

Department of Energy

Yucca Mountain Project Office P. O. Box 98608 Las Vegas, NV 89193-8608

WBS 1.2.9.3 QA

SEP 13 1990

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Technical Project Officer
for Yucca Mountain Project
Sandia National Laboratories
P.O. Box 5800
Organization 6310
Albuquerque, NM 87185

ISSUANCE OF STANDARD DEFICIENCY REPORTS (SDRs) 571 THROUGH 578, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 90-04 OF SANDIA NATIONAL LABORATORIES (SNL)

Enclosed are SDRs 571 through 578, Revision 0, generated as a result of Project Office QA Audit 90-04 of SNL.

Please identify the corrective actions to be taken and implemented to correct the deficiencies by completing Blocks 14 through 18, as appropriate, on each SDR.

Responses to the SDRs are due within 20 working days of the date of this letter. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send the original of your responses to Nita J. Brogan, Science Applications International Corporation, 101 Convention Center Drive, Las Vegas, Nevada 89109.

Your cooperation and timely response is appreciated. If you have any questions, please contact Catherine E. Hampton at (702) 794-7973 or FTS 544-7973, or Stephen R. Dana at (702) 794-7176 or FTS 544-7176 of the Yucca Mountain Project QA staff.

Donald G. Horton, Director

Quality Assurance

Yucca Mountain Project Office

QA:CEH-4882

Enclosure:

SDRs 571 thru 578, Revision 0

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Thomas O. Hunter

cc w/encl:

D. G. Horton, HQ (RW-3) FORS

R. R. Richards, SNL, 6319, Albuquerque, NM

N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08

S. W. Zimmerman, NWPO, Carson City, NV K. R. Hooks, NRC, Washington, D

cc w/o encl:

J. H. Hines, NWQA, AL

S. R. Dana, SAIC, Las Vegas, NV, 517/T-06

C. H. Prater, SAIC, Las Vegas, NV, 517/T-04

J. W. Gilray, NRC, Las Vegas, NV

	YMPO STANDARD DEFICIENCY REPORT N-QA-038 4/89						
	1 Date 8-24-96	2 Severi	ity Level □ 1 🗵 2	□ 3 Page	1 of 2		
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	5 Organization SNL	6 Person(s) Co F. Schelling,	•	20 Worl	se Due Date is king Days from Transmittal		
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by	9 Deficiency 1. Contrary to requirement No. 1 stated above, SNL-NWRT-DOP 2-8, Revision A requires that a management assessment of the QA Program be initiated at least once during each fiscal year. This makes it possible						
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8 Requirement (continued)

that are established to achieve and assure quality...".

- 2. SNL-NWRT-DOP 2-8, Revision A, Section 4.2 requires the designated management assessment team to perform the following action: "As a minimum, address the effectiveness of implementation of the QA Program, and whether personnel are trained in regards to the QA Requirements of the Program."
- 9 Deficiency (continued)

to exceed the annual requirement of the QAPP.

- 2. Contrary to requirement No. 2 stated above, a review of SNL management assessments for fiscal years 1989 and 1990 indicated that they did not address effectiveness of implementation of the QA Program.
- 10 Recommended Actions (continued) action to prevent recurrence.

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	1 Date 8/22/90	2 Severity Le	vel ⊠ 1 □ 2 □ 3	Page 1 of 2		
Organization	3 Discovered During Audit 90-04	3a Identified By M.R. Diaz		SDR No. 72 Rev0		
	5 Organization SNL	6 Person(s) Contact G. Smit/D. Brockm		7 Response Due Date is 20 Working Days from Date of Transmittal		
Originating QA	Checklist 4.2. SNL-NWRT-QAPP,	Checklist Reference, if Ap 1 Revision E, Para. 4.1 required, their retent	.1 states in part, "W			
ą	9 Deficiency SNL has not specified QA Record requirements in any of the procurement documentation for suppliers or subcontractors performing quality affecting activities. At this time, this omission does not permit to determine the					
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8 Requirement (continued)

will be specified in accordance with Section 17.0. Contractors for QA Level I or II procurement shall be required to have a documented QA Program that is consistent with all, or appropriate portions of, the requirements of the YMP QA Plan." Para. 17.1.2 states in part, "QA Records include (1) individual documents that have been executed, completed, and approved and that furnish evidence of the quality and completeness of activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs. A completed record is a document that will either receive no more entries or whose revision would normally consist of reissue of the document; and is signed and dated by the originator, and, as applicable, by personnel authorized to approve the document."

DOP 7-1, Revision C, Para. 6.3.3.6 states, "Procurement documents will specify supplier responsibilities for QA records identification, maintenance, safeguarding, and turnover to this organization (SNL)."

9 Deficiency (continued)

adequate implementation of the appropriate portions of Section 17 of SNL QAPP.

SNL has only determined requirements for the submittal of records. However, these requirements are different than for those classified as QA records in the QAPP.

NOTE:

In accordance with an SNL list of contracts important to safety or waste isolation, dated 8/23/90, thirty contracts dealing with quality have already been awarded to date.

10 Recommended Actions (continued)

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Originating QA Organization	3 Discovered During R.P. Audit 90-04	Identified By owe & ocoros		4 SDR No. 573 Rev. 0		
	5 Organization SNL	6 Person(s) Contacte R. Sandoval	ed	7 Response Due Date is 20 Working Days from Date of Transmittal		
	8 Requirement (Audit Checklist Reference, if Applicable) 1. SNL QAP 2-3, Revision A, Paragraph 4.1.4 states in part, "The Work Plan shall have 13 sections (with appropriate subsections) as follows:					
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8 Requirement (continued)

- 7. Quality Assurance Requirements
 - A. OA Level Assignments
 - B. Applicable SNL QA Procedures, DOPs, and QAPs"
- 2. SNL-NWRT-QAPP, Revision E, Paragraph 5.2 states, "Principal Investigators are individually responsible for ensuring that they have obtained approved documentation to perform their assigned tasks prior to initiation of those tasks. Instructions, procedures, and drawings (if applicable) will be used at the work location.
- 9 Deficiency (continued)

Discussion:

- 1. QAP 3-2, Revision A, requires that WPs have 13 sections. WP 12611, Revision 0 and other 1990 WPs have only 5 sections (Refer to Requirement 1), i.e. SNL changed the format of WPs without revising the governing QAP 2-3 procedure. (Refer to Requirement 2).
- 2. Neither WP 12611 (PCA's 4 and 5) nor the WP 12611, "Grading Report" identify DOP 3-4, "Design Investigation Control" as an applicable procedure. (Refer to Requirement 1).
- 10 Recommended Actions (continued) action to prevent recurrence.

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	5 Organization SNL	6 Person(s) Co G. Smit/D. Br			7 Response D 20 Working Date of Trai	Days from
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) Checklists 4.2.2, 7.2.2, and 7.4.1 SNL-NWRT-QAPP, Revision E, Para. 7.2.9.2 states in part, "Nonconformances to the procurement requirements or SNL-approved documents that consist of one or 9 Deficiency					
by	the requiremen	Some subcontractor procedures dealing with nonconformances do not contain the requirements described in Block 8 above, i.e., RE/SPEC procedure QAP-14, Revision 0, "Identification, Control, and Corrective Action of				
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8 Requirement (continued)

more of the following shall be submitted to this organization for approval of recommended disposition:

- o Technical or material requirement is violated.
- o Requirement in supplier documents, which has been approved by the purchaser, is violated.
- o Nonconformance cannot be corrected by continuation of the original process or by rework.
- o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired."
- 9 Deficiency (continued)

Nonconformances."

A contributing factor to this deficiency could be the fact that the SNL implementing procedure for these requirements was not written with the same mandatory language as the QAPP (Ref. DOP 4-1, Revision C, Para. 4.2.1).

10 Recommended Actions (continued)

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Organization	3 Discovered During Audit 90-04	3a Identified By J. Martin & C. Prater		4 SDR No. 575 Rev. 0
	5 Organization SNL	6 Person(s) Contact Jim Voigt	ed	7 Response Due Date is 20 Working Days from Date of Transmittal
Originating QA	Audit Checklist SNL QAP 10-1, 1	Checklist Reference, if A t Item No. 10-4, Quest Revision D, Para. 3.5. the Team Leader and s	ion No. 1: 2 states, "The surv	-
by	9 Deficiency Contrary to the above requirement, the following surveillances were not issued as procedurally mandated: CBM-90-1, CBM-90-2, and CBM-90-3.			
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8 Requirement (continued)

surveillance to:

- o The organization surveilled,
- o the individual within the SNL NWRT Department responsible for the item or activity surveilled,
- o concerned management personnel,
- o the SNL NWRT QA Coordinator, and
- o the Records Management System.
- 10 Recommended Actions (continued) action to prevent recurrence.

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Organization	3 Discovered During Audit 90-04	3a Identified By J. Martin & C. Prater		SDR No. Rev. 0	
	5 Organization SNL	6 Person(s) Contact Jim Voigt	ted	7 Response Due Date is 20 Working Days from Date of Transmittal	
Originating QA	Audit Checkli SNL QAP 16-2,	Checklist Reference, if A st Item No. 16-2, Quest Revision B, states in m will "Identify organi	ion No. 3: part, that the dispos		
þ	9 Deficiency Contrary to the above, it was noted that numerous Deficiency Reports (DRs) did not contain the required schedule for completion, personnel responsible for implementation, nor individual or organization responsible for				
aldı	10 Recommended Ad	tion(s): 🛛 Remedial 🖾 In	vestigative 🗵 Correctiv	e	
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8 Requirement (continued)

implementation of these actions and a schedule for completion of the disposition." In addition, it is stated, "Identify who shall verify completion of the disposition."

9 Deficiency (continued)

verification of completion of the corrective action. Typical examples include DR 90-52, DR 90-68, and DR 90-69.

10 Recommended Actions (continued)

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Organization	3 Discovered During Audit 90-04	3a Identified By J. Martin & C. Prater	1	4 SDR No. 577 Rev. 0		
1	5 Organization SNL	6 Person(s) Contact J. Voigt/C. Barne		7 Response Due Date is 20 Working Days from Date of Transmittal		
Originating QA		Checklist Reference, if April 1 tem No. 18-3, Quest Revision E, Section 1 hall be performed in ac	ion No. 2: 8, Para. 18.1 states			
by	checklists are	9 Deficiency Contrary to the above requirement; review of SNL audits indicated that checklists are not retained as Quality Records within their Local Records Center (LRC). To not utilize or make the checklists part of the audit				
aldi	10 Recommended Act	tion(s): 🛛 Remedial 🖾 In	vestigative 🛮 Correctiv	/e		
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8 Requirement (continued)

checklists...."

SNL-NWRT-QAPP, Revision E, Section 17, Para. 17.1.2 states in part: "A document or other item is not considered a QA Record until it satisfies the definition of a QA Record as defined below. The term "records", used throughout this section, is to be interpreted as QA Records. QA Records include 1) individual documents that have been executed, completed, and approved and that furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; 2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports)..."

In addition, SNL-NWRT-QAPP, Revision E, Para. 18.4 states in part: "Objective evidence shall be examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively...."

9 Deficiency (continued)

report or a QA record, the audit report must stand alone and state in detail what was specifically examined. For example: audit report SNL-A90-1 did not list any documents observed or specific criteria examined and audit report PB-A90-1 did list documents examined although it did not state in detail what those documents (specific criteria) were examined for. If audit checklists are not to be retained as QA records, the reports must contain sufficient detail to identify what specific criteria each document was examined to.

10 Recommended Actions (continued)

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Organization	3 Discovered During Audit 90-04	3a Identified By J. Martin & C. Prater	•	4 SDR No. 578 Rev. 0	
	5 Organization SNL	6 Person(s) Contact Jim Voigt/Curtis		7 Response Due Date is 20 Working Days from Date of Transmittal	
Originating QA	Audit Checklis SNL-NWRT-QAPP	Checklist Reference, if A st Item No. 18-5, Quest , Revision E, Section 1 iled by the audit team,	ion No. 2: 8.5.1 states in part,		
by	9 Deficiency Contrary to the above requirement, audit reports are not being issued within 30 calendar days of the audit. These are Audit Numbers: PB-A90-1 performed 12/14-15/89 and issued 2/8/90				
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8 Requirement ( continued )
  days....
9 Deficiency ( continued )

LTA-A90-1 performed 6/20/90 is not yet issued

AGA-A90-1 performed 6/13/90 and issued 7/18/90

BNI-A90-1 performed 1/24-25/90 and issued 3/5/90

RE/SPEC-A90-1, Audit Report Designator RES-A89-2
  performed 10/17-18/89 and 11/1-2/89, and issued on 12/5/89.
10 Recommended Actions ( continued )
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action to prevent recurrence.