




Department of Energy

Washington, DC 20585

QA: QA

APR 24 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-006 Resulting From Not Having Implementing Procedures to Control Spent Nuclear Fuel Activities at the National Spent Nuclear Fuel Program

The Office of Civilian Radioactive Waste Management staff has verified the completion of the corrective actions of DR EM(O)-03-D-006 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 Samuel E. Archuleta at (702) 794-1476.

OQA:KMG-1048

Enclosure:
DR EM(O)-03-D-006

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
S. E. Archuleta, NQS, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
D. G. Opielowski, NQS, 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(0)-03-D-006
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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
 Neal MacKay, Chris Dahl, Rob Batten

5. Requirement

QARD, Section V.1 states in part, "This supplement applies to processes and controls for the management of data that either exist or are used in an electronic format. This includes electronic formatted data used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling analysis."

6. Description of Condition:

INEEL personnel using the Goth_SNF Software Program routinely transfer electronic files from a computer workstation to a PC and vice versa. The NSNFP does not have process controls in the form of an implementing procedure to address the requirements of Supplement V of the QARD.

Has work been stopped? Yes No

7. Initiator:
 Samuel E. Archuleta *Samuel Archuleta* 10-8-02
 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
 SA E. ARCHULETA *Samuel Archuleta* 10-8-02
 Printed Name Signature Date

12. Response Due Date
 10 Working days after issuance

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

14. Corrective Actions Verified/Closure
Samuel Archuleta 4-10-03
 QAR Printed Name Signature Date

15. QAM Closure Approval
 R.D. Brown *R. Dennis Brown* 4/23/03
 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)

The NSNFP technical work that relies on data derived from Goth SNF Software Program has been controlled and disseminated in hardcopy paper media. Data selected is fully transparent in the NSNFP Technical Reports provided in hardcopy paper media. Reviews (checking) for accuracy of the information relied on for NSNFP technical reports have been performed as part of the hardcopy document review and approval process. None of the information has been provided in electronic format as repository design input, NSNFP design output, support for the repository performance assessment, or as a scientific investigation output for the repository performance assessment. The Goth-SNF Software program has been verified and validated.

The NSNFP technical work relying on Goth generated data is related to analysis of a SNF MCO package response to theoretical breaches. The results of this analysis may be used to help evaluate RW facility reactions to the event. This beyond-category-2 analysis is not part of the licensing activity and is not part of the Repository Safety Case. Therefore no impact exists that affects the current Repository Safety Case.

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

This beyond-category-2 analysis is not part of the licensing activity and is not part of the Repository Safety Case. Therefore no impact exists that affects the current Repository Safety Case.

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

To eliminate transfers of electronic files from a computer workstation to a PC and vice versa, a single mass storage device will be used for the Goth-SNF analysis work.

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

Insufficient equipment capacity.

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:

January 15, 2003

10. Responsible Manager:

R. Blyth, NSNFP QAPM

Printed Name

Signature

Date

11. QAR Evaluation: Accept Partially Accept Reject

12. QAM Concurrence:

SAM E ARCHULETA
Printed Name

Signature

Date

DENNIS BROWN
Printed Name

Signature

Date

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Your initial/complete response dated 12/19/02 is partially accepted. More information/explanation is required.

Your response, as submitted, adequately addresses one portion of the requirements of Supplement V of the QARD, that of integrity verification and maintaining the accuracy and completeness of information placed onto or modified within an electronic information management system or on electronic media. Further, your explanation pertaining to use of Goth-SNF software adequately clarifies that data generated by that software is not used in work that is part of the Repository Safety Case, and is therefor not subject to Supplement V controls.

However, Supplement V controls address other aspects of the control of electronic information, such as: a) How is information protected from damage or destruction? b) How is access to information on a personal computer controlled? c) When and if backup copies are made, how are they labeled and stored? d) How are electronic media identified? e) What process controls are in place to maintain the security and integrity of information in electronic form?

Recommend a thorough review of the requirements of Supplement V controls be conducted with respect to your work activities that DO support the Repository Safety Case be conducted. If any Supplement V requirements are involved in work which is in support of the QARD, then these activities will have to be covered by procedural controls. Procedural controls may be established in a single procedure, or they may be incorporated into other procedures covering the activities themselves.

An amended response is required within 10 working days of receipt of this document which states that none of the Supplement V requirements are applicable due to the nature of the work not being in support of the Repository Safety Case, or, if there is QARD related work wherein Supplement V requirements are impacted, state what the planned corrective action(s) to address the deficiency will be.



Sam E. Archuleta
QA Representative

1-6-03
Date

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 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

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

The NSNFP technical work that relies on data derived from Goth SNF Software Program has been controlled and disseminated in hardcopy paper media. Data selected is fully transparent in the NSNFP Technical Reports provided in hardcopy paper media. Reviews (checking) for accuracy of the information relied on for NSNFP technical reports have been performed as part of the hardcopy document review and approval process. None of the information has been provided in electronic format as repository design input, NSNFP design output, support for the repository performance assessment, or as a scientific investigation output for the repository performance assessment. The Goth-SNF Software program has been verified and validated.

The NSNFP technical work relying on Goth generated data is related to analysis of a SNF MCO package response to theoretical breaches. The results of this analysis may be used to help evaluate RW facility reactions to the event. This beyond-category-2 analysis is not part of the licensing activity and is not part of the Repository Safety Case. Therefore no impact exists that affects the current Repository Safety Case.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)
 This beyond-category-2 analysis is not part of the licensing activity and is not part of the Repository Safety Case. Therefore no impact exists that affects the current Repository Safety Case.

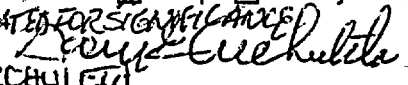
6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)
 The National Spent Nuclear Fuel Program will develop and issue a procedure(s) to address QARD Revision 12 Supplement V, Control of the Electronic Management of Data.

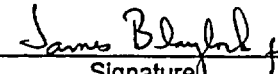
7. Root Cause (For a significant CAQ, attach results of formal root cause determination prepared in accordance with AP-16.4Q)
 Apparent Cause
 Insufficient equipment capacity.

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:
 March 31, 2003

10. Responsible Manager
 Robert Blyth, NSNFP  2/10/02
 Printed Name Signature Date

11. QAR Evaluation: Accept Partially Accept Reject
 2/20/03
 Printed Name Signature Date

12. QAM Concurrence:
 DENNIS BROWN  2/25/03
 Printed Name Signature Date

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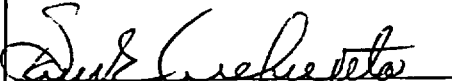
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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Your amended complete response dated 2/10/03 is accepted. The expected completion date falls well beyond the procedurally controlled corrective action time period of 100 days, however. A request for extended processing is required.



Sam E. Archuleta
QA Representative

2/20/03
Date

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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)

Develop and issue a NSNFP procedure(s) to address QARD Revision 12 Supplement V (Control of the Electronic Management of Data), as listed in Block 6 of the revised response for EM-ARC-02-10/EM(O)-03-D-006, dated 2/10/03.

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, develop the appropriate subject procedure(s) 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. This beyond-category-2 analysis is not part of the licensing activity and is not part of the Repository Safety Case. Therefore no impacts exist that affects the current Repository Safety Case.

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:

R. Dennis Brown 3/19/03
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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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Verification of corrective action commitments was completed on 4/10/2003.

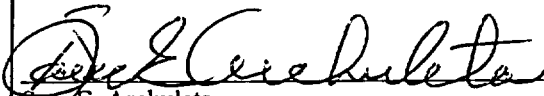
The initial response to this deficiency indicated a cause of "insufficient equipment capacity" and a remedial action plan to use a mass storage device to preclude the need for information transfers during the use of Goth-SNF. Subsequently, we concurred with the National Spent Nuclear Fuel Program (NSNFP) position that the use of Goth-SNF did not involve any work in support of the Repository Safety Case, and therefore was not subject to Quality Assurance Requirements and Description (QARD) requirements.

The corrective action described below does not address the original cause because such cause was set aside during investigation of the extent of condition for this deficiency. Similarly, the original remedial action plan is set aside due to nonapplicability.

Recognizing the possibility of a need for control of electronic information management, the NSNFP elected to develop a procedure to be used in such circumstances, and committed to development of a procedure. The procedure was developed and signed on 3/31/03. Verified the issuance of PSO 19.01/Rev 0, CONTROL OF THE ELECTRONIC MANAGEMENT OF INFORMATION, with an effective date of 04/02/2003. Reviewed the procedure for compliance with Supplement V of the QARD. The procedure provides process controls which appear to be very adequate to achieve the controls prescribed by Supplement V. The process has been tailored to respond to current business practices of the NSNFP. Implementation of these process controls can be assessed in future audits and/or surveillances.

IMPACT: Concur with the NSNFP Quality Assurance Program Manager assessment that "this beyond-category-2 analysis is not part of the licensing activity and is not part of the Repository Safety Case," and as such, "...no impact exists that affects the current Repository Safety Case."

Based upon the adequacy of process controls described in the above-referenced procedure, the corrective actions taken are adequate and appropriate. Recommend closure of this DR at this time.



Sam E. Archuleta
QA Representative

4-10-03
Date