

OCRWM-HQ QUALITY ASSURANCE SURVEILLANCE REPORT

SURVEILLANCE OF THE YMP QA PROGRAM QUALIFICATION
AUDIT OF SANDIA NATIONAL LABORATORIES (SNL)

SURVEILLANCE NUMBER OCRWM-HQ-SR-89-014

CONDUCTED SEPTEMBER 11 - 15, 1989

PREPARED BY: Berry L. Faust ^{By WRM} DATE 10/26/89
Surveillance Team Leader

APPROVED BY: Laurel D. Shuler DATE 10-26-89
Director, OQA

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A. INTRODUCTION

A surveillance to assess the QA Program compliance, adequacy and effectiveness of the YMP QA audit program was performed by the OCRWM Office of Quality Assurance on September 11-15, 1989.

The surveillance team consisted of the following persons:

Team Leader - G.L. Faust (WESTON)
Member - G. Rolbin, (WESTON)

Personnel contacted during this surveillance:

J. Blaylock, (YMP)
S. Dana (SAIC)
J. Friend (SAIC)
D. Hedges (SAIC)

B. SURVEILLANCE SCOPE

The scope of this surveillance was the YMP QA Program Qualification Audit 89-03 of Sandia National Laboratories (SNL). The purpose of the surveillance was to assess the QA Program compliance, adequacy, and effectiveness of the YMP QA audit program. The surveillance included investigation of the following YMP QA Program elements:

1. QA Audit program system.
2. Standard deficiency reporting system.

C. REQUIREMENTS SURVEILLED

1. YMP Quality Assurance Plan 88-9 (as applicable)
2. YMP Quality Assurance Program Plan 88-1 (as applicable)
3. QMP-16-03, Rev. 1 Standard Deficiency Reporting System
4. QMP-18-01, Rev. 3 Audit System for the Waste Management Project Office

D. RESULTS OF SURVEILLANCE

The following is a summary of the results of the surveillance:

1. The audit material was well prepared and in conformance with the requirements of QMP-18-01, Rev. 3, "Audit Systems for the WMPO". Audit preparation included a pre-audit procedure review. Prior NRC concerns and the results of previous audits were considered and incorporated into the audit checklist.

2. The audit was conducted in a professional manner with the interface and coordination between the audit team, audit organization, and the audit observers going very well. With very little program implementation to verify, the audit team did a thorough and effective job of going beyond verification of the SNL QA Program compliance with the Project QA requirements of NNWSI/88-9, Rev. 2, to evaluate:
 - a) Whether the QA Program, when implemented, would achieve the required quality, and
 - b) The level of SNL personnel knowledge and understanding of the SNL QA Program.
3. The technical specialists assigned to the audit team were knowledgeable and well versed in the Project QA requirements and added significant value to the effectiveness of the audit.
4. The YMP QA Audit 89-03 identified twelve (12) deficiencies, which will be documented on SDRs in accordance with QMP-16-03, Rev. 1, "Standard Deficiency Reporting System" and four (4) observations. The twelve (12) deficiencies related to:
 - o Minimum personnel qualification requirements not established.
 - o Inaccurate logs (i.e., missing entries).
 - o DIM not approved by QA coordinator, as required by procedure.
 - o QL-1 purchase orders did not include right access and nonconformance requirements, as required.
 - o SNL did not forward copies of QL-1 purchase orders to the Project Office (YMP), as issued.
 - o Numerous procedures do not contain adequate QA record sections.
 - o No objective evidence of QA review and approval of technical/test procedures.
 - o Sample inventories not developed, as required.
 - o Inadequate basis exists for establishing a surveillance schedule, based on lack of identification of on-going and near-term activities.
 - o Numerous completed calibration records did not contain all of the required data.
 - o Deficiency reports issued on conditions that qualified as significant deficiencies (15 of 30) were not elevated to corrective action requests.
 - o Completed QA records are not being forwarded to the local records center within the required ten (10) days after completion.

The four (4) observations dealt with procedure weaknesses and/or implementation inconsistency.

5. The YMP audit team conclusions presented at the audit exit meeting were as follows:

- o With the exception of a software QA Plan and applicable QALAs, the SNL QA Program appears to be adequate to support the initiation of ESF Title II design and new site characterization activities.
- o Due to limited implementation, the effectiveness of the SNL QA Program could not be determined at this time.

E. OBSERVATIONS

Some technical specialists tended to drift into a technical review of the documents being audited rather than a technical audit of the documents. It is recommended that this point be emphasized during subsequent technical specialist audit training.

Also in the technical area of the audit, it is recommended that the technical checklists be developed based on the types of technical procedures and products that will be reviewed. This will provide for an appropriate mix of technical, implementation, and effectiveness evaluations.

f. CONFERENCES

A separate pre-surveillance conference was not conducted. The surveillance purpose, scope, team member introductions, etc., was presented as part of the audit team briefing meeting held on September 11, 1989. A post-surveillance conference was held on September 15, 1989. (Reference Attachment 1, "Attendance Record").



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QA

MAR 01 1990

Dwight E. Shelor, Acting Director, Quality Assurance, HQ (RW-3) FORS

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE SANDIA NATIONAL LABORATORIES (SNL) QUALITY ASSURANCE (QA) PROGRAM

Reference: Letter, Gertz to Shelor, dated December 26, 1989

The purpose of this memorandum is to provide an update documenting the Project Office acceptance of the Yucca Mountain Project QA Program of SNL. This acceptance is based upon the following:

1. The U.S. Nuclear Regulatory Commission (NRC) has accepted the SNL Quality Assurance Program Plan (QAPP), Revision E, based upon the safety evaluation letter dated October 24, 1989, from Linehan to Stein. All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA surveillance of the SNL QA Program procedures for adequacy to control the subject activities and conformance with applicable SNL QAPP requirements (reference enclosure 1 for surveillance report numbers, scope, and summary of results).
3. Project Office performance of the SNL QA Program Qualification Audit 89-3 conducted September 11-20, 1989 (reference letter, Wilmot to Hunter, dated October 12, 1989). No NRC staff observations were issued as a result of the Qualification Audit of SNL. This audit concluded that the QA Program is capable of identifying, tracking, and closing deficiencies.
4. Project Office review of outstanding SNL QA Program deficiencies that could have technical or quality impact on output products (reference enclosure 2 for outstanding deficiency numbers and descriptions).
5. The Privacy Act issue prohibited the audit team to fully assess the qualification of individuals performing quality-affecting activities leaving Criterion II indeterminate.

The Severity Level Checklist criteria established in Project Office Quality Management Procedure QMP-16-03 were used to determine impact of the open deficiencies (reference enclosure 3). If the deficiency did not meet Severity Level I criteria, it was regarded as not having significant impact on the start of either Title II activities or in support of new site characterization activities.

MAR 01 1990

Based on the above, the Project Office has concluded that the SNL QA Program is in conformance with the applicable requirements of the Yucca Mountain Project QA Plan NWSI/88-9, Revision 2, and is adequate to support the initiation of either Title II quality-affecting activities or work in support of new site characterization activities with the following exceptions:

1. Software QA Program Plan - Estimated date of completion is March 9, 1990. The Project Office has directed SNL not to perform quality-related software activities until Project Office acceptance of SNL's Software QA Program Plan (reference YMP-SR-89-117, dated August 14, 1989).
2. Upon resolution of the Privacy Act issues, the Project Office will assess the qualifications of all individuals to perform their respective quality-affecting activities.

The Project Office will track, verify, and document resolution of these exceptions by Yucca Mountain Project QA surveillances.

If you have any questions or comments regarding the Project Office position on this matter, please contact Donald G. Horton of my staff at (702) 794-7504 or FTS 544-7504.



Carl P. Gertz, Project Manager
Yucca Mountain Project Office

YMP:DGH-2237

Enclosures:

1. Task Force Surveillances of the SNL QA Program
2. SNL Open QA Deficiencies
3. SDR Severity Level Checklist
4. Surveillance Report YMP-SR-89-117, August 14, 1989

cc w/encls:

Ralph Stein, HQ (RW-30) FORS
T. O. Hunter, SNL, 6310, Albuquerque, NM
R. R. Richards, SNL, 6310, Albuquerque, NM
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08
J. W. Gilray, NRC, Las Vegas, NV

TASK FORCE SURVEILLANCES
OF THE SNL QA PROGRAM

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED	
YMP-SR-89-013	DOP 2-4	Analysis Control and Verification.	One generic DR was issued against these procedures for not identifying a QA Record Section.	SNL-DR-89-6 (Closed)
	DOP 3-3	Analysis Definition Requirements.		
	DOP 3-4	Design Investigation Control.		
	DOP 3-5	Design Control and Verification.		
	DOP 3-6	Design Change Control.		
YMP-SR-89-014	DOP 3-7	Technical Data Base Requirements.	One generic DR issued against these procedures for not identifying a QA Record Section.	SNL-DR-89-6 (Closed)
	DOP 3-8	Reference Information Base Change Control.		
	DOP 3-9	SNL Interface Control and Engineering Design.		
	DOP 3-10	NNWSI Routine Design Calculations.		
	DOP 3-11	Requirements for Submitting Data to the NNWSI Project Site and Engineering Properties Data Base (SEPOB).		
YMP-SR-89-015	DOP 2-6	Qualification and Certification of Project Personnel.	A DR was written for the recertification of a Lead Auditor not being documented as required.	SNL-DR-89-7 (Closed)
	QAP 2-7	Quality Assurance Procedure Qualification of Quality Assurance Program Audit Personnel.		
	DOP 3-12	Peer Reviews.	A DR was written to identify the lack of procedural implementation for certification of personnel assigned to perform quality affecting activities.	SNL-DR-89-8 (Closed)

TASK FORCE SURVEILLANCES
OF THE SNL QA PROGRAM

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-016	DOP 17-1 Records Management System.	A DR was written for improper issuance, maintenance, and generation of the procedures and records list.	SNL-DR-89-9 (Closed) SNL-DR-89-10
YMP-SR-89-017	DOP 5-1 Procedure Format and Content Requirements. DOP 5-2 Technical Procedure Requirements. DOP 5-3 QA Review of Department Operating Procedures. DOP 6-1 Document Control System. DOP 6-2 Reviewing Approving and Issuing Technical Information Documents. DOP 3-1 Preparing, Reviewing, Approving and Issuing Engineering Drawings. QAP 1-3 Quality Related Work Stoppage.	A DR was issued to identify a generic deficiency against these procedures for lack of identifying the Record Section as "QA Records"	SNL-DR-89-6 (Closed)
YMP-SR-89-018	QAP 16-1 Corrective Action Reporting. QAP 16-2 Deviation Reporting. QAP 18-1 Quality Assurance Audits. QAP 10-1 Surveillance.	A generic DR was issued against these procedures for lack of identifying the Record Section as QA Records.	SNL-DR-89-6 (Closed)

Enclosure 1
Page 2 of 6

TASK FORCE SURVEILLANCES
OF THE SNL QA PROGRAM

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-074	DOP 3-16	Specification for Design Requirements.	SNL QA did not perform a QA review of Laboratory Instructions.
	DOP 4-1	Procurement Document Requirements.	DOPs 4-1, 7-1, and 7-2 do not address all aspects of NWSI/88-9.
	DOP 7-1	Procurement Planning.	DOP 14-1 does not address all aspects of NWSI/88-9.
	DOP 7-2	Evaluation for Acceptance of Purchased Items and Services.	DOP 13-1 does not address all aspects of NWSI/88-9.
	DOP 13-1	Identification, Handling, Shipping and Storage Procedures for Items and Materials.	No auditor certification available for auditor who performed internal audit.
	DOP 14-1	Indication of Items.	No receipt inspection report found for purchase req. 55-3514.
	DOP 1-4	Resolution of QA Related Disputes.	
	DOP 15-1	Nonconformance Control and Reporting for Items and Activities.	
YMP-SR-89-075	DOP 3-13	Technical Reviews.	A DR was issued against these procedures for a generic lack of identifying a QA Record Section.
	DOP 5-2	Technical Procedure Requirements.	
	DOP 8-1	Sample Identification and Handling Requirements.	
	DOP 8-2	Operation of the SNL-NWSI Project Sample Library.	
	DOP 11-1	Experiment and Equipment Test Procedure Requirements.	
	DOP 11-2	Requirements for Experiment and Equipment Test Log Books.	

TASK FORCE SURVEILLANCES
OF THE SNL QA PROGRAM

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-106	DOP 2-9	Readiness Reviews.	
	DOP 3-2	Software Quality Assurance Requirements.	SNL-DR-89-25 (Closed)
	DOP 3-15	Providing Instructions for NTS Contractor Work.	DOP 2-9 does not address selection and qualification of readiness review board members.
	DOP 11-3	Requirements for Interaction with the Data Records Management System.	DOP 3-2 does not meet procedure format requirements and definitions are inconsistent with NWSI/88-9, App. A. Computer Codes FRACT1.0 and INTERPO do not have QA approval.
		DOP 3-15 does not meet the requirements for procedure format.	SNL-DR-89-27 (Closed)
		DOPs 2-9, 3-2, and 11-3 do not have a section identifying QA Records (generic deficiency).	SNL-DR-89-6 (Closed)

TASK FORCE SURVEILLANCES
OF THE SNL QA PROGRAM

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-107	QAP 1-1	Quality Assurance Program Plan Control.	N/A
	QAP 7-3	Evaluation of Contractor QA Program Documents.	
	QAP 16-3	Quality Assurance Program Report.	

DEFICIENCY #: DESCRIPTION OF DEFICIENCY:

SDR-173 Level III scoping work being performed in a QA Level I activity without proper justification.

SDR-430 SNL has not forwarded copies of 1989 purchase order documents to T&MSS QA Dept. as required.

SDR-431 SNL procedure DOP 2-6, Rev. C, does not adequately establish minimum education and experience requirements.

SDR-432 The QA Coordinators basis for scheduling audits and surveillances is not in compliance with project requirements.

SDR-433 Deficiency Report evaluation to determine whether to elevate to a CAR were made prior to obtaining sufficient information.

SDR-434 SNL procedures disclosed that several procedures did not contain QA Record sections.

SDR-435 Calibration certificates of equipment used on project activities do not meet procedure requirements.

SDR-437 Semi-annual checks of samples in the sample library by the sample library manager were not conducted nor was an inventory list of samples generated.

SDR-438 Reference and cross-references in product logs are not accurate.

SDR-439 Design Information Memo DIM 205 was not approved by the QA Coordinator as required.

SDR-440 Records are not being processed to the local record center or the central record facility within the required time frame.

SDR-441 Procurement documents revealed a lack of access clause that was not included in the documents.

(Continued)

All of the above deficiencies were evaluated and determined to be either Severity Level 2 or 3 in accordance with QMP-16-03. This evaluation concluded that the deficiency did not result in a loss of licensing data, an error in the design or construction of an engineered item nor the potential for an adverse impact to the public health and safety or safety of the operations personnel.

DEFICIENCY #: DESCRIPTION OF DEFICIENCY:

AFR-SNL-
88-07

SNL's procedure DOP 3-2, "Software QA Requirements", was not imposed on contractors.

The deficiency identified above could have an impact on quality affecting activities with respect to software generated from their contractors. A possible loss of licensing data could occur if it is not corrected. It is for this reason that the Project Office must verify and document resolution of this exception as noted in the exception on page 2.

STATUS OF ABOVE DEFICIENCIES

YMP-SDR-173	Corrective actions not completed to date.
SDR-430	Verification Department to verify corrective action completion.
SDR-431	Verification Department to verify corrective action completion.
SDR-432	Verification Department to verify corrective action completion.
SDR-433	Extension for corrective action granted to February 28, 1990.
SDR-434	Verification Department to verify corrective action completion.
SDR-435	Amended response under evaluation by Project Office.
SDR-436	SNL to complete corrective action. Effective date is February 28, 1990.

Enclosure 2
Page 3 of 4

STATUS OF DEFICIENCIES

SDR-437	Verification Department to verify corrective action completion.
SDR-438	Verification Department to verify corrective action completion.
SDR-439	Verification Department to verify corrective action completion.
SDR-440	Verification Department to verify corrective action completion.
SDR-441	Extension for corrective action granted to February 28, 1990.
SDR-444	Project Office in process of accepting amended response.
SDR-445	Verification Department to verify corrective action completion.
SDR-492	SNL to provide response.
SDR-493	SNL to provide response.
AFOR No. SNL 89-06	Corrective action complete; awaiting verification.
SNL DR-90-46	Requires verification of disposition by SNL.
SNL DR-89-38	Verification of corrective action required.
SNL DR-90-47	Requires verification of disposition by SNL.
SNL DR-89-26	Pending approval of the SQAP.
AFR-SNL-88-07	Pending approval of the SQAP.
SNL CAR-89-1	Corrective action ongoing; preparedness reviews being done for each WBS activity.

SDR SEVERITY LEVEL CHECKLIST

N-QA-037
4/89

I. ASSIGN A SEVERITY LEVEL OF 1 IF ONE OR MORE OF THE FOLLOWING IS TRUE.

	Yes	No
1. Did the deficiency result in significant damage to natural barriers, structures, systems, or components that will require extensive evaluation, extensive redesign, or extensive repair in order to assure public health and safety?	—	—
2. Does this deficiency involve loss of essential data or information needed for licensing?	—	—
3. Does the deficiency constitute a significant deficiency in design, construction, testing, or performance assessment that were detected subsequent to formal quality verification and acceptance?	—	—
4. Does the deficiency constitute a significant deficiency in design as approved for construction such that the design deviates extensively from design criteria and bases?	—	—
5. Does the deficiency constitute a significant deviation from performance objectives or specifications that will require extensive evaluation, extensive redesign, or extensive repair to establish the adequacy of a natural barrier, structure, system, or component to meet design criteria and bases?	—	—
6. Does the deficiency constitute a significant error detected in a computer program after it has been released for use?	—	—
7. Does the deficiency constitute a significant breakdown in a participant's QA program and/or repetitive, programmatic and hardware deficiencies for which previous corrective action has not been reasonably prompt or effective?	—	—

II. ASSIGN A SEVERITY LEVEL OF 2 IF THE ANSWERS TO ALL QUESTIONS IN PART I ARE NO AND ONE OR MORE OF THE FOLLOWING IS TRUE:

	Yes	No
1. Could failure to correct deficiency have a potentially adverse impact on the health or safety of operations personnel?	—	—
2. Does the deficiency constitute operating outside the scope of the quality program or approved quality procedures where both remedial and corrective actions are required?	—	—
3. Does the deficiency constitute a repetitive hardware deficiency for which no previous corrective action measures exist?	—	—

III. ASSIGN A SEVERITY LEVEL OF 3 IF THE ANSWERS TO ALL QUESTIONS TO PARTS I AND II ARE NO.

QAE/Lead Auditor	QA Division Manager	PQM
_____ Signature/Date	_____ Signature/Date	_____ Signature/Date