



Department of Energy

Washington, DC 20585

QA: L

SEP 24 1997

L. D. Foust, Technical Project Officer
for Yucca Mountain Site
Characterization Project
TRW Environmental Safety Systems, Inc.
1180 Town Center Drive, M/S 423
Las Vegas, NV 89134

ISSUANCE OF DEFICIENCY REPORTS (DR) YM-97-D-083 THROUGH
YM-97-D-085 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA)
AUDIT SNL-ARC-97-24 OF SANDIA NATIONAL LABORATORIES

Enclosed are DRs YM-97-D-083 through YM-97-D-085, generated as a result of OQA
Audit SNL-ARC-97-24.

Please provide responses to these deficiencies that meet the applicable requirements of
Administrative Procedure 16.1Q, Performance/Deficiency Reporting. Send the originals of
your responses to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las
Vegas, Nevada 89036-0307. Responses to the DRs are due 20 working days from the date
of this letter. Extensions to due dates must be requested in writing, with appropriate
justification, prior to the due dates.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or
Stephen D. Harris at (702) 734-0870.

R.W. Cep

for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2321

Enclosure:
DRs YM-97-D-083 through
YM-97-D-085

Recip: nms/PAHL

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SEP 24 1997

L. D. Foust

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cc w/encl:

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S. W. Zimmerman, NWPO, Carson City, NV
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV
J. F. Graff, OQA/SNL, Albuquerque, NM, M/S 1395
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Andrew Orrell, M&O/SNL, Las Vegas, NV

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
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D. G. Sult, OQA/QATSS, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Quality Assurance Requirements and Description (QARD), Revision 7	2 Related Report No. SNL-ARC-97-24
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3 Responsible Organization: Sandia National Laboratories (SNL)	4 Discussed With: Joe Schelling, Andrew Orrell
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5 Requirement/Measurement Criteria:

QARD, Section 5.2:

- Work shall be performed in accordance with controlled implementing documents.

QARD, Section 2.2.1B:

- Affected Organizations shall establish implementing documents applicable to their scope of work that translate QARD requirements into work processes.

6 Description of Condition:

Contrary to the above requirements no procedure had been implemented to meet QARD, Supplement V requirements. Note: a draft procedure, QAIP 19-2, "Electronic Data Management System Control," is in preparation but has not been issued.

Two activities were identified that need to be implemented using Supplement V requirements: An electronic data maintenance system for Performance Assessment work, and an electronic controlled document system.

7 Initiator Stephen D. Harris <i>S. D. Harris</i>	Date 8/25/97	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)

Complete QAIP 19-2 for the applicable scope of work and include instruction for development of activity specific implementing documents as needed to comply with Supplement V requirements.

SNL needs to evaluate activities performed for the Yucca Mountain Project to determine if any other work is subject to these requirements, and implement them accordingly.

11 QA Review: QAR <i>S. D. Harris</i>	Date 9-5-97	12 Response Due Date 20 working days from issuance
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13 Director, OQA Issuance Approval: (QAR for PR) Printed Name Donald G. Horton	Signature <i>R. W. Cull</i>	Date 9/23/97
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22 Corrective Action Verified QAR	Date	23 Closure Approved by: (N/A for PR) DOQA
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PR/DR NO. YM-97-D-083

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

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:

19 Response by:

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

DOQA

Date

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WASHINGTON, D.C.

8 Performance Report
 Deficiency Report

NO. YM-97-D-084

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QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

QAIP 19-1, Revision 3, "Software Quality Assurance Requirements"

2 Related Report No.

SNL-ARC-97-24

3 Responsible Organization:

Sandia National Laboratories (SNL)

4 Discussed With:

Joe Schelling, Andrew Orrell

5 Requirement/Measurement Criteria:

Quality Assurance Requirements and Description (QARD), Supplement I, Sections I.2.6A.2b, I.2.8B and I.2.8C:

- The software version or revision identifier shall be included with the generated output, when feasible.
- Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.
- If use of a software item falls outside the range of validation, further validation shall be performed prior to use.

QARD, Section 5.2.2, "Content of Implementing Documents," requires methods for demonstrating that the work was performed as required.

6 Description of Condition:

Contrary to the above requirements, QAIP 19-1, Revision 3, does not address these sections of the QARD, Supplement I. In addition, implementation detail needs to be added to methods described within this procedure such that the actions to be taken are clearly expressed step by step such that two or more individuals can implement the procedure the same way each time. Examples are:

- Section 4.0, paragraph 1, sentence two, "Software may be used before all baseline elements have been completed and approved, provided the use of such software is adequately controlled." The adequate controls need to be included.
- Section 4.1, first sentence, "Identification of the baseline configuration for a software item includes classifying the software and assigning a unique identifier." The process for unique identification needs to be included.
- Section 4.4.5.1, "The SCM Coordinator shall maintain a copy of the Change Control Form or memorandum, forward a copy to project records, and notify all approved Code Users of the changes to the baseline software via memorandum." The system used to identify the approved Code Users needs to be included.

7 Initiator

S. D. Harris
Stephen D. Harris

Date 8/25/97

9 Is condition an isolated occurrence?

Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

Add implementation steps for missing QARD requirements and emphasize method steps for configuration management.

11 QA Review:

QAR

S. D. Harris

Date 9-3-97

12 Response Due Date

20 working days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)

Printed Name Donald G. Horton

Signature

R. W. Coffey

Date 9/23/97

22 Corrective Action Verified

QAR

Date

23 Closure Approved by: (N/A for PR)

DOQA

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

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:

19 Response by:

20 Response Accepted

21 Response Accepted (N/A for PR):

QAR

Date

DOQA

Date

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8 Performance Report
 Deficiency Report
NO. YM-97-D-085
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QAIP 19-1, Revisions 02 and 03, "Software Quality Assurance Requirements."	2 Related Report No. SNL-ARC-97-24
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3 Responsible Organization: Sandia National Laboratories (SNL)	4 Discussed With: John Pelletier, Joe Schelling, Andrew Orrell.
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5 Requirement/Measurement Criteria:
QAIP 19-1, Revision 02, was current from 7/21/95 to 6/2/97 and was used to evaluate work during Audit SNL-ARC-97-24. Revision 3 was effective June 2, 1997 and has yet to be implemented.

Quality Assurance Requirements and Description (QARD), Supplement I, I.2.1C, requires specific software requirements, of a limited nature, be applied. Section I.2.6 requires configuration identification, control and status accounting. Supplement I, I.2.6A.2b., requires the software version to be included in output, when feasible. QAIP 19-1, Revision 2, requires a Life Cycle Plan, independent technical review of specific baseline elements and a configuration management process for software.

6 Description of Condition:
Contary to the above requirements, several deficiencies were found in ^{both} implementation of QAIP 19-1, Revision 02 ^{and the} configuration management process ~~was not adequately controlled.~~ ^{RWC 9/12/97} The following are specific issues of concern:

QARD, Section I.2.1C and QAIP 19-1, Revision 02, Section 5.2, Step 5c, "WINFIT", software used for X-ray diffraction analyses, was not found in the baseline listing of SNL's configuration management system.

QAIP 19-1, Revision 02, Section 5.1, Step 1, Note: JAC3D, Revision 6.1-04, user requirements were deficient in required anticipated errors and how the user can respond, and hardware and software environments. The Validation Plan was incomplete.

QAIP 19-1, Revision 02, Section 5.2, Step 2; and QARD, I.2.6A.2b: JAC3D, Revision 6.2-04, independent technical review memo dated August 20, 1996, is incomplete. TOUGH2 vs. 3.0 Validation Plan and Report does not indicate version of the code in text.

(See Continuation Page 2 ...)

7 Initiator Stephen D. Harris <i>S.D. Harris</i> Date 8/25/97	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)

- 1) SNL must establish and initiate a process to obtain configuration management information of software such as acquired software used to perform analyses (software that falls into I.2.1C requirements of the QARD).
- 2) SNL needs to clean up issues not in compliance to QAIP 19-1, Revision 02, to support work performed in the time frame of effectivity.

(See Continuation Page 2...)

11 QA Review: QAR <i>S.D. Harris</i> Date 9-3-97	12 Response Due Date 20 working days from issuance
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13 Director, OQA Issuance Approval: (QAR for PR) Printed Name Donald G. Horton Signature <i>R.W. Cl...</i> Date 9/23/97
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22 Corrective Action Verified QAR _____ Date _____	23 Closure Approved by: (N/A for PR) DOQA _____
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PR/DR NO. YM-97-D-085

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QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

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:

19 Response by:

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

DOQA

Date

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⁸ Performance Report

Deficiency Report

NO. YM-97-D-085

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PR/DR CONTINUATION PAGE

6 Description of Condition:

QAIP 19-1, Revision 02, Section 5.5, Step 1: JAC3D vs. 6.1-05 had a change request form prepared for retirement that was approved; however, attached documentation included reason not to retire it and no justification is given for retirement to address this. TOUGH2, vs. 3.2, had a prepared change request form with "none" indicated for affected baseline. Since this was an enhanced capability, the user information and tests would be affected at a minimum.

10 Recommended Actions:

- 3) SNL needs to evaluate current documentation of software on the configuration management Master Log to:
 - a) Determined if the supporting documentation is accurate and complete for past work; and
 - b) Determine what current software will be used under the future requirements of QAIP 19-1, and update this software to meet them.
- 4) SNL also needs to address actions to preclude recurrence.