



Department of Energy
Yucca Mountain Site Characterization
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WBS 1.2.9.3
QA


DEC 20 1990

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ACCEPTANCE OF RESPONSE TO STANDARD DEFICIENCY REPORT (SDR) 577, REVISION 0,
RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT 90-04
OF SANDIA NATIONAL LABORATORIES (SNL)

The YMQAD staff has evaluated and accepted your response to SDR 577,
Revision 0, generated as a result of YMQAD Audit 90-04 of SNL. The SDR will
be closed after verification of satisfactory completion of the specified
corrective actions. A copy of the SDR is enclosed for your information.

If you have any questions, please contact either Catherine E. Hampton at
(702) 794-7973 or FTS 544-7973 or John S. Martin of Science Applications
International Corporation at (702) 794-7881 or FTS 544-7881.


Donald G. Horton, Director
Yucca Mountain Quality Assurance Division

YMQAD:CEH-1333

Enclosure:
SDR 577, Revision 0

cc w/encl:
K. R. Hooks, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. R. Richards, SNL, 6319, Albuquerque, NM
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:
J. H. Hines, OQD, AL
J. W. Gilray, NRC, Las Vegas, NV

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YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 8/24/90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 90-04		3a Identified By J. Martin & C. Prater		4 SDR No. 577 Rev. 0	
	5 Organization SNL		6 Person(s) Contacted J. Voigt/C. Barnes		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) Audit Checklist Item No. 18-3, Question No. 2: SNL-NWRT-QAPP, Revision E, Section 18, Para. 18.1 states in part: "....Audits shall be performed in accordance with a written procedure using					
Completed by Originating QA Organization	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					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation					
	11 QAE/Lead Auditor/Date <i>John S. Martin</i> 9-10-90		12 Division Manager/Date N.A.		13 Project Quality Mgr./Date <i>John Voigt</i> 9-10-90	
Completed by Org.	14 Remedial/Investigative Action(s) None Required. Audit checklists are not identified or required as QA records by the YMP QA Plan, NNWSI/88-9, Section XVIII, SNL-NWRT-QAPP, Section 18.0 and/or SNL procedure QAP 18-1, QA Audits. Note also that neither NNWSI/88-9, Appendix E nor SNL-NWRT-QAPP Appendix F include checklists as Quality Assurance QA records. NQA-1, which was a basis for the NNWSI/88-9 requirements, and DOE QARD also do not require checklists to be QA records.					
	15 Effective Date Complete					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence None required.					
Comp. by Org.	17 Effective Date Complete					
	18 Signature/Date <i>Thomas E. Bejwan</i> 10-12-90					
	19 Response Accepted		QAE/Lead Auditor/Date <i>John Martin</i> 12-4-90		Division Manager/Date N/A	
Comp. by Org.	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date	
					Project Quality Mgr./Date <i>John Voigt</i> 10-12-90	
	21 Remarks Accepted 12-4-90 SNL's Response based upon Project Office's determination that Audit checklists would not be considered as QA records. <i>John</i> 12-4-90					
Comp. by Org.	22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date	
					PQM/Date	

ENCLOSURE

**YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET**

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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)

to determine the extent and depth of similar deficient conditions to those listed on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

Block 14 Remedial Actions (Continued):

The content of an audit report is specified by the above referenced QAP/QAPP Sections and the SNL QA procedure. The audit report (SNL-A90-1) cited as an example of a deficient report complies with these requirements. The auditor's interpretation of audit report content is at variance with stated content requirements. Checklists are retained for record purposes, both historical and planning, as "personal working files" (SNL ~~ROP~~ 17-1, para. 3.16) by SNL's contractor (MACTEC) and/or by SNL QA. Checklists are maintained temporarily in the contractor's files and periodically submitted for retention by SNL QA. The Audit report cited had just been completed and forwarded to SNL when the YMP audit started; the checklists were still at the contractor's facility.

A review of the contractor's files was made soon after the audit (YMP) and checklists not previously forwarded were forwarded to and are retained by SNL QA. Checklists are necessary for planning and performing audits and serve as a basis for preparing the audit report. These lists are essential to managing an audit program and their content and use for each audit is the lead auditor's responsibility in conducting and reporting an audit.