



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

OCT 24 1994

Les E. Shephard
 Technical Project Officer
 for Yucca Mountain
 Site Characterization Project
 Sandia National Laboratories
 P.O. Box 5800, Mail Stop 1333
 Albuquerque, NM 87185

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

The YMQAD staff has evaluated the response to CAR YM-94-096.
 The response has been determined to be unsatisfactory for
 reasons identified on the enclosed evaluation of response to
 CAR YM-94-096.

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, YMQAD/QATSS,
 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.
 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 either Robert B.
 Constable at (702) 794-7945 or James Blaylock at (702) 794-7913.



Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-419

Enclosure:
 CAR-YM-096

cc w/encl:
 J. H. Hines, OOD, AL
~~G. G. Spraul~~, NRC, Washington, DC
 S. W. Zimmerman, NWPO, Carson City, NV
 R. R. Richards, SNL, 6319, Albuquerque, NM
 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

*NH03-11
 102-7
 WM-11*

YMP-5

9411100288 941024
 PDR WASTE
 WM-11 PDR

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YM-94-096</u> PAGE: <u>1</u> OF <u>2</u> QA
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: 1. 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. 2. 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 <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
12 Recommended Actions: 1. Correct the identified deficiency. 2. Evaluate all QAIPs to determine level of detail needed to adequately implement them. 3. Evaluate for impact to quality.		
7 Initiator <i>Kenneth McFar</i> Charles E. Betts <i>for</i> 9/8/94	14 Issuance Approved by: QADD <i>McWaltke</i> <i>for</i> Date 9.12.94	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____	

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

8 CAR NO.: YM-94-096
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

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.

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

8 CAR NO.: YM-94-096
PAGE: 3 OF
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

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

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

⁸ CAR NO. YM-94-096
PAGE OF
 QA

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