



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

AUG 07 1995

Laurence S. Costin
Acting Technical Project Officer
for Yucca Mountain
Site Characterization Project
Sandia National Laboratories
P.O. Box 5800, Mail Stop 1325
Albuquerque, NM 87185

VERIFICATION OF CORRECTIVE ACTION OF CORRECTIVE ACTION REQUEST
(CAR) YM-94-096 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION'S (YMQAD) AUDIT YMP-94-09 OF SANDIA NATIONAL
LABORATORIES (SNL) (SCPB: N/A)

The YMQAD staff has verified the corrective action to CAR
YM-94-096 and determined the results to be unsatisfactory. The
basis for the CAR and this rejection is failure to implement the
Quality Assurance Requirements and Description (QARD) Section
5.0, paragraph 5.2.2, requirements for implementing procedures.
The revised procedures still fail to meet those requirements.
The revised SNL implementing procedures typically assign
implementation responsibility to a job title with instructions to
accomplish the requirement. This is not the intent of the QARD
requirement. In particular, there is a lack of
quantitative/qualitative criteria for the acceptance of
procedural output.

Your response, indicating the appropriate corrective action
completion date, is required to be submitted to this office
within ten working days of the date of this letter. Verification
of completion of the required corrective action will be performed
after the date provided.

If you have any questions, please contact either Robert B.
Constable at (702) 794-7945 or James Blaylock at (702) 794-7913.

R. E. Spence

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4159

Enclosure:
CAR YM-94-096

YMP-5

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PDR WASTE
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WM-11

Laurence S. Costin

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AUG 07 1995

cc w/encl:

~~E. G. Spraul~~ NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. R. Richards, SNL, Albuquerque, NM, M/S 1333
M. C. Brady, SNL, Las Vegas, NV

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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

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CORRECTIVE ACTION REQUEST

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:

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 Adverse 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 were found included: (1) use of looseleaf notebooks, (4) non-sequentially

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No X
If Yes, Check One: A B C D E

10 Does a stop work condition exist? Yes ___ No X; If Yes - Attach copy of SWO
If Yes, Check One: A B C

13 Response Due Date:
20 Working Days From Issuance

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:

- Correct the identified deficiency.
- Evaluate all QAIPs to determine level of detail needed to adequately implement them.
- Evaluate for impact to quality.

7 Initiator *Kenneth McFar* *for* Charles E. Betts *9/13/94*

14 Issuance Approved by: *M. Blount* *for* QADD *for* Date *9-12-94*

15 Response Accepted

QAR _____ Date _____

16 Response Accepted

QADD _____ Date _____

17 Amended Response Accepted

QAR *Sara Blount* Date *12/15/94*

18 Amended Response Accepted

QADD *M. Blount* *for* Date *12-22-94*

19 Corrective Actions Verified

QAR _____ Date _____

20 Closure Approved by: QADD _____ Date _____

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6 Adverse Condition (continued)
numbered pages.

3. The detail in QAIP 01-05, although incorporating the appropriate requirements from QARD 5.2.2 A through I, is not clearly delineated and confusing by providing several options for inclusion of requirements in work agreements. Consequently, work agreements are written that do not address, either by incorporation or reference as not applicable, all of the procedural/QARD requirements.
4. The level of detail in QAIPs 02-05 and 02-06, although addressing the appropriate QARD 2.2.1.1 requirements, is not sufficient for personnel to adequately implement the procedures. The procedures incorporate the QARD requirements, but do not include sufficient implementing details or process steps for people to adequately comply with the requirements. For example, SNL staff do not adequately assign training to achieve or maintain proficiency and do not adequately complete training and qualification requirements.
5. The detail in QAIP 19-01 (Software) is insufficient to provide that acquired or developed software would be suitable for use in licensing. The requirements in the QAIP are merely a restatement of the QARD Supplement I requirements. Unsatisfactory conditions were in verification and validation control of acquired and developed software, change control and use of software.

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Attention is drawn to the following statement in the cited requirement: "The organization responsible for preparing the document shall determine the appropriate level of detail." That indicates that, for SNL documents, SNL is responsible for determining the appropriate level of detail in those documents. SNL does that in a manner that is integrated with the overall system in which those documents are used, i.e., considering the training provided about procedures, the daily guidance on and overview of the implementation of those procedures provided by supervisors, and the qualified, proficient personnel who utilize the procedures.

In any case, since the QARD specifies that the organization responsible for preparing documents decides the appropriate level of detail, any observations made by persons outside the responsible organization about the level of detail included are essentially differences of opinion. While they may offer valuable insights and ideas, those observations do not constitute conditions-adverse-to-quality.

Concerning the cited examples:

1. "Packaging" of procurement records is a practice that enhances the organization of records in the Local Records Center and Central Records Facility. It is not based on requirements and, therefore, need not be called out in QAIP 4-1.
2. The observations made during the audit concerning SNL practices with scientific notebooks has caused this organization to initiate actions to make those practices more rigorous and consistent. However, QAIP 20-2 addresses all QARD requirements for scientific notebooks. If information is available concerning what characteristics make a scientific notebook "suitable for licensing," such information should be disseminated to all affected organizations by OCRWM/YMPO in order that we can all act on that information in a consistent manner.
- 3&4. These examples repeat information that is provided in CARs YM94-088 and YM94-092. Responses to these CARs address the problems cited in those examples.
5. During the audit, the audit team found the programmatic area of Software QA to be indeterminate as to effectiveness based on there being insufficient evidence of implementation to date to make an evaluation of compliance. In any case, no examples of noncompliance with QAIP 19-1 or the QARD were found that indicated an inability to adhere to the QAIP due to insufficient procedural detail.

for  10/12/94
L. E. Shephard
SNL YMP Technical Project Officer

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

EVALUATION OF THE RESPONSE TO CAR YM-94-096

The response to CAR YM-94-096 is rejected. This rejection is based on two factors. First, the QARD establishes the minimum content of the implementing documents for quality assurance procedures in Paragraph 5.2.2 A-I. The examples cited are indicative of the inherent problems identified with the Sandia National Laboratories (SNL) implementing procedures. Second, it is the Department of Energy Quality Assurance organization that makes the interpretation of the intent of the QARD, not the participating organization. It is inappropriate for SNL to claim responsibility to interpret the intent of the QARD with respect to the appropriate level of detail in the documents.

The response reinforces the YMQAD position that the SNL procedures consist of repeating the QARD requirement without the how to detail. If this approach were acceptable, there would be no need for implementing documents and organizations could be told to implement the QARD directly. That is not an acceptable position. Hence, there is no agreement with your response to the CAR.

James Blaylock
James Blaylock, QAR

10/19/94
Date

Proposed Amended Response for CAR YM-94-096

This response completely supersedes the initial response to this CAR

A. Remedial Actions

SNL will conduct a detailed evaluation of the procedures cited in the five examples provided in block 6 against the criteria in the QARD, Section 5.0, paragraph 5.2.2 to identify weaknesses or shortcomings of those procedures. Any such shortcomings will be corrected by revising the procedures.

Responsible party: R. R. Richards

Anticipated Completion Date: For evaluation of the procedures - 1 Dec. 1994.
For revision of the procedures - 15 Jan. 1995.

B. Extent of Deficiency:

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: 10 Dec. 1994

C. Actions to Preclude Recurrence:

Initiate implementation of the plan mentioned above.

Responsible Party: R. R. Richards

Anticipated Completion Date: 3 Jan. 1995

*forwarded to K.11
11/10
of 11/10/94*

*Jared J. Blaylock
11/29/94 of 11/29/94*

Proposed Amended Response for CAR YM-94-096

This response completely supersedes the initial response to this CAR

A. Remedial Actions

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Responsible party: R. R. Richards

Anticipated Completion Date: For evaluation of the procedures - 1 Dec. 1994.
For revision of the procedures - 15 Jan. 1995.

B. Extent of Deficiency:

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: 10 Dec. 1994

C. Actions to Preclude Recurrence:

Initiate implementation of the plan mentioned above.

Responsible Party: R. R. Richards

Anticipated Completion Date: 3 Jan. 1995

Amended Response for CAR YM-94-096 (Part A. Only.)

A. Remedial Action

SNL will conduct a detailed evaluation of the procedures cited in the five examples provided in block 6 against the criteria in the QARD, Section 5.0, paragraph 5.2.2 to identify weaknesses or shortcomings of those procedures. Any such shortcomings will be documented on a Procedure Action Request.

Responsible Person: R.R. Richards Completion Date: 01/15/95.