

OCRWM-HQ QUALITY ASSURANCE SURVEILLANCE REPORT
SURVEILLANCE OF THE YMP QA PROGRAM QUALIFICATION AUDIT 89-06
OF LAWRENCE LIVERMORE NATIONAL LABORATORIES (LLNL)

SURVEILLANCE NUMBER OCRWM-HQ-SR-89-009

CONDUCTED JUNE 5 - 9, 1989

Prepared by: *[Signature]* Date 07/28/89
Surveillance Team Leader

Approved by: *[Signature]* Date 8/2/89
Director, OQA

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SURVEILLANCE REPORT NUMBER
OCRWM-HQ-SR-89-009

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 June 5 - 9, 1989.

The surveillance team consisted of the following person:

Team Leader - A. W. Spooner (Weston)

Personnel contacted during this surveillance:

J. Friend (SAIC)	F. Ramirez (DOE-SF)
H. Caldwell (SAIC)	P. Cloke (SAIC)
W. Mansel (YMP)	
F. Kratzinger (SAIC)	

B. SURVEILLANCE SCOPE

The scope of this surveillance was the YMP QA Program Qualification Audit 89-06 of Lawrence Livermore National Laboratories (LLNL). The purpose of the surveillance was to assess the adequacy and effectiveness of the YMP QA audit program. The surveillance included investigation of the following YMP QA Program elements:

1. Audit personnel performance.
2. QA audit program system.
3. 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 considered to be very effective.

It is of particular importance to note that the interface between the audit team and the observers (State of Nevada, and the NRC) was exceptional in nature and contributed significantly to the overall success of the audit.

3. The technical specialists assigned to the audit team were knowledgeable and well aware of the project QA requirements and the scope of LLNL activities. Mr. Cloke is to be complimented on his management of the technical team.
4. No deficiencies were identified by the YMP audit team.
5. The YMP audit team conclusion(s) presented at the audit exit were that the LLNL QA program appears to be adequate to support the initiation of the quality affecting work. This is contingent on LLNL closing several items on the self-imposed stop work and issuance of the remaining implementing procedures (i.e., software QA).

E. OBSERVATIONS

There were no deficiencies or observations identified during this surveillance.

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 April 24, 1989. An informal post-surveillance conference was held on April 28, 1989.

G. REQUIRED ACTION

As a result of no deficiencies/observations being identified during this surveillance, there is no action required by the YMP with respect to this report.

7. NRC and State of Nevada concerns were not specifically related to the scope of the audit and therefore are not addressed in this report.



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
QA

MAR 01 1990

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) QUALITY ASSURANCE (QA) PROGRAM

Reference: Letter, Gertz to Shelor, dtd. October 25, 1989

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

1. The U.S. Nuclear Regulatory Commission (NRC) has accepted the LLNL QA Program Plan (QAPP) based upon 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 LLNL QA Program procedures for adequacy to control the subject activities and conformance with applicable LLNL QAPP requirements (reference enclosure 1 for surveillance reports numbers, scope, and summary of results).
3. Project Office performance of the LLNL QA Program Qualification Audit 89-6, conducted June 5-9, 1989 (reference letter, Wilnot to Jardine, dated July 2, 1989). Responses have been provided to NRC observations generated as a result of the audit. This audit concluded that the QA Program is capable of identifying, tracking, and closing deficiencies.
4. Project Office review of outstanding LLNL QA Program deficiencies that could have technical or quality impact on output products (reference enclosure 2 for outstanding deficiency numbers and descriptions).

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 Title II activities.

Based on the above, the Project Office has concluded that the LLNL QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NNWSI/88-9, Revision 2, and is adequate to support the start of Title II activities.

Dwight E. Shelor

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MAR 01 1990

If you have any questions or comments regarding the Project Office position on this matter, please call 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-2234

Enclosure:

1. Summary of Surveillance Results
2. LLNL Open QA Deficiencies
3. SDR Severity Level Checklist

cc w/encl:

Ralph Stein, HQ (RW-30) FORS
L. J. Jardine, LLNL, Livermore, CA
D. W. Short, LLNL, Livermore, CA
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06
J. W. Gilray, NRC, Las Vegas, NV

**TASK FORCE SURVEILLANCES
OF THE LLNL QA PROGRAM**

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-041	033-YMP-QP 1.0 Rev. 0 "Organization" 033-YMP-QP 2.0 Rev. 0 "Assurance" 033-YMP-QP 2.2 Rev. 0 "Peer Review" 033-YMP-QP 2.7 Rev. 0 "Stop Work Order"	No findings or deficiencies were noted.	None
YMP-SR-89-042	033-YMP-QP 2.9 Rev. 0 "Indoctrination and Training of Personnel" 033-YMP-QP 2.10 "Qualification of Personnel"	Proficiency evaluation record not well defined. LLNL Change Notice 2.9-0-1 was initiated to clarify its usage. QA Records section not specific. LLNL Change Notice 2.9-0-1 added a "laundry list" of typical QA records.	None
YMP-SR-89-043	033-YMP-QP 2.8 Rev. 0 "Assigning Levels of Quality Assurance" 033-YMP-QP 3.1 Rev. 0 "Design Control"	Item activity summary sheet not being used. LLNL Change Notice 2.8-0-1 added the summary sheet. Review by QA was omitted. Change Notice 3.1-0-1 added the QA Review requirement. Organization chart does show Deputy for QA per paragraph 3.1.5.5. Change Notice 3.1-0-1 added to remove typo.	None

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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-044	033-YMP-QP 2.1 Rev. 0 "Preparation, approval and Revision of Quality Procedures and Requirements.	Required documentation not defined. Change Notice 2.1-0-1 has defined the term above as "QA Records".	None
YMP-SR-89-045	033-YMP-QP 15.0 Rev. 0 "Nonconforming Items, Procedural Nonconformances, and Conditions Adverse to Quality" 033-YMP-QP 16.0 Rev. 0 "Corrective Action" 033-YMP-QP 16.1 Rev. 0 "Processing of Externally Originated Corrective Action Documents"	Procedural inadequacies regarding identification of item with no adverse impact. Change Notice 15.0-0-1 issued to address this issue. Conditional release not addressed. LNL's QA Program does not authorize conditional release, see Change Notice 15.0-0-1. Procedural inadequacies with respect to personnel evaluating dispositions or nonconformances. Change Notice 15.0-0-1 added to clarify. Procedural inadequacies regarding technical justification on use-as-is or repair dispositions. Change Notice 15.0-0-1 clarified this discrepancy.	None

**TASK FORCE SURVEILLANCES
OF THE LLNL QA PROGRAM**

SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-045 (Continued)	See above.	QA Records not defined. Change Notice 2.1-0-1 defines "Required Documentation" as "QA Records." "Significant conditions" adverse to Quality not addressed. LLNL's QA Program was found adequate after review of QP 15.0 and QP 16.0.	None
YMP-SR-89-046	033-YMP-QP 18.0 Rev. 0 "Audits" 033-YMP-QP 18.1 Rev. 0 "Surveillances" 033-YMP-QP 18.2 Rev. 0 "Qualification of Quality Assurance Audit Personnel"	Procedural inadequacies regarding technical specialists. Change Notice 18.0-0-1 issued for clarification. QA Records not defined. Change Notice 2.1-0-1 assigned to clarify.	None
YMP-SR-89-047	033-YMP-QP 2.4 Rv. 0 "Technical Review" 033-YMP-QP 3.3 Rev. 0 "Review of Technical Publications" 033-YMP-QP 3.0 Rev. 0 "Scientific Investigation Control" 033-YMP-QP 3.4 Rev. 0 "Scientific Notebooks" 033-YMP-QP 3.2 Rev. 0 "Software Quality Assurance"	Procedural inadequacies relating to 033-YMP-QP 3.0 wherein it does not stipulate the intent of scientific notebooks. Change Notice 3.0-0-1 was modified to address this deficiency. No summary section addressed regarding documentation on scientific investigation activities.	None

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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
<p>YMP-SR-89-047 (Continued)</p>	<p>See above.</p>	<p>Change Notice 3.0-0-1 was issued to include a "Summary Section".</p> <p>033-YMP-QP 3.0 Rev. 0 para. 3.0.11 did not provide details or methods for identifying field or laboratory scientific investigations that may impact other activities. LLNL will include interface controls in their planning documents and Technical Implementing Procedures.</p> <p>033-YMP-QP 3.0 did not include details for planning verification activities in scientific investigations. Change Notice 3.0-0-1 now describes the methodology for these planning activities.</p> <p>Authority to waive hold points not addressed. Change Notice 3.0-0-1 was modified to include the required language for waiver by the QA manager.</p>	<p>None</p>

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<p>YMP-SR-89-047 (Continued)</p>	<p>See above.</p>	<p>033-YMP-QP 3.2 Rev. 0 did not specifically identify what documentation is to be retained as QA Records. LLNL stated that due to the wide variety of scientific tasks utilizing computer programs the planning documents will dictate what specific documents are to be retained.</p> <p>Section 3.2.4 of QP 3.2 does not specify that documentation of a software configuration management program will be provided to the Records Management System. LLNL stated that the software configuration management programs are described in Scientific Planning documents which follow the requirements of Appendix H to the 88/9 Rev. 2 document.</p>	<p>None</p>
<p>YMP-SR-89-053</p>	<p>033-YMP-QP 6.0 Rev. 0 "Document Control" 033-YMP-QP 17.0 Rev. 0 "Quality Assurance Records"</p>	<p>No discrepancies noted.</p>	<p>None</p>

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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-054	033-YMP-QP 2.5 Rev. 0 "Acceptance of Data Not Generated Under the Control of the YMP-QAPP" 033-YMP-QP 2.3 Rev. 0 "Management Assessment" 033-YMP-QP 8.0 Rev. 0 "Identification and Control of Items, Samples and Data" 033-YMP-QP 13.0 Rev. 0 "Handling, Storage, and Shipping"	033-YMP-QP 2.3 indicates that the YMP leader has responsibility for designating the management assessment members and approving the scope. LLNL Change Notice 2.3-0-1 was changed to show this as the responsibility of the Energy Program Leader.	None
YMP-SR-89-055	033-YMP-QP 2.6 Rev. 0 "Readiness Review"	No findings or deficiencies were noted.	None
YMPSR-89-057	033-YMP-QP 4.0 Rev. 0 "Procurement Control and Documentation"	Section 4.0.7 did not explain how documenting evidence of conformance to codes, regulations or contract requirements gets into the YMP QA Records management system. Change Notice 4.0-0-1 was made to clarify this situation. 033-YMP-QP 4.0 did not include the requirement for the LLNL YMP QA manager to request the Project Office to conduct surveillances over other project participants who provide support activities to LLNL.	None

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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-057	033-YMP-QP 4.0 Rev. 0 "Procurement Control and Documentation"	<p>Change Notice 18.1-0-1 was issued to address this deficiency.</p> <p>033-YMP-QP 4.0 did not include a requirement to furnish the supplier documented evidence of purchases acceptance of source verification.</p> <p>LLNL Change Notice 4.0-0-1 was revised to require purchaser acceptance documentation to be sent to the supplier.</p> <p>033-YMP-QP 4.0 does not stipulate the type of QA Records to be contained in the procurement action folder. Due to the differences in procurement actions the content will vary.</p> <p>Change Notice 4.0-0-1 was processed to note that situation.</p> <p>033-YMP-QP 4.0 mentions "commercial services while there are no provisions in the 88/9 Rev. 2 document for this type of procurement.</p> <p>Change Notice 4.0-0-2 was issued to delete all references to commercial services.</p>	None

**TASK FORCE SURVEILLANCES
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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-072	033-YMP-QP 16.2 Rev. 0 "Trend Analysis"	No findings or deficiencies were noted.	None
YMP-SR-89-073	033-YMP-QP 10.0 Rev. 0 "Inspection" 033-YMP-QP 11.0 Rev. 0 "Test Control" 033-YMP-QP 14.0 Rev. 0 "Inspection, Test and Operating Status"	<p>Personnel qualifications for NDE personnel not addressed. Change Notice 10.0-0-1 was issued specifying that inspection personnel are certified in writing to QP 2.11.</p> <p>033-YMP-QP 10.0 does not identify the person with authority to permit work to proceed beyond a mandatory inspection or hold point. Change Notice 10.0-0-1 was issued describing that the QA manager or his designee has that authority and the basis for the authorization will be documented.</p> <p>033-YMP-QP 11.0 does not describe methods for verifying that design requirements of test plans and procedures are met.</p>	None

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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
<p>YMP-SR-89-073 (Continued)</p>	<p>See above.</p>	<p>Change Notice 11.0-0-1 was issued to assure that those test plans and procedures be reviewed in accordance with the applicable verification provisions of 033-YMP-QP 3.1 "Design Control."</p> <p>033-YMP-QP 11.0 does not identify those persons responsible for the control of tests of engineering items.</p> <p>Change Notice 11.0-0-1 was revised to note that the task leaders now have this responsibility. In addition the QA manager has been assigned the responsibility to monitor these activities.</p> <p>033-YMP-QP 14.0 Rev. 0 did not identify those persons responsible for the control of the inspection, test, and operating status of engineered items.</p> <p>Change Notice 14.0-0-1 was revised to assign responsibilities to the task leader with the QA manager responsible for monitoring the activities.</p>	<p>None</p>

**TASK FORCE SURVEILLANCES
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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-073 (Continued)	See above.	033-YMP-QP 14.0 did not identify those persons with authority to apply and remove tags, markings, labels and stamps indicating the operating status of systems and components. As noted in the previous resolution, Change Notice 14.0-0-1 assigned those responsibilities to the task leaders.	None
YMP-SR-89-077	033-YMP-QP 2.11 Rev. 0 "Qualification and Certification of Inspection and NDE Personnel" 033-YMP-QP 9.0 Rev. 0 "Control of Process" 033-YMP-QP 12.0 Rev. 0 "Control of Measuring and Test Equipment"	033-YMP-QP 2.11 did not specify education and experience requirements. Change Notice 2.11-0-1 added these requirements to meet 88/9. 033-YMP-QP 2.11 did not specify that persons not meeting the qualification requirements may be used for data-taking or equipment operation if supervised by a qualified individual. Change Notice 2.11-0-1 added this requirement. On-the-job training not described. Change Notice 2.11-0-1 was revised to include on-the-job training.	None

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SURVEILLANCE NUMBER	PROCEDURE AND SCOPE	SUMMARY RESULTS	DEFICIENCIES ISSUED
YMP-SR-89-077	See above.	033-YMP-QP 2.11 does not specify the removal of a person from a job if the person's qualifications are in doubt. Change Notice 2.11-0-1 added the necessary changes. 033-YMP-QP 2.11 did not specify the contents of certification documents for NDE and Inspection personnel. Change Notice 2.11-0-1 was revised to include certification documentation requirements. 033-YMP-QP 12.0 did not discuss nor was the identity of management responsibility defined to accepting calibration standard of equal value. Change Notice 12.0-0-1 was amended to fully describe those areas.	None.

LLNL OPEN QA DEFICIENCIES

DEFICIENCY NUMBER	DESCRIPTION OF DEFICIENCY
SDR-38 & 90	This has no impact as no services are currently being supplied.
SDR-479	Incorporating procurement QA requirements to sub-tier suppliers.
SDR-480	Reporting out-of-tolerance M&TE
LLNL NCR-021	EQ 3/6 Manual Control
LLNL NCR-025	M&TE out-of-tolerance at time of calibration
LLNL NCR-026	M&TE out-of-tolerance at time of calibration
LLNL CAR-002	Calibration related nonconformances

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 the 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