencing the specific paragraphs. Other portions of this document provide reference to 10CFR 72 Part 72.122, 130, etc. In other cases, the reference provides traceability to the sentences which specify the requirements. It is recommended that references to requirements be specified in a consistent manner to the level of detail necessary to ensure traceability to the requirements.
- CR4 Activity evaluations are no longer used to document whether activities are subject to QARD requirements. Section 2, second paragraph of QAP-2-0, Revision 3, "Conduct of Activities" states, "Activity evaluations prepared and distributed as controlled documents in accordance with the previous revision of this procedure will be decontrolled in accordance with QAP-6-1 following approval of this revision." Prior to canceling activity evaluations, the CRWMS M&O should evaluate whether documents such as Technical Document Preparation Plans reference these activity evaluations. In addition, Section 5.2C.10 and

Attachment I, VII of QAP-3-5, "Development of Technical Documents" should be revised to clarify that activity evaluations are no longer documented.

- CR5 Section 5.3.3A. of QAP-3-9, Revision 6, "Design Analysis" states, "The reviewer shall: Review the design review copy to determine the adequacy of the design relative to the reviewer's functional area." It is recommended that additional detailed review criteria be provided for reviewers as was provided for the checker in section 5.2.3.

Vienna, Virginia

- VR1 Vienna and Charlotte should be consistent in their implementation of VLP-3-2 (see Section 5.4).
- VR2 Assumptions should be identified, when being developed by the originator, prior to the final analysis review and approval process.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit

Attachment 2: Summary Table of Audit Results

ATTACHMENT 1
Personnel Contacted During the Audit
Charlotte, North Carolina

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
S. Bader	M&O/Engineer		X	
B. Broome	M&O/Senior Designer		X	
J. Cassidy	M&O/Quality Engineering Manager	X	X	X
R. Deklever	M&O/Engineer		X	
R. Garrett	M&O/Engineering Supervisor	X	X	X
J. Hartsell	M&O/Mechanical Engineer		X	
R. Howell	M&O/Engineer	X	X	X
J. Jenkins	M&O/Senior Engineer		X	
J. McConaghy	M&O/Engineering Supervisor	X	X	X
J. Stringer	M&O/ISF Design Manager	X	X	X
D. Williford	M&O/Senior Engineer		X	

ATTACHMENT 1
Personnel Contacted During the Audit
Vienna, VA

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
J. Blandford	M&O/Deputy Assistant General Manager	x		
G. Carruth	M&O/System Integration Manager		x	
J. Cassidy	M&O/Quality Engineering Manager	x	x	x
R. Eble	M&O/Engineering Supervisor	x	x	
S. Gillespie	M&O/System Engineer	x	x	
J. Hadley	M&O/Engineer		x	
R. Peck	QATSS/Quality Engineering Manager	x		
J. Stringer	M&O/ISF Design Manager			x
J. Watson	M&O/Vienna Training Manager	x		x
P. White	M&O/QA Sr. Specialist			x

ATTACHMENT 2
Summary Table of Audit Results
For Process/Product Evaluations

ACTIVITY	PROCESS STEPS	DETAILS (Checklist)	DEFICIENCIES	RECOMMEN- DATIONS	PROCESS EFFEC- TIVENESS	PRODUCT ADEQUACY	OVERALL
PERFORMANCE BASED							
M&O CRITERIA FOR TSAR DEVELOPMENT	CLASSIFICATION OF PERMENANT ITEMS	pgs. 1 (C&V)		REC# C2 & C5	SAT	SAT	SAT
	ESTABLISH DESIGN BASIS	pgs. 2-9 (C) pgs. 2-6 (V)	CDA# C2	REC# C1, C3, C5, V1 & V2	SAT	SAT	
	DEVELOP TECHNICAL DOCUMENTS	pgs. 1-5 (V)		REC# C4	SAT	SAT	
	REVIEW AND APPROVE ISF DESIGN/ TECHNICAL DOCUMENTS	pgs. 1-6 (C) pgs. 1-4 (V)	YM-96-D-101 CDA# C1		SAT	SAT	
TOTAL	Pages- Process: 30		3	7	SATISFACTORY		

"DOCUMENTS REVIEWED" includes the referenced procedure or process step and the associated records/objective evidence

CDA Corrected During Audit
 REC Recommendation
 C Charlotte, NC
 V Vienna, VA
 SAT Satisfactory

ADEQUACY Meets Requirements or Expectations
 COMPLIANCE .. Procedures Implemented
 EFFECTIVENESS Satisfies Measurement Criteria
 OVERALL Summary of Element or Process