

QA: QA

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT REPORT EM-ARC-00-17
OF THE
NATIONAL SPENT NUCLEAR FUEL PROGRAM
AT
IDAHO FALLS, IDAHO
AUGUST 14-18, 2000

Prepared by: _____ **Date:** _____

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**Office of Quality Assurance/
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Approved by: _____ **Date:** _____

Robert W. Clark
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

This Quality Assurance (QA) compliance-based audit was conducted at the Idaho National Engineering and Environmental Laboratory, Idaho Falls, Idaho, on August 14-18, 2000, to evaluate the QA Program elements directly related to the National Spent Nuclear Fuel (NSNF) Program for compliance to the Quality Assurance Requirements and Description (QARD), DOE/RW 0333P.

The audit team determined that compliance to the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) QARD, Revision 8, and the NSNF's implementing procedures, was overall satisfactory for QA Program elements: 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 16.0, 17.0, and 18.0. Elements 3.0, 11.0, and Supplements I and III were determined to have no implementation since the Office of Environmental Restoration and Waste Management (EM) audit in August of 1999. In addition, Supplement V was determined not to be applicable at this time.

The audit team identified several deficiencies during the audit that resulted in the issuance of six Deficiency Reports (DR): EM-00-D-138 – annual supplier performance evaluations per Project Management Procedure (PMP) 4.01 are not being performed; EM-00-D-139 – Memorandum of Agreements (MOA) failed to require implementation of the latest QARD revisions; EM-00-D-140 – the Document Action Requests (DAR) failed to list all the PMPs affected by a PMP revision; EM-00-D-141 – the Document Review Transmittals (DRT) and Review Comment Records (RCR) were not completed and sent to the Document Control Center prior to controlled distribution of MOA revisions; EM-00-D-142 – PMP-16.03, Quality Assurance Trending fails to address assignments of codes for multiple deficiencies on one document and cause codes were not consistent with accepted corrective actions or root cause evaluations; and, EM-00-D-143 – performance-based audits were not scheduled or performed. These adverse conditions are described in Section 5.5 of this report. Additionally, five recommendations are offered for the NSNF program management's consideration for improvement. The recommendations are described in Section 6.0 of this report.

The audit team noted that EM performed an impact analysis of QARD, Revision 9, and determined that changes to three of the PMP implementing procedures and the QARD Matrix were required. A schedule for the changes was submitted to the Office of Quality Assurance (OQA) Director. The impact analysis of QARD, Revision 10, determined that no impact occurred to the Project Management Procedures or QARD Matrix.

The audit team evaluated the effectiveness of the corrective actions on the Corrective Action Report (CAR) and ten DRs issued as a result of last year's EM-ARC-99-04 audit. The audit team determined the corrective actions to be effective. The evaluation results are described in Section 5.5.4 of this report.

The audit team identified a notable improvement in the area of Training. The Training Coordinator has developed an electronic system to send out delinquency notices whenever an individual failed to return a Training Assignment Acknowledgment form on time. The Training Coordinator demonstrated excellent control over the training process.

2.0 SCOPE

Auditors representing the OQA conducted a compliance-based audit to evaluate NSNF implementation of the OCRWM QA Program, as described in the QARD and implementing procedures at the NSNF facilities in Idaho Falls, Idaho.

In addition, the audit team reviewed the closed OCRWM deficiency documents identified during the previous OCRWM OQA audit to determine the effectiveness of completed corrective actions by NSNF.

The audit team conducted interviews and reviews of documentation to evaluate the adequacy, compliance, and effectiveness of implementation of the QA program at NSNF.

In accordance with the approved audit plan, the following QA program elements were evaluated:

QARD Program Elements

1.0	Organization
2.0	QA Program
3.0	Design Control
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
11.0	Test Control
16.0	Corrective Action
17.0	QA Records
18.0	Audits
Supp I	Software
Supp III	Scientific Investigation
Supp V	Control of the Electronic Management of Data

The following QARD program elements were not reviewed during the audit since NSNF is not currently implementing them:

8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
15.0	Nonconformances
Supp II	Sample Control
Supp IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation
Appendix C	Monitored Geologic Repository

3.0 AUDIT TEAM

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

<u>Name/Title/Organization</u>	<u>QA Program Elements</u>
Donald J. Harris, Audit Team Leader, OQA/Quality Assurance Technical Support Services (QATSS)	3.0, 4.0/7.0, 5.0, 17.0, and Supplement V
James Blaylock, Auditor, OQA	11.0, 16.0, and Supplements I and III
William J. Glasser, Auditor, OQA/QATSS	1.0, 2.0, 5.0, and 6.0
Kenneth T. McFall, Auditor, OQA/QATSS	2.0, 6.0, and 18.0

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at NSNF on Monday, August 14, 2000. Daily debriefings were held to apprise NSNF management and staff of the progress of the audit and any identified Conditions Adverse to Quality (CAQ). A post-audit meeting was conducted at NSNF on Friday, August 18, 2000.

Attachment 1, "Personnel Contacted During the Audit," includes those personnel who attended the pre-audit and post-audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, NSNF's implementation of the QA Program has improved significantly during the past year and was determined to be adequate and effective for QA Program elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 16.0, 17.0, and 18.0. Elements 3.0, 11.0, and Supplements I and III were determined to

have no implementation since the OCRWM OQA audit of the NSNF program in August 1999. In addition, Supplement V was determined not to be applicable at this time. The results for each QARD program element evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Action Taken

There were no Stop Work Orders or immediate corrective actions taken as a result of the audit.

5.3 QA Program Implementation

Attachment 2 provides results for each QA Program element audited. Details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of CAQ

The audit identified CAQ, which resulted in the issuance of DRs EM-00-D-138 through EM-00-D-143.

A synopsis of the CAQ documented on the DRs are detailed below. The DRs have been transmitted to NSNF under separate letters.

5.5.1 Corrective Action Request (CAR)

None issued.

5.5.2 Deficiency Reports (DR)

EM-00-D-138

There is no documented objective evidence in the NSNF Records Processing Center (RPC), filed under PMP 4.01, that NSNF performed annual supplier performance evaluations. Additionally, PMP 4.01, Subsection 4.3e, addresses supplier performance evaluations, but fails to provide the methodology.

EM-00-D-139

The MOA for Savannah River, Richland, Oak Ridge, and Idaho failed to require implementation of the QARD's latest revision. The QARD Requirements Matrices do not reflect QARD, Revision 10, and two MOAs failed to require the contractor to review QARD revisions to determine impacts on site QA Program and prepare a schedule for program and procedure revisions.

EM-00-D-140

DAR NSNF-125 failed to list all the affected PMPs; DAR NSNF-260 listed several PMPs - at least one PMP, 6.02, had no DAR or pending change; DAR NSNF-194 identified the change affects the QARD Matrix in total; however, no changes to the QARD Matrix were made.

EM-00-D-141

The DRTs and RCRs were not completed for three MOAs prior to submittal and distribution of the MOAs. The DRTs and RCRs were not in the RPC within the 60-day requirement.

EM-00-D-142

PMP-16.03, Revision 0, "Quality Assurance Trending," only allows a cause code for each deficiency document and does not address the assignment of codes for multiple deficiencies on one document. Deficiency documents had multiple elements with different corrective actions, and the PMP does not address how a single cause code is assigned. Assigned cause codes were not consistent with accepted corrective actions. Root cause determinations may have multiple cause codes identified, but the initial assigned cause code was not changed to reflect the root cause determination.

EM-00-D-143

NSNF has neither scheduled nor conducted performance-based audits of internal or external work.

5.5.3 Deficiencies Corrected During Audit

None.

5.5.4 Follow-up of Previously Issued Deficiency Documents

EM-99-C-005

NSNF completed records were not submitted to QA records in a timely manner. Ten examples were identified where the records were not captured, but subsequent records with a much later date were, and/or the records were incomplete or incorrect.

PMP 17.01, "Quality Assurance Records and Management Control," was completely rewritten to reflect a streamline process. The record review during this audit reflected an improved process. The corrective action was determined to be effective.

EM-99-D-083

NSNF quarterly status reports were not issued within the 30 working days required by PMP 2.01.

The PMP 2.01 Expedited Change Notice (ECN) was revised to state, "Quarterly status reports will normally be issued within 30 working days following each quarter." The Quarterly status reports, since the last audit, were issued within an acceptable time frame. The correction action was determined to be effective.

EM-99-D-084

Design input source documents were not transmitted to QA records, as required by PMP 3.01, Revision 1, "Design Control," for the Spent Nuclear Fuel (SNF) Canister or the High Integrity Can. This should have occurred prior to release of the final Controlled Design Input document.

PMP 3.01 was changed to require the design organization to maintain file copies of unique design input source documents not routinely available to the public, such as studies, analysis, field test, and DOE guidelines. The corrective action was determined to be effective.

EM-99-D-085

Implementation of PMP 16.02, Revision 3, "Corrective Action and Stop Work," was ineffective. The CAR Notification Log had not been generated, and the NSNF Action Tracking System, per PMP 2.02, was not complete or current and did not provide sufficient information to be useful for reporting or management of a Corrective Action Program. In addition,

PMP 16.02 did not provide quantitative or qualitative criteria for evaluating the CAR responses or verification of the corrective action.

PMP 16.02 was revised to provide quantitative and qualitative criteria for evaluating deficiency responses and verifications. A DR/CAR Log was generated that tracks and statuses the DRs/CARs. The corrective action was determined to be effective.

EM-99-D-086

PMP 2.04, Revision 2, "Personnel Indoctrination, Training and Qualification," did not address management responsibilities for qualification of personnel above the Program Manager/Team Leader (PM/TL) level. Assigned individual PMs/TLs signed their own qualification forms. In addition, there were management levels above the PM/TL that were not addressed in the procedure.

PMP 2.04 was revised to require PM/TL qualification evaluation of personnel to extend to all personnel, and the individual who signed the qualification must be at a functional position above the position being reviewed. The corrective action was determined to be effective.

EM-99-D-087

The impact analyses of QARD revisions were not sent to OCRWM OQA. Additionally, two PMPs did not identify the DAR in the revision history.

The QARD impact analysis for Revision 9 and the schedule for implementation were transmitted to the OQA Director. The Revision History on the revised PMPs were determined to be present and acceptable. The corrective action was determined to be effective.

EM-99-D-088

No objective evidence was provided that the approved MOAs were reviewed on an annual basis and revised, as required.

Three MOAs were revised this fiscal year, and one was reviewed and documented that no revision was required. The corrective action was determined to be effective.

EM-99-D-089

There were no time limits established for expedited changes to be processed through the normal change process in PMP 5.01.

A DAR #194 ECN was issued to PMP 5.01 to require processing into a revision after four changes, or semi-annually. NSNF initiated a DR for not processing expedited changes into a revision. It was determined the corrective action was effective.

EM-99-D-090

Names of the personnel contacted during the course of audit 98-NSNF-AU-037 were not documented on the checklist.

Missing information was included and the records were updated. The corrective action was determined to be effective.

EM-99-D-091

Surveillance Technical Specialists were not qualified and certified to the PMP 18.04 requirements.

The NSNF issued an ECN to PMP 18.03 to allow technical specialists, who are not qualified as auditors, to be used as surveillance team members. The corrective action was determined to be effective.

EM-99-D-092

PMP 19.01, Revision 0, "Computer Software Management," identifies the type and documentation needed for computer software management. Within the procedure, PMP 3.03, Revision 0, "NSNF Configuration Management," is referenced for the Configuration Management of the documentation generated by PMP 19.01. PMP 3.03 was not issued and two software packages should have been under formal configuration management.

NSNF issued DAR-244 to expedite a change to PMP 19.01 to incorporate the QARD requirements for Software Configuration Management. The corrective action was determined to be effective.

6.0 RECOMMENDATIONS

1. Revise PMP 2.04, “Personnel Indoctrination Training and Qualification,” to incorporate the methodology developed by the Training Coordinator for delinquency notices on past due training assignments.
2. Revise PMP 4.01, “Acquisition of Products and Services,” to correct Paragraph 4.b (11), which states: “Ensure changes that affect the technical or QA requirements for the work are processed in accordance with Subsection 4.c of this procedure,” which is evaluation of the Service Supplier QA Program. Procurement changes that affect technical or QA requirements should be processed the same as the original procurement document. Paragraph 4.f(1)(b) 3 requires completed DRT and RCR forms generated during the review of supplier technical documents. However, Paragraph 4.d.(2) does not require a PMP 6.01 review.
3. Revise PMP 4.01, “Acquisition of Product and Service,” to provide a definition of what constitutes “augmented staff” (e.g., an individual or organization that performs at the direction of the responsible NSNF manager. All work being performed and accepted in accordance with the OCRWM QARD approved NSNF QA Program and NSNF Project Procedures).
4. Revise the NSNF QA Program Qualified Suppliers List for John Marvin, Inc. The column for QA elements only reflects QARD, Supplement I, Software. Actually, the John Marvin, Inc. QA Manual is an 18 Criteria Manual that includes Supplement I.
5. PMP 16.02 should be more definitive in describing management follow-up for overdue corrective actions.

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

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Arenaz, M. R.	DOE-ID/NSNF/Manager	X		
Armour, D. A.	NSNF/QA Specialist	X		
Batt, D. L.	SNF, HLW/Director		X	
Bendixsen, C. L.	NSNF/Technical Lead		X	
Berg, V. E.	NSNF/QA Specialist	X	X	X
Blyth, R. L.	NSNF/QA Specialist	X		X
Bohrer H. A.	DOE-ID/QAD Director	X	X	
Burda, P. A.	NSNF/Technical Specialist			X
Cook, J. A.	NSNF/Advisory Engineer		X	
Dahl, C. A.	NSNF/Advisory Engineer		X	
Dalle, J. R.	NSNF/QA Specialist	X		
Davis, R. D.	DOE-ID/NSNF/QA Program Manager	X	X	X
Gladson, S. C.	NSNF/QA Technical Lead	X		X
Henderson, R. R.	NSNF/QA Specialist		X	
Hill, T. J.	NSNF/Technical Lead		X	X
Keating, M. C.	NSNF/QA Specialist	X	X	
Kido, Clarke	NSNF/QA Specialist	X	X	X
Luptak, A. J.	NSNF/QA Team Leader	X	X	
Loo, H. H.	NSNF/Technical Lead	X		
MacKay, N. S.	NSNF/QA Specialist	X		X
McCardell, J. L.	NSNF/Sr. Admin. Specialist		X	
McManamon, W. L.	NSNF/Document Control Coordinator	X	X	
Mena, Arturo	NSNF/QA Specialist	X		
Morgan, T. L.	NSNF/QA Specialist			X
Morton, S. L.	NSNF/Project Manager			X
Passey, Tana	NSNF HLW Program Support	X	X	
Reynolds, J. C.	NSNF/QA Specialist	X	X	X
Shaber, E. L.	NSNF/Advisory Engineer	X	X	
Smith, E. R.	NSNF/Advisory Specialist	X	X	
Smith, N. L.	NSNF/Advisory Engineer		X	

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Sowder, W. K.	NSNF/Technical Lead		X	
Taylor, L. L.	NSNF/Systems Engineer		X	
Truman, D. W.	NSNF/QA Specialist	X	X	
Wheatly, P. D.	NSNF/Technical Lead	X	X	

Legend:

- NSNF..... National Spent Nuclear Fuel
- SNF..... Spent Nuclear Fuel
- DOE-ID..... U.S Department of Energy-Idaho
- HLW High-Level Waste
- QA..... Quality Assurance

ATTACHMENT 2
SUMMARY TABLE OF AUDIT RESULTS

DETAIL SUMMARY								
QA Program Element	Implementing Documents	Details (✓) List	Deficiency Reports	CDAs	Recommendations	Program Adequacy	Procedure Compliance	Overall
1	PMP 1.01, Rev. 2	Pages 1-5	N	N	N	SAT	SAT	SAT
2	PMP 2.01, Rev. 2	Pages 6-7	N	N	N	SAT	SAT	SAT
	PMP 2.04, Rev. 3	Pages 8-11	N	N	#1	SAT	SAT	
	PMP 2.05, Rev. 2	Pages 12-14	N	N	N	SAT	SAT	
	PMP 2.06, Rev. 1	Pages 15-17	N	N	N	SAT	N/I	
3	PMP 3.01, Rev. 0	Pages 18-27	N	N	N	SAT	N/I	SAT
4/7	PMP 4.01, Rev. 2	Pages 28-33	EM-00-D-138	N	# 2, 3, 4	SAT	UNSAT	SAT
5	PMP 5.01, Rev. 3	Pages 34-39	N	N	N	SAT	SAT	SAT
	PMP 5.02, Rev. 5	Pages 40-46	EM-00-D-139	N	N	SAT	UNSAT	
6	PMP 6.01, Rev. 4	Pages 47-51	EM-00-D-140 EM-00-D-141	N	N	SAT	SAT	SAT
	PMP 6.02, Rev. 2	Pages 52-55	N	N	N	SAT	SAT	
11	PMP 11.01, Rev. 0 DAR 170, 231, and 269	Page 56	N	N	N	SAT	N/I	SAT
16	PMP 16.02, Rev. 4 DAR 270	Pages 57-58	N	N	# 5	SAT	SAT	SAT
	PMP 16.03, Rev. 0	Pages 59-60	EM-00-D-142	N	N	UNSAT	SAT	
	PMP 16.04	Pages 61	N	N	N	SAT	SAT	

DETAIL SUMMARY								
QA Program Element	Implementing Documents	Details (✓) List	Deficiency Reports	CDAs	Recommendations	Program Adequacy	Procedure Compliance	Overall
17	PMP 17.01, Rev. 3	Pages 62-68	EM-00-D-141	N	N	SAT	SAT	SAT
18	PMP 18.01, Rev. 2 DAR 120	Pages 69-73	EM-00-D-143	N	N	SAT	UNSAT	SAT
	PMP 18.02, Rev. 4	Pages 74-77	N	N	N	SAT	SAT	
	PMP 18.03, Rev. 4	Pages 78-82	N	N	N	SAT	SAT	
	PMP 18.04, Rev. 3	Pages 83-87	N	N	N	SAT	SAT	
SI	PMP 19.01, Rev. 0 DAR 243-244 and 259	Pages 88-89	N	N	N	SAT	N/I	SAT
SIII	Scientific Investigation	Page 56	N	N	N	SAT	N/I	SAT
SV	Control of Electronic Management of Data	Page 90	N	N	N	N/A	N/A	N/A
TOTAL		90	6	0	5			

Adequacy..... Procedures Contain Requirements
 CDA..... Corrected During Audit
 Compliance..... Procedures Implemented
 N/A..... Not Applicable
 N..... None

N/I..... No Implementation
 Overall..... Summary of Element
 PMP..... Program Management Procedures
 SAT..... Satisfies Criteria