



Department of Energy

Washington, DC 20585

QA: L

MAR 11 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

EVALUATION OF RESPONSE TO UNSATISFACTORY VERIFICATION OF DEFICIENCY
REPORT (DR) YM-96-D-004 RESULTING FROM OFFICE OF QUALITY ASSURANCE
(OQA) AUDIT YMP-94-09 OF SANDIA NATIONAL LABORATORIES (SNL)

One of the purposes of OQA Audit YMP-94-09 was to verify corrective actions taken as a result of DR YM-96-D-004. However, the audit results identified that the procedures still did not adequately provide direction for implementing the OQA program requirement.

The response, dated January 9, 1997, committed to providing two draft procedures. The draft for QAIP 1-5 was provided on February 18, 1997. In total, however, the response did not provide a completion date for revision of the affected suite of SNL procedures. The actions required for closure will be considered complete when the procedures have been revised. Your response did not provide such a date. The OQA requests a clarification for the completion of the SNL procedure revisions commitment.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact James Blaylock at (702) 794-1420.

James Blaylock
Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1139

Enclosure:
DR YM-96-D-004

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L. D. Foust

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MAR 11 1997

cc w/encl:

T. A. Wood, DOE/HQ (RW-55) FORS
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV
S. Y. Pickering, M&O/SNL, Albuquerque, NM, M/S 1395
M. C. Brady, M&O/SNL, Las Vegas, NV
Records Processing Center = " " "

cc w/o encl:

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

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RADIOACTIVE WASTE MANAGEMENT
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
OCRWM QARD DOE/RW-0333P, Revision 0

2 Related Report No.
YMP-94-09

3 Responsible Organization:
SNL

4 Discussed With:
L. Shephard

5 Requirement/Measurement Criteria:
This DR is issued to supersede CAR YM-94-096 in order to implement the revised OCRWM Corrective Action Program.

Section 5.0, Paragraph 5.2.2, "Contents of Implementing Documents" states in part: "Implementing documents shall include the following information as appropriate to the work to be performed: (C) A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operation. The organization responsible for preparing the document shall determine the appropriate level of detail. (D) Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished....."

6 Description of Condition:
Contrary to the above, SNL's QAIPs do not meet all of the requirements of the OCRWM QARD as identified by those specific examples cited and referenced below:

- The record packaging process implemented for procurement records is not addressed in QAIP 04-01 or QAIP 17-03. QAIP record sections do not clearly identify what records are processed individually and what records are processed as record packages.

The record packaging process should be reflected in all applicable procedures.

- The detail in QAIP 20-02 (Scientific Notebooks) is insufficient to provide a Scientific Notebook that would be suitable for use in licensing. The instructions in the QAIP are merely a restatement of the guidance provided in the QARD. Scientific Notebooks should be of a type and quality that would be suitable in a court of law. Unsatisfactory conditions that (continued)

7 Initiator
James Blaylock *James Blaylock*
Date 1/30/96

9 QA Review
James Blaylock *James Blaylock*
QAR James Blaylock
Date 1/30/96

10 Response Due Date
N/A

11 QA Issuance Approval
PBC
QAR (PRI/AOCAM) (DR) *for*
Date 2-1-96

12 Remedial Actions:
See response to CAR YM-94-096

13 Remedial Action Response By:
N/A
Date

14 Remedial Action Due Date
Date

15 Remedial Action Response Acceptance
QAR N/A
Date

16 PR Verification/Closure
QAR N/A
Date

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17 Recommended Actions:

~~See Continuation page~~ N/A
 PRR
 1/16/96

18 Investigative Actions:

See Continuation page

19 Root Cause Determination:

See Continuation page

20 Action to Preclude Recurrence:

See continuation page

21 Response by:

J. Richards
 Date Jan 16, 1996

22 Corrective Action Completion Due Date:

APR. 30, 1996

23 Response Accepted

QAR

N/A

Date

24 Response Accepted

AOQAM

N/A

Date

25 Amended Response Accepted

QAR

James Blaylock

Date

1/21/96

26 Amended Response Accepted

AOQAM

K. Kama

Date

2/1/96

27 Corrective Actions Verified

QAR

Date

28 Closure Approved by:

AOQAM

Date

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Second Amended Response for Deficiency Report YMQAD-96-D-004 (previously CAR YM-94-096)

This response completely supersedes the previous response to this CAR.

12. Remedial Actions

SNL will conduct an evaluation of the following procedures cited in the examples provided in block 6 against the attached criteria, in order to identify weaknesses or shortcomings of those procedures: QAIPs 1-5, 2-5, 2-6, 4-1, and 17-3. Any such shortcomings will be corrected by revising the procedures. (Note: QAIP 19-1, cited in block 6, requires extensive revision as a result of QARD Revision 5; therefore evaluation of that procedure for the purposes of this CAR to determine if it needs revision is unnecessary. In the case of QAIP 20-2, also cited in block 6, that procedure has already been extensively revised to incorporate additional detail as a result of the earlier evaluation for this CAR and for other reasons. Therefore, for that procedure, the objectives of this CAR have been addressed, and no further evaluation is needed.)

Responsible party: R. R. Richards

Anticipated Completion Date: For evaluation of the procedures - Mar. 15, 1996. For revision of the procedures - Apr. 30, 1996.

18. Investigative Actions:

The results of the evaluation cited above will be analyzed for trends or commonalities. To the extent that such trends or commonalities exist, a plan for the evaluation of all remaining Quality Assurance Implementing Procedures and the correction/improvement of the QAIPs found lacking will be developed.

Responsible party: R. R. Richards

Anticipated Completion Date: Apr. 1, 1996.

20. Action to Preclude Recurrence:

Initiate implementation of the plan mentioned above.

Responsible Party: R. R. Richards

Anticipated Completion Date: Apr. 30, 1996.

Screening: Screen all QAIPs to determine if either of the following conditions exist.

- Is there evidence of inconsistencies in products generated by a procedure which have resulted in violation of requirements or a need for corrective action? Have investigative actions, root cause evaluations, or management assessments resulted in recommendations to modify and provide additional detail for specific procedural steps?
- Have personnel responsible for executing a procedure requested clarification or expressed confusion regarding implementation? Would additional training suffice to resolve this uncertainty?

Evaluation of Selected Procedures: For those procedures identified by screening, above, evaluate them against these criteria.

- Are the process steps following a decision point well-defined, e.g., if a process step requires someone's concurrence to proceed but that individual is unavailable, does the procedure provide alternatives or describe what actions are to be taken next?
- Are process steps clear and unambiguous to the average reader? Would rewording of certain steps, rather than incorporation of additional detail, improve clarity?
- Are expected actions and contextual terms adequately clear to the average reader, e.g., Are the meanings of "certify", "verify", "qualify", etc. understood in the context of the procedure? As another example, if a review is required, is it clear: (a) who may or may not be a reviewer; (b) if it is necessary to define and/or document review criteria; (c) if a formal, documented review and comment resolution process is to be conducted?
- Can products generated by a procedure (forms, documents, reports, etc.) be readily evaluated for whether they address the requirements stated in the procedure, i.e., do they satisfy qualitative or quantitative acceptance criteria?

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Third Amended Response for Deficiency Report YMQAD-96-D-004
(previously CAR YM-96-D004)

Block 18, Investigative Action (continued):

As an investigative action, an independent review and evaluation using the review criteria established earlier will be conducted of a representative sample of QAIPs. The criteria were developed for the Second Amended Response for Deficiency Report YMQAD-96-D-004 (previously CAR YM-96-D004), and will be continue to be used in evaluating the format, content, flow, and utility of individual procedures. To assure independence and obtain a fresh perspective on the issue, a new addition to the SNL QA staff, John Pelletier, will be tasked with an initial assignment to perform this evaluation. Mr. Pelletier has significant quality assurance and YMP experience as a former member of the QATSS staff, but is new to the SNL implementation of the program. John will be asked to complete his review of the selected procedures and provide his evaluation by mid-January.

Of the total of 25 SNL QAIPs, five may be excluded from the review for the following reasons: QAIP 1-2 is more descriptive than process oriented, QAIP 2-2 is rarely used, QAIP 3-4 will be retired upon completion of processing of old design related records; QAIP 3-12 has not been used (and would probably follow the AP if needed); and QAIP 10-1 will be archived upon OQA consolidation.

Of the remaining 20 procedures, half (10) are cited in the deficiency documentation. This subset of ten procedures, identified in the following table, should provide an adequate sample for the evaluation.

QAIP 1-5	Establishing Work Agreements
QAIP 2-5	Training
QAIP 2-6	Qualification and Certification of Personnel
QAIP 4-1	Procurement
QAIP 5-1	Quality Assurance Implementing Procedures
QAIP 6-3	Conducting and Documenting Reviews of Documents
QAIP 17-1	Protecting, Preparing, and Submitting YMP QA Records
QAIP 17-3	Processing, Storing, and Protecting YMP QA Records
QAIP 19-1	Software Quality Assurance Requirements
QAIP 20-2	Scientific Notebooks

Anticipating that the results of this review will identify areas for which process is confusing or inconsistent (determined without the benefit additional training or consultation with experienced staff), the following action will be taken.

(Continued)

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Third Amended Response for Deficiency Report YMQAD-96-D-004
(previously CAR YM-96-D004)

Block 18. Investigative Action (continued):

Two of the ten evaluated procedures will be revised and submitted in response to this deficiency report to provide objective evidence sufficient to close out the deficiency. The two procedures will be selected on the basis of the evaluation results, significance with respect to quality impacts, and frequency of use. (The software QA procedure QAIP 19-1 will not be considered for revision as part of this action, however, because major procedural changes are planned as part of the implementation of QARD Revision 5 and could delay closure of the subject deficiency.)

Additional procedure revisions have been requested in response to the OQA consolidation effort and other recent Project directions (e.g. changes in the records process), but are not considered part of this corrective action. Any process improvements resulting from this corrective action, however, will certainly be incorporated into future revision actions. Independent of this corrective action response, procedure development efforts are also being coordinated with new SNL training initiatives, which include the development of reference training materials for specific procedures as well as for more general topic areas (e.g. documenting work, records-related processes, etc.), and the assignment of more specialized training on specific subjects than the typical read/understand method.

To provide a sufficient basis to close DR YM-96-D004, the following objective evidence will be provided:

- Documentation of the independent review and evaluation of ten selected QAIPs (anticipated completion date: January 17, 1997);
- Revised versions of two selected procedures (anticipated completion date: February 15, 1997).

These investigative actions supplement those already committed to and completed in earlier responses.