



Department of Energy

Washington, DC 20585

QA: L

MAY 22 1997

J. H. Boyd, Program Manager
National Spent Nuclear Fuel Program
U.S. Department of Energy
Idaho Operations Office
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Idaho Falls, ID 83401-1563

EVALUATION OF RESPONSES TO DEFICIENCY REPORT (DR) YM-97-D-029, YM-97-D-030, AND PERFORMANCE REPORT (PR) YM-97-P-009 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) AUDIT EM-ARC-97-05 OF THE NATIONAL SPENT NUCLEAR FUEL PROGRAM

The OQA staff has evaluated the responses to DRs YM-97-D-029, YM-97-D-030, and PR YM-97-P-009. The responses have been determined to be satisfactory. Verification of completion of the remedial actions will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Charles C. Warren at (702) 794-1487.

Handwritten signature of Donald G. Horton

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1602

Enclosure:
DRs YM-97-D-029, YM-97-D-030
and PR YM-97-P-009

cc w/encl:
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RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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 Deficiency Report  
NO. YM-97-D-029  
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: PMP 18.02, Revision 1, Administration and Conduct of Audits	2 Related Report No. EM-ARC-97-05
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3 Responsible Organization: EM-67-NSNF Program	4 Discussed With: R. Davis
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5 Requirement/Measurement Criteria:  
PMP 18.02, Revision 1, Section 4.c(4), requires Audit Team Members to record conditions adverse to quality on a Deviation and Corrective Action Request (DCAR). The PMP Glossary of Terms and Acronyms, Revision 1, defines a condition adverse to quality as, "a state of noncompliance with quality assurance requirements or when implementing document requirements are not met."

6 Description of Condition:  
The below listed audit reports documented instances of noncompliance with QARD requirements and/or procedural requirements of PMPs as Observations rather than as DCARS.  
  
96-NSNF-AU-001  
97-NSNF-AU-002  
97-NSNF-AU-004

7 Initiator <u>C. C. Warren</u> C. C. Warren Date <u>4/4/97</u>	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Action: (Not required for PR)  
  
o Evaluate Observations issued during audits to identify those that document a state of noncompliance with quality assurance requirements (condition adverse to quality).  
o Assure Corrective Actions for Observations identifying conditions adverse to quality are tracked and completed in a timely manner.  
o Implement action to assure conditions adverse to quality are documented on DCARS in future

11 QA Review: QAR <u>C. C. Warren</u> Date <u>4-8-97</u>	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA Manager Issuance Approval: (QAR for PR) Printed Name <u>D. G. Horton</u> Signature <u>[Signature]</u> Date <u>4/15/97</u>
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22 Corrective Action Verified: QAR _____ Date _____	23 Closure Approved by: (N/A for PR) AOQAM _____ Date _____
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PR/DR NO. YM-97-D-029

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Attachment.

15 Extent of Condition: (Not required for PR)

See Attachment.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

See Attachment.

18 Corrective Action Completion Due Date:

June 30, 1997

19 Response by:

*As D. Anderson for*  
Robert D. Davis

Initial

NSNF QAPM

Amended

Date 5/14/97 Phone (208) 526-4244

20 Response Accepted

QAR *C.C. Wan*

Date 5-16-97

21 Response Accepted (QA for PR)

*ASB*

Date 5/22/97

PERFORMANCE /DEFICIENCY REPORT - No. YM-97-D-029, ( Attachment )  
( Reference OCRWM Administrative Procedure, AP-16.1Q )

YM-97-D-029, Block 14 - Remedial Actions:

Perform a review of all the NSNF program audit reports and the Observations identified by NSNF program auditors to date. Determine if the documented Observations were reported to appropriate management and whether formal responses were required or requested. Where Observations have been brought to the attention of appropriate management, with corrective actions requested and initiated, no determination in relation to the use of an Observation in lieu of a DCAR for identifying the condition, will be required. Determine that Observations where formal corrective action was requested are either closed or being tracked to assure a proper resolution. Determine that the Observations where corrective action was not requested, were indeed reported to appropriate management and that corrective action has been considered and initiated. Assure that all corrective actions needed to address identified Observations that have not been completed are placed in the NSNF Commitment Tracking System (CTS) to allow proper tracking and closure.

YM-97-D-029, Block 15 - Extent of Condition;

To date, NSNF Auditors have performed and reported the results of five formal audits. The five audits consisted of both internal and external audits and resulted in the identification of 54 Observations. For all but 18 of the identified Observations, the Audit Team Leader (ATL) required the audited organization to respond to the Observations and provide a corrective action. For the 18 Observations that were identified with no response required, a proposed corrective action was indeed provided and a subsequent audit verified that corrective actions were completed and closed out. The cognizant Audit Team Leaders requested corrective action responses for each of the remaining 36 Observations. Of these, 15 have been input to the Commitment Tracking System (CTS), 13 will be closed as a result of a follow-up audit conducted the week of May 5, 1997, the other 8 will be input into CTS by May 17, 1997. All Observations identified in the audit reports were being tracked by the ATLs with the intent to address proposed corrective action and follow-up verifications. NSNF Program Management Procedures (PMPs), 18.02, "Administration and Conduct of Audits" and PMP 16.02, "System Deviations and Corrective Actions" provide the requirements for performing audits and reporting deficiencies and potential problems by using DCARs and Observations; however, the program auditors are allowed to use their own judgment when selecting the appropriate document. The PMPs are not clear about the method for tracking Observations where corrective actions have been requested.

YM-97-D-029, Block 17 - Action to Preclude Recurrence:

PMPs 16.02, "System Deviations and Corrective Action", PMP 18.02, "Administration and conduct of Audits", and PMP 18.03, "Administration and conduct of Surveillances" will be revised to more clearly define the use of Observations to identify concerns discovered while performing audits. New guidance will be added requiring ATLs and Auditors to provide sufficient information within the audit reports to justify why a given Observation is not classified as a condition adverse to quality. NSNF Audit Team Leaders and auditors will be required to review this audit finding and receive additional training by completing a required reading assignment for the revised PMPs.

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Program Management Procedures - NSNF	2 Related Report No. EM-ARC-97-05
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3 Responsible Organization: EM-67 NSNF	4 Discussed With: Tom Lewallen, Vance Berg, Greg Law
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5 Requirement/Measurement Criteria:  
PMP 5.02, Section 4.e.1(c) states, "After resolution of comments and acceptance of the M&O contractor's QARD requirements matrix, [the QAPM] schedules and conducts an on-site implementation audit of the M&O's QA program in accordance with PMP 18.01 and PMP 18.02."

6 Description of Condition:  
In violation of the sequence established in PMP 5.02, Section 4.e.1(c), the on-site implementation audit of the Savannah River Site (SRS) was conducted before complete resolution of comments and acceptance of the SRS QARD requirements matrix.

7 Initiator J. E. Clark <i>J.E. Clark</i> Date 4/4/97	9 Is condition an isolated occurrence? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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- 10 Recommended Action: (Not required for PR)
- o Document the resolution of comments and the acceptance of the SRS QARD requirements matrix.
  - o Evaluate the impact of conducting the SRS implementation audit before acceptance of the QARD requirements matrix.
  - o Determine if the QA program acceptance process needs greater sequencing flexibility and revise PMP 5.02 as appropriate.

11 QA Review: QAR <i>J.E. Clark</i> Date 4/8/97	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA Manager Issuance Approval: (QAR for PR) Printed Name: D. G. Horton	Signature: <i>[Signature]</i> Date 4/15/97
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22 Corrective Action Verified QAR _____ Date _____	23 Closure Approved by: (N/A for PR) AOQAM _____ Date _____
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Attachment.

15 Extent of Condition: (Not required for PR)

See Attachment.

16 Root Cause Determination: (Not required for PR)

Required  Yes  No

17 Action to Preclude Recurrence: (Not required for PR)

Required  Yes  No

See Attachment.

18 Corrective Action Completion Due Date:

June 30, 1997

19 Response by: *H. W. Anderson for*  
Robert D. Davis, NSNF QAPM

Initial

Amended

Date 5/14/97 Phone (208) 526-4244

20 Response Accepted

QAR *J. E. Clark*

Date 5/16/97

21 Response Accepted (N/A for PR):

*[Signature]*

Date 5/22/97

PERFORMANCE/DEFICIENCY REPORT - No. YM-97-D-030, ( Attachment )

YM-97-D-030, Block 14 - Remedial Actions:

Review the documentation associated with the receipt, review, and resolution of comments for the SRS QARD requirements matrix. Assure that deficiencies noted were identified and provided to SRS management for resolution and that a schedule for completion of the planned corrective actions was provided. Verify acceptance of the proposed corrective actions and determine if corrective actions have been completed and/or the current schedule for completion and acceptance of the SRS requirements matrix. Establish the events in chronological order, including the original schedule for review of the Matrix and for performing the subsequent implementation audit. Determine the ramifications of performing the SRS implementation audit and acceptance of the SRS program prior to final acceptance of the SRS QARD requirements matrix. Review PMP 5.02, "Program Execution Documents" and determine the need for revising the sequence or chain of events needed to allow proper acceptance of both the documented QA programs and the subsequent verification of implementation of those programs.

YM-97-D-030, Block 15 - Extent of Condition:

In June of 1996, the NSNF program initiated a request for DOE-SR to submit a QARD requirements matrix identifying the procedures that the M&O Contractor would use implement the applicable requirements of DOE/RW-0333P relative to their SNF activities. In July of 1996, DOE-SR submitted the WSRS matrix and the NSNF program initiated a review. The submitted matrix and implementing procedures addressed Revision 4 of the QARD and WSRS was in the process of updating the matrix and procedures to meet the requirements of Revision 5 and re-submit it prior to the implementation audit, which was tentatively scheduled for November 1996. In November 1996, the NSNF program scheduled a scoping visit to SRS to discuss the revised matrix and conduct a preliminary informal review of the SRS QA program. This visit was conducted December 3 through 5, 1996. The NSNF program received the revised matrix, completed the review, documented the results on Review Comment Records (RCR) forms, and transmitted the RCR forms to DOE-SR on December 17, 1996. On December 20, 1996, the NSNF program scheduled the DOE-SR implementation audit for the week of February 9, 1997. At this time the RCR forms with the responses to the matrix review comments had not been received. On January 24, 1997, the NSNF program received the completed RCR forms with the WSRS proposed comment resolutions. With the implementation audit scheduled two weeks later the NSNF program made a decision to evaluate the WSRS proposed responses, during the implementation audit. The audit team evaluated the WSRS responses and proposed corrective actions during the audit and found that several of the proposed corrective actions were inadequate or incomplete. The problems identified were documented as Observations in the audit report, and DOE-SR was requested to respond to the observations and provide corrective actions. All the observations were being tracked for resolution and closure. A follow-up visit was conducted the week of the week of May 5, 1997 to evaluate resolution of the observations identified during the implementation audit. The observations that identified the incomplete resolutions for the original matrix RCR forms were indeed completed and ready for closure. The final closure of the observations and acceptance of the WSRS QARD requirements matrix will be addressed in a memorandum that will be issued the week of May 19, 1997, and all issues will be evaluated during the follow-up implementation audit scheduled for September 1997.

In summary, the implementation audit was indeed conducted prior to final acceptance of the matrix; however, the deficiencies noted during the matrix review were documented and later evaluated during the audit. The incorrect and incomplete corrective actions were documented as "Observations" during the audit and were being tracked for correction, verification and closure. At the exit meeting for the implementation audit, WSRS was given a verbal acceptance of their QA program. This was followed by a letter of acceptance dated March 6, 1997. The transmittal memorandum for the WSRS audit report dated March 14, 1997 again notified WSRS of acceptance of their QA program based upon the audit results and correcting the identified deficiencies and observations. PMP 5.02, "Program Execution Documents" does provide the sequence for acceptance of a documented QA program prior to performing an implementation audit; however, the impact of acceptance of the WSRS QA program prior to their QARD requirements matrix is negligible.

YM-97-D-030, Block 17 - Action to Preclude Recurrence.

PMP 5.02 will be revised to relax the rigid sequence for QA program acceptance. Where deficiencies are noted during documentation reviews, and properly identified for tracking purposes, the implementation audit may be utilized as the vehicle for verification and closure of open document issues.

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DS  
4/9/97

**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: QARD, Revision 5	2 Related Report No. EM-ARC-97-05
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3 Responsible Organization: EM-67-NSNF Program	4 Discussed With: R. Davis
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5 Requirement/Measurement Criteria:  
QARD, Revision 5, Section 17.2.1.A requires that documents that provide evidence of the quality of those activities associated with the characterization of DOE Spent Fuel, and conditioning through acceptance of DOE Spent Fuel be classified as lifetime QA records.

6 Description of Condition:  
PMP 18.03, Revision 1, "Administration and Conduct of Surveillances" designates surveillance reports that may document the quality of work activities as nonpermanent quality records.

7 Initiator <u>C.C. Warren</u> C. C. Warren                      Date <u>4/4/97</u>	9 Is condition an isolated occurrence? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown; Must be Yes if PR
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10 Recommended Action: (Not required for PR)

11 QA Review: QAR <u>C.C. Warren</u> Date <u>4-8-97</u>	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA Manager Issuance Approval: (QAR for PR)	
Printed Name    C. C. Warren	Signature <u>C.C. Warren</u> Date <u>4-8-97</u>

22 Corrective Action Verified QAR    Date	23 Closure Approved by: (N/A for PR) AOQAM    Date
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**PERFORMANCE/DEFICIENCY REPORT RESPONSE**

**14 Remedial Actions:**

PMP 18.03, "Administration and Conduct of Surveillances," will be revised to identify surveillance reports as "project lifetime records." Obtain the surveillance reports for surveillances 97-NSNF-S-003 and 97-NSNF-S-014 from the NSNF Document Control Center and reidentify them as project lifetime records.

**15 Extent of Condition: (Not required for PR)**

NSNF auditors have completed two surveillances and submitted the surveillance reports to the NSNF Document Control Center - surveillances numbered 97-NSNF-S-003 and 97-NSNF-S-014.

**16 Root Cause Determination: (Not required for PR)**

Required  Yes  No

**17 Action to Preclude Recurrence: (Not required for PR)**

Required  Yes  No

**18 Corrective Action Completion Due Date:**

June 30, 1997

**19 Response by:**

R. D. Davis, NSNF QAPM *A.D. Anderson for*

Initial  
 Amended

Date 5/14/97

Phone (208) 526-4244

**20 Response Accepted**

QAR

*CC. Wa*

Date *5-16-97*

**21 Response Accepted (N/A for PR):**

AOQAM

*N/A*

Date