



Department of Energy

Washington, DC 20585

QA: QA

APR 11 2003

MEMORANDUM FOR: Mark R. Arenaz, DOE/ID

FROM: R. Dennis Brown, Director
Office of Quality Assurance

SUBJECT: Verification of Corrective Action and Closure of Deficiency Report (DR) EM(O)-03-D-004 Resulting from Inconsistency Between National Spent Nuclear Fuel Program Procedures and Quality Assurance Requirements and Description

The Office of Civilian Radioactive Waste Management staff has verified the completion of the corrective actions of DR EM(O)-03-D-004 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either Kerry M. Grooms at (702) 794-1367 or Patrick V. Auer at (702) 794-1353.

OQA:KMG-1030

Enclosure:
DR EM(O)-03-D-004

cc w/encl:
C. A. Kouts, DOE/HQ (RW-20E), FORS
N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV (2 cys)
S. W. Lynch, State of Nevada, Carson City, NV
L. W. Bradshaw, Nye County, Pahrump, NV
P. V. Auer, NQS, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
W. J. Arthur, III, DOE/ORD (RW-2W), Las Vegas, NV
B. M. Terrell, DOE/ORD (RW-40W), Las Vegas, NV



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ORIGINAL
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8. Deficiency Report
 Corrective Action Report

No EM(O)-03-D-004

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1 Controlling Document (Document ID and Revision or Date)
 DOE/RW-0333P, Revision 12, *Quality Assurance Requirements and Description*
 (QARD)

2 Related Report No
 EM-ARC-02-10

3. Responsible Organization
 National Spent Nuclear Fuel Program (NSNFP)

4 Discussed With
 Don Arnold, Bob Blyth

5 Requirement:

a) QARD, Section III.2.6.F requires that "Technical review through publication in a referred professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following"

b) QARD Supplement I.2.1A requires that software acquisition, development, modification and maintenance to proceed "in a planned, traceable and orderly manner utilizing a defined software life-cycle methodology."

c) QARD Supplement III.2.6.A requires in part, "Model development and approaches to validation shall be planned, controlled, and documented."
 (Continued on page 2)

6 Description of Condition

a) Contrary to the above requirement, NSNFP procedure PSO 3.03, Revision 1, *Engineering Analysis*, 01/15/2002, Section III.B.1.b 4, allows model validation using a "technical review through publication in open literature" without corroboration. NSNFP is generating technical reports, e.g , DOE/SNF/REP-071, Revision 1 and DOE/SNF/REP-078 (draft), which indicate in their respective summary and analysis plan that a model is documented.

b) Contrary to the requirement, NSNFP Procedure PSO 19-01, Revision 1, *Software Control*, 1/25/2002, Section II, does not provide a methodology to implement the requirement.

c) Contrary to the requirement, NSNFP Procedure PSO 3.03, Revision 1, 1/25/2002, Section III.B, does not provide a methodology to implement the requirement.
 (Continued on page 2)

Has work been stopped? Yes No

7. Initiator
 Patrick V. Auer *Patrick Auer* 10/8/2002
 Printed Name Signature Date

9 Does a stop work condition exist?
 Yes No N/A
 If Yes, Check One A B C D

10 Recommended Actions
 None.

11. QAR Review
 Patrick V. Auer *Patrick Auer* 10/8/2002
 Printed Name Signature Date

12 Response Due Date
 10 Working days after issuance

13 QAM Issuance Approval
 R. Dennis Brown *James Blaylock* 10/17/02
 Printed Name Signature Date

14 Corrective Actions Verified/Closure:
 Pat Auer *Pat Auer* 4/9/2003
 QAR Printed Name Signature Date

15 QAM Closure Approval
 RD Brown *RD Brown* 4/10/03
 Printed Name Signature Date

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

5. Requirement: (Continued)

- d) QARD, Supplement III.2.6.B.6 requires a "discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases."
- e) QARD, Section 2.2.10.C states, "The review shall be performed by individuals other than the preparer."

6. Description of Condition: (Continued)

- d) Contrary to the requirement, NSNFP procedure PSO 3.04, *Engineering Documentation*, Attachment A, does not provide guidance or methodology to require the procedure user to provide the required information.
- e) Contrary to the requirement, NSNFP Procedure PMP-6.01, Revision 6, *Review and Approval of NSNFP Internal Documents*, does not address the requirement. For example, during the review of QAPP-001, Revision 01, the originator was identified on the Document Review Transmittal as a mandatory reviewer.

2. Check if Amended

3 Extended Processing
 No Yes (If yes, submit
 Extended Processing request)

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT INITIAL RESPONSE

4. Immediate Actions Necessary to Bring the Process Under Control: (If none, provide justification statement)

Blocks 5 and 6 of deficiency report EM(0)-03-D-004 are subdivided into five sections labeled a) through e). The following response in this block corresponds to those subsections.

- a) Prior to the release of QARD Revision 11, a technical review through publication in open literature without corroboration was an acceptable singular approach to model validation. No model validation activities have taken place subsequent to the release of QARD Rev 11. Therefore no impact has occurred prior to release of Revision 11 (5/3/02). This determination appears to be consistent with the following communication of April 3, 2002 between NSNFP and OQA. The effect of this communication and the non-prescriptive nature of the QARD Revision Impact Evaluation Process itself should be considered as a separate issue.

From Duane_Allred@notes ymp gov [mailto:Duane_Allred@notes ymp gov]
 Sent: Wednesday, April 03, 2002 8:05 AM
 To Blyth, Robert L
 Subject: QARD Revision 11 Impact Analysis

A preliminary impact analysis of QARD Revision 11 was conducted earlier by your organization using the final draft This revision was approved 03/27/02 with no changes to the final draft Accordingly, no further impact evaluation for this revision is necessary.

The effective date established for QARD Revision 11 is 05/03/02

- b) An uncontrolled working copy of a detailed NSNFP QARD Requirements Matrix, provided as a courtesy for "information only" to OQA. This detailed matrix was not current with respect to NSNFP implementation of QARD Supplement I. Use of this incomplete draft matrix appears to have influenced the assessment.

PSO 19.01 Revision 1 was designed to meet the full spectrum of requirements from QARD Rev 10 Supplement I for the known and potential work scope of NSNFP in manner consistent with the size and complexity of the organization. The process includes using a traditional hardcopy document control system to document software configurations and changes thereto.

Since the draft supplemental matrix is not an implementing document and a previous review by OQA found of PSO 19.01 Revision 1 to be acceptable, no impact has occurred.

- c) The PSO 3 03 Revision 1 Step III. A.1 and Step III.B. 1.a provide a methodology to implement QARD Rev 10, Supplement III. 2.6 A. Further, PSO 3.03 also specifies that engineering analyses be documented in accordance with PSO 3.04, Engineering Documentation. PSO 3.04 Rev 1 page 10 of 12 requires that engineering analyses include documentation of the approach used for model validation.

Since NSNFP procedures require planning, control and documentation of model validation, no impact has occurred.

- d) PSO 3.04 Revision 1 page 10 of 12 requires that documentation of engineering analyses "...provides a description of systems, processes, or phenomena analyzed and the scientific, engineering, and mathematical concepts and principles on which the analysis are based ...along with a description of the calculations, models, or other analytical processes used to translate the inputs into the outputs." This language communicates the QARD Supplement 2.6.B 6 requirement to the NSNFP Technical Staff. . Since implementation of PSO 3 04 Revision 1 results in an outcome consistent with the requirement as stated in QARD Revision 11 Supplement 2.6.B.6, no impact has occurred.

- e) The cited QARD requirement does not preclude the originator from participating in the review but merely requires that other reviewers be included. In the case cited by the deficiency report, reviewers other than the preparer participated in the review of DOE/SNF/QAPP-001. Consistent with QARD section 2.2.10.E, multiple reviewers representing each of the applicable organizations within NSNFP are required per NSNFP PMP 6.01 Revision 7. Consistent with NSNFP procedures, no cases have occurred where the preparer was the sole reviewer representing the NSNFP Management, NSNFP QA, or NSNFP Technical Staff. For the above reasons, no impact has occurred.

Date when process will meet requirements: None

5. Immediate Remedial Actions Completed:

To ensure proper sequencing of corrective actions related to this deficiency report, PMP 6.01, "Review and Approval of NSNFP Internal Documents" was immediately revised to specify that reviews should be performed by other than the preparer. This change was captured in PMP 6.01 Revision 7 with an effective date of 11/13/02.

6. Plan for Determining the Extent of Condition:

Review the NSNFP QARD Requirements Matrix against QARD Rev 11 Supplements I and III to determine any omissions in NSNFP implementing documents. Revise NSNFP procedures, as needed. As a minimum, revise NSNFP procedure steps addressing model validation to align with QARD Rev 11 Supplement III.

7. Due Date for Submittal of Completed Response:
2/14/03

8. Response by: (Responsible Manager)

R. Blyth, NSNFP QAPM



12/11/02
Date

9. QAR Evaluation: Accept Partially Accept Reject

Pat Auer
Printed Name



1/9/2003
Date

10. QAM Concurrence:

DENNIS BROWN
Printed Name



1/16/03
Date

AP-16.1Q.7

Rev. 03/25/2002

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REQUEST FOR EXTENDED PROCESSING

3. Extended Actions: (Identify those corrective actions planned for completion beyond 100 days from issuance of the DR/CAR)

Review the NSNFP QARD Requirements Matrix against QARD Rev 11 Supplements I and III to determine any omissions in NSNFP implementing documents in sufficient detail to respond fully to the deficiency report. Based on the review, revise the applicable NSNFP procedures, as needed.

Expected Completion Date: 2-26-03

4. Justification: (Provide an explanation as to why the required actions cannot be completed within 100 days)

Mandatory INEEL work curtailments must be factored into the schedule.

5. Impact: (Provide an impact statement to indicate what affect not completing within 100 days will have relative to waste isolation and safety, and impact to other work, if any)

With respect to the repository licensing activity, performance assessment and performance confirmation modeling and analysis is a function of OCRWM. Therefore no impact exists that affects the repository safety case.

Validation of all models currently in use by NSNFP completed prior to the release of QARD Rev 11. The need to perform additional new validation activities is not indicated based on the currently planned work for FY 2003. Therefore no impact exists as a result of exceeding the 100-day guideline.

Approvals

6. Responsible Manager:

Don Armour *Don Armour* 1-08-03
Printed Name Signature Date

7. Senior Manager:

ROBERT R. LYTT *[Signature]* 1/6/03
Printed Name Signature Date

8. DOE Project Management

Printed Name Signature Date

9. DOQA:

Printed Name Signature Date

10. Director, OCRWM (required for scheduled completion dates one year or more from initial issue)

Printed Name Signature Date

2. Check if Amended
 3. Extended Processing
 No Yes (If yes, submit Extended Processing request)

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition investigations are not complete and documented herein)

A review of the NSNFP QARD Requirements Matrix based on QARD Revision 10 against QARD Revision 12 indicates revisions to NSNFP QA Program implementing documents effective as of 2/10/03 are needed to fully incorporate the following sections of QARD Revision 12.

Supplement I Software

QARD Sections I.2.2.C.2, I.2.3.B.2.f, I.2.3.D.4, II.2.3.F.1, I.2.4.A, I.2.8.A, and I.2.8.D.

Supplement III Scientific Investigation

QARD Section III.2.6.F

QARD Glossary Terms

- Model, Abstraction
- Model, Conceptual
- Model, Mathematical
- Model, Process
- Model, System
- Model, Validation
- Transparent

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

No model validation activities have been performed by NSNFP post release of QARD Revision 11. Updates to NSNFP PSO 19.01 are for clarification only and do not affect current software activities performed by NSNFP.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)

Revise NSNFP Procedures PSO 3.03, PSO 3.04, PSO 19.01 and the NSNFP Documents Manual Introduction and Glossary to incorporate QARD revision 12 sections as listed block 4 above.

7. Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16.4Q)
 Apparent Cause

None

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

NA

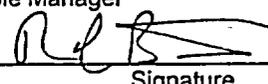
9. Due Date for Completion of Corrective Action:

3/31/03

10. Responsible Manager

Robert Blyth

Printed Name



Signature

2/10/03

Date

11. QAR Evaluation: Accept Partially Accept Reject

12. QAM Concurrence:

Printed Name

Signature

Date

Printed Name

Signature

Date

2. Check if Amended

3. Extended Processing
 No Yes (If yes, submit Extended Processing request)

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition investigations are not complete and documented herein)

A review of the NSNFP QARD Requirements Matrix based on QARD Revision 10 against QARD Revision 12 indicates revisions to NSNFP QA Program implementing documents effective as of 2/10/03 are needed to fully incorporate the following sections of QARD Revision 12.

Supplement I Software

QARD Sections I.2.2.C.2, I.2.3.B.2.f, I.2.3.D.4, II.2.3 F.1, I.2.4.A, I.2.8.A, and I.2.8.D.

Supplement III Scientific Investigation

QARD Section III.2.6.A, III.2.6.B.6, and III.2.6.F.

QARD Glossary Terms

- Model, Abstraction
- Model, Conceptual
- Model, Mathematical
- Model, Process
- Model, System
- Model, Validation
- Transparent

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

No model validation activities have been performed by NSNFP post release of QARD Revision 11. Updates to NSNFP PSO 19.01 are for clarification only and do not affect current software activities performed by NSNFP.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)

Revise NSNFP Procedures PSO 3.03, PSO 3.04, PSO 19.01 and the NSNFP Documents Manual Introduction and Glossary to incorporate QARD revision 12 sections as listed block 4 above.

7. Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16 4Q)
 Apparent Cause

None

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

NA

9. Due Date for Completion of Corrective Action:

3/31/03

10. Responsible Manager

Robert Blyth

Printed Name

Signature

03/19/03

Date

11. QAR Evaluation: Accept Partially Accept Reject

Pat Auer

Signature

3/20/03

Date

12. QAM Concurrence:

Dennis Brown

Printed Name

Signature

3/20/03

Date

Not Significant Ad. 3/20/03

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REQUEST FOR EXTENDED PROCESSING

3. Extended Actions: (Identify those corrective actions planned for completion beyond 100 days from issuance of the DR/CAR)

Revise NSNFP Procedures PSO 3.03, PSO 3.04, PSO 19.01, and the NSNFP Documents Manual Introduction and Glossary to incorporate QARD Revision 12 sections as listed in Block 6 of the revised response for EM-ARC-02-10/EM(O)-03-D-004, dated February 10, 2002.

Expected Completion Date: April 11, 2003

4. Justification: (Provide an explanation as to why the required actions cannot be completed within 100 days)

Extension time is required to define the required changes, appropriately revise the subject procedures, and complete the required NSNFP reviews prior to issue. The extension time requested includes time to assemble and transmit a closure package for RW OQA approval.

5. Impact: (Provide an impact statement to indicate what affect not completing within 100 days will have relative to waste isolation and safety, and impact to other work, if any)

None. No model validation activities have been performed by NSNFP post release of QARD Revision 11. Updates to NSNFP PSO procedures are for clarification only and do not affect current software activities performed by NSNFP.

Approvals

6. Responsible Manager:

D. A. Armour D.A. Armour 2-25-03
Printed Name Signature Date

7. Senior Manager:

R. L. Blyth R. L. Blyth 2/25/03
Printed Name Signature Date

8. DOE Project Management

Ronald A. Miller 3-24-03
Printed Name Signature Date

9. DOQA:

Dennis Brown 3/9/03
Printed Name Signature Date

10. Director, OCRWM (required for scheduled completion dates one year or more from initial issue)

N/A N/A N/A
Printed Name Signature Date

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VERIFICATION OF CORRECTIVE ACTIONS FOR DEFICIENCY REPORT (DR) EM(O)-03-D-004

Verification of corrective actions for DR EM(O)-03-D-004 was performed on April 9, 2003. The following documents were reviewed with regard to NSNFP procedures not meeting the QARD, revision 12:

1. PMP 6.01, Revision 7, dated 11/13/2002, "Review and Approval of NSNFP Internal Documents"
2. INTRODUCTION, Revision 1, dated 4/2/2003, "NSNFP Document Manual Introduction and Glossary"
3. PSO 3.03, Revision 2, dated 4/2/2003, "Engineering Analysis"
4. PSO 3.04, Revision 2, dated 4/2/2003, "Engineering Documentation"
5. PSO 19.01, Revision 2, dated 4/2/2003, "Software Control."

Based on the reviews of the revised NSNFP procedures, it is recommended that DR EM(O)-03-D-004 be closed.

Evaluation by Pat Auer QAR, April 9, 2003
Pat Auer