

YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE SURVEILLANCE REPORT
OF
SANDIA NATIONAL LABORATORIES
SURVEILLANCE NUMBER YMP-SR-90-027
CONDUCTED APRIL 23 THROUGH 26, 1990

ACTIVITIES SURVEILLED:

SCIENTIFIC INVESTIGATION AND DESIGN CONTROL,
INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS, DOCUMENT CONTROL,
CONTROL OF MEASURING AND TEST EQUIPMENT, CORRECTIVE ACTION AND
SDR VERIFICATION

Prepared by: Richard L. Weeks
Richard L. Weeks
Quality Assurance Engineer

Date: 5/7/90

Approved by: Donald G. Horton
Donald G. Horton, Director
Quality Assurance Division
Yucca Mountain Project Office

Date: 5/7/90

1.0 EXECUTIVE SUMMARY

The Yucca Mountain Project Office (Project Office) Quality Assurance (QA) Surveillance of Sandia National Laboratories (SNL) identified program deficiencies in the area of document review which has resulted in an ineffective document review process. Three Standard Deficiency Reports (SDRs) and three Observations were issued.

2.0 PURPOSE AND SCOPE

The purpose of this surveillance was to review the adequacy of implementation of selected SNL procedures and to determine the status of open SDRs. The following procedures were reviewed as the basis for the surveillance:

QAP	16.1	Corrective Action
DOP	2-2	Study Plan Requirements
DOP	3-4	Design Investigation Control
DOP	3-13	Independent Technical and Management Reviews of Documents
DOP	5-2	Technical Procedures Requirements
DOP	6-1	Document Control System
DOP	12-1	Measuring and Test Equipment Control

3.0 SURVEILLANCE PERSONNEL

M. J. Mitchell, QA Engineer (Lead), SAIC, Las Vegas, NV
R. B. Constable, QA Engineer, YMP, Las Vegas, NV
R. L. Weeks, QA Engineer, SAIC, Las Vegas, NV

Observers:

~~T. Verma, NRC~~
S. Zimmerman, State of Nevada

5.0 SUMMARY OF SURVEILLANCE REPORT

SNL personnel stated that they are working to NNWSI/88-9, Revision 2 rather than NNWSI/88-9, Revision 1, which is the current Revision.

Deficiencies which reduce the effectiveness of the document review process were identified and resulted in three SDRs. A summary of the deficiencies follows:

1. QA documents, which are required to provide objective evidence of compliance to the document review process requirements, were not available. Consequently, the quality of the review is indeterminate.
2. Copies of original documents as they existed when submitted for internal review are not being retained as a QA record.

3. Acceptance and rejection criteria were not described in the Experiment Procedures (EPs) as required in the SNL Quality Assurance Program Plan (QAPP).

A summary of areas of weakness that have resulted in Observations follows:

1. Study Plan 8.3.1.15.1.8 was submitted to the Project Office with the incorrect format.
2. DOP 3-4, Revision D interfaces with DOP 3-13, Revision B to complete the review and approval of a Design Investigation Memo (DIM). However, DOP 3-4, Revision D does not provide instructions to direct the reviewer to DOP 3-13. Note: DOP 3-4, Revision E, which is being reviewed, corrects this problem.
3. The distinction between an internal and external review of a DIM is not clearly stated in DOP 3-4, Revision D. Criteria are not established for determining when a review is internal or external.
4. It is unclear how DOP 3-13 and DOP 6-2 interface with each other.
5. Accountability of controlled documents is inadequate.
6. The number of internal audits and surveillances has not been sufficient and has resulted in inadequate record packages.

The status of implementation of corrective action to the SDR Nos. 173, 433, 434, 435, 436, 441 and 445 was determined. SDR Nos. 435 and 436 will be closed due to verification of completion of corrective action. All other SDRs remain open.

6.0 PERSONNEL CONTACTED

J. Bemederfer, Division, Contract, SNL
J. T. George, Division 6314, SNL
J. D. Gibson, Division 6315, SNL
F. D. Hansen, Division 6314, SNL
J. G. Lee, Division 9325, SNL
F. B. Nimick, Division 6315, SNL
R. H. Price, Division 6315, SNL
C. Rautman, Division 6315, SNL
J. Phillips, Division 6311, SNL
R. R. Richards, Division 6319, SNL
S. E. Sharpton, Division 6313, SNL
L. E. Shephard, Division 6315, SNL
G. A. Smit, Division 6319, SNL

E. Stanley, Document Clerk, SNL
A. L. Stevens, Division 6311, SNL
M. A. Tang, Division 6318, SNL
J. V. Voigt, MACTEC, SNL
G. Warner, MACTEC, SNL

7.0 SYNOPSIS OF DEFICIENCY DOCUMENTS/OBSERVATIONS

SDR No. 532 Original copies of reviewed QA documents have not been retained as QA records.

SDR No. 533 Acceptance and reject criteria have not been addressed in EPs as required.

SDR No. 534 Although QA signed the Manuscript Review Sheet indicating review and approval of the stated Study Plan, neither Document Review and Comment sheets nor marked-up copies of the Study Plan were retained as a QA record to provide objective evidence of the completed QA review.

Observation No. YMP-SR-90-027-001 The QA review process does not adequately evaluate the document review process or records produced.

Observation No. YMP-SR-90-027-002 Individuals assigned controlled documents, who no longer wish to be on distribution for the assigned controlled documents, should return assigned documents to the document control center.

Observation No. YMP-SR-90-027-003 Sufficient internal audits and surveillances have not been conducted to establish adequate records packages.

9.0 REQUIRED ACTIONS

SNL is requested to provide responses and effective dates for completion of corrective action to SDR No. 532 through SDR No. 534 within 20 working days of the date of transmittal of the SDRs.

SNL is requested to provide responses to Observations YMP-SR-90-027-001 through YMP-SR-90-027-003 within 20 working days of the transmittal of the Observations.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 4/27/90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2		
	3 Discovered During YMP-SR-90-027		3a Identified By M.J. Mitchell and R.L. Weeks		4 SDR No. 532 Rev. 0		
	5 Organization SNL		6 Person(s) Contacted L. E. Shephard		7 Response Due Date is 20 Working Days from Date of Transmittal		
	8 Requirement (Audit Checklist Reference, if Applicable) NNWSI/88-9, Revision 4, Section XVII, Paragraph 1.2.2 states in part " Sufficient records shall be specified, prepared, and maintained to furnish documented evidence of activities that affect quality.... "						
Completed by Organization in 5 Aprvl.	9 Deficiency Contrary to the above requirement, copies of documents entering the internal review process are not maintained as part of the QA record of the review process. Since an original document has not been retained as a QA record,						
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective It is recommended that the records package include a copy of the original document subjected to review. As the review process proceeds, this original						
	11 QAE/Lead Auditor/Date <i>Richard L. Weeks 5/7/90</i>		12 Division Manager/Date <i>N/A</i>		13 Project Quality Mgr./Date <i>Cathy A. [unclear] 3/10/90</i>		
Completed by Org. QA Org.	14 Remedial/Investigative Action(s)						
	15 Effective Date _____						
	16 Cause of the Condition & Corrective Action to Prevent Recurrence						
17 Effective Date _____							
18 Signature/Date							
19 Response Accepted		QAE/Lead Auditor/Date		Division Manager/Date		Project Quality Mgr./Date	
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date		Project Quality Mgr./Date	
21 Remarks							
22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date		PQM/Date	

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
2/89

SDR No. 532

Page 2 of 2

8 Requirement (continued)

9 Deficiency (continued)

it is impossible to verify comment resolution of text changes or other changes to the original document.

10 Recommended Actions (continued)

document will allow for comparison of changes made to the original text and thus, provide objective evidence of compliance to the comment resolution process requirements.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization

Aprvl.

Completed by Organization In Block 5

Completed by Orig. QA Org.

1 Date 4/27/90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
3 Discovered During YMP-SR-90-027		3a Identified By M. J. Mitchell and R. L. Weeks		4 SDR No. 533 Rev. 0	
5 Organization SNL		6 Person(s) Contacted J. S. Phillips, J. G. Lee, J. D.		7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) SNL-NWRT-QAPP, REV. E, Section 3.7.3.1 states in part, " Experiment Procedures (EPs) utilized for QA Level I and II scientific investigations shall provide for the following as appropriate:					
9 Deficiency Contrary to the requirement as stated above, the programmatic requirements to address acceptance and rejection criteria were not addressed in the following Experiment Procedures: EP-0001, Rev. A, EP-0002, Rev. C, EP-0004, Rev. B and					
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Remedial Action: Remedial actions are taken to correct the specific deficiencies noted on the SDR.					
11 QAE/Lead Auditor/Date <i>Richard L. Weeks</i> 5/10/90		12 Division Manager/Date N/A		13 Project Quality Mgr./Date <i>Cathie D. [Signature]</i> 5-10-90	
14 Remedial/Investigative Action(s)				15 Effective Date _____	
16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____	
18 Signature/Date					
19 Response Accepted		QAE/Lead Auditor/Date		Division Manager/Date	
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date	
21 Remarks					
22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date	
				PQM/Date	

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
2/89

SDR No. 533

Page 2 of 2

6 Persons contacted (continued)

Gibson and R. H. Price

8 Requirement (continued)

o Acceptance and rejection criteria, including required levels of precision and accuracy."

DOP 11-1, REV. G, Section 5.4.1, Paragraph 7 states " Requirements, acceptance and rejection criteria, precision and accuracy levels shall be provided by the organization responsible for the scientific investigation and should be based on pertinent technical documents."

9 Deficiency (continued)

EP-0018, Rev. 0.

10 Recommended Actions (continued)

Corrective Action: Corrective actions are taken to identify the cause of the deficiency and to prevent recurrence of the deficiency identified on the SDR.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization

Aprvl.

Completed by Organization in Block 5

Completed by Orig. QA Org.

1 Date 4-27-90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
3 Discovered During YMP-SR-90-027		3a Identified By R. L. Weeks		4 SDR No. 534 Rev. 0	
5 Organization SNL		6 Person(s) Contacted L. E. Shephard		7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) DOP 3-13, Revision C, Section 4.5 states " Completed DRC forms and other review records shall be included in the Records Management System along with other procedurally required document preparation, review, and					
9 Deficiency Contrary to the requirements stated above, neither Document Review and Comment forms nor marked-up copies of Study Plans were preserved to support the QA review sign-off of Study Plan 8.3.1.15.1.1.8, "In Situ					
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Remedial Action: Remedial actions are taken to correct the specific deficiencies noted on the SDR.					
11 QAE/Lead Auditor/Date <i>Richard L. Webb</i> 5/11/90		12 Division Manager/Date N/A		13 Project Quality Mgr./Date <i>Robert Langate</i> 5-10-90	
14 Remedial/Investigative Action(s)				15 Effective Date _____	
16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____	
18 Signature/Date					
19 Response Accepted		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
21 Remarks					
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
2/89

SDR No. 534

Page 2 of 2

8 Requirement (continued)
approval records."

9 Deficiency (continued)
Design Verification," by B.A. Luke.

10 Recommended Actions (continued)

Investigative Action: Investigative actions are taken to further examine the deficient condition to determine its extent and depth. This action should identify all conditions similar to the examples listed on the SDR.

Corrective Action: Corrective actions are taken to identify the cause of the deficiency and to prevent recurrence of the deficiency identified on the SDR.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. YMP-SR-90-027-001

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: YMP-SR-90-027	3 Identified By: M. J. Mitchell	4 Date: 4/26/90
5 Organization: SNL	6 Person(s) Contacted: R. R. Richards	7 Response Due Date is 20 Days from Date of Transmittal

8 Discussion:
The Quality Assurance (QA) review process evaluates the document but does not adequately evaluate the document review process or records produced. Two SDRs were generated during this surveillance to address specific deficiencies related to records produced during the document review process; however, other potential inadequacies are noted below:

9 QAE/Lead Auditor <i>Robert L. Miller</i>	Date 5/7/90	10 Branch Manager <i>Catherine Hampton</i>	Date 5-10-90
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Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable

Initiator	Date	QA/Lead Auditor	Date
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14 Remarks:

8 Discussion: (continued)

1. Study Plan 8.3.1.15.1.8 was submitted to the Project Office with the incorrect format.
2. DOP 3-4, Revision D interfaces with DOP 3-13 , Revision B to complete the review and approval of a DIM. However, DOP 3-4, Revision D does not provide instructions to direct the reviewer to DOP 3-13. Note: DOP 3-4, Revision E, which is being reviewed, corrects this problem.
3. The distinction between an internal and external review of a DIM is not clearly stated in DOP 3-4, Revision D. Criteria are not established for determining when a review is internal or external.
4. It is unclear how DOP 3-13 and DOP 6.2 interface with each other. DOP 3-13 does not refer to DOP 6.2 within the text of the procedure even though it references it at the end of the procedure.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. YMP-SR-90-027-002

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: YMP-SR-90-027	3 Identified By: R. B. Constable	4 Date: 4/26/90
5 Organization: SNL	6 Person(s) Contacted: R. R. Richards	7 Response Due Date is 20 Days from Date of Transmittal

8 Discussion:
Individuals assigned controlled documents, who no longer wish to be on distribution for the assigned controlled documents, should return assigned documents to the document control center. This will ensure accountability and proper maintenance of the documents.

9 QAE/Lead Auditor <i>Richard L. Walker</i>	Date 5/7/90	10 Branch Manager <i>Catherine Hampton</i>	Date 5-10-90
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Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable

Initiator	Date	QA/Lead Auditor	Date
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14 Remarks:

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. YMP-SR-90-027-r

N-QA-012
 4/89

Completed by Originating Organization

2 Noted During: YMP-SR-90-027 3 Identified By: M. J. Mitchell 4 Date: 4/26/90

5 Organization: SNL 6 Person(s) Contacted: R. R. Richards 7 Response Due Date is 20 Days from Date of Transmittal

8 Discussion:
 Sufficient internal audits and surveillances have not been conducted to establish adequate records packages. Examples of this are SDRs 532 and 534 identified during this surveillance.

9 QAE/Lead Auditor: *Richard L. White* Date: *5/7/90* 10 Branch Manager: *Arthur [unclear]* Date: *5-10-90*

Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable
 Initiator _____ Date _____ QA/Lead Auditor _____ Date _____

14 Remarks: