

U.S. NUCLEAR REGULATORY COMMISSION
REPORT OF OBSERVATION AUDIT 93-13
OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT YMP-93-14
OF THE LAWRENCE LIVERMORE NATIONAL LABORATORY

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1.0 INTRODUCTION

During July 19 through 23, 1993, members of the quality assurance (QA) and technical staff of the NRC Division of High-Level Waste Management (HLWM) observed a U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) audit of the Lawrence Livermore National Laboratory - Yucca Mountain Project (LLNL-YMP). The audit, YMP-93-14, was conducted at the LLNL-YMP facilities in Livermore, California. The audit evaluated the adequacy and effectiveness of the LLNL-YMP QA program. Four technical areas and six QA programmatic areas were audited.

This report addresses the effectiveness of the YMQAD audit and the adequacy of implementation of the QA controls in the audited areas of the LLNL-YMP QA program.

2.0 OBJECTIVES

The objectives of the audit by YMQAD were to determine whether the LLNL-YMP QA program and its implementation meet the applicable requirements and commitments imposed by the OCRWM Quality Assurance Requirements Document, the LLNL-YMP quality Assurance Program Description, and associated LLNL-YMP implementing procedures.

The NRC staff's objective was to gain confidence that YMQAD and LLNL-YMP are properly implementing the requirements of their QA programs in accordance with Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the LLNL-YMP implementation of the LLNL-YMP QA program on direct observations of the audit team members; discussions with audit team, LLNL-YMP, and LLNL-YMP contractor personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents. The NRC staff has determined that YMQAD QA Audit YMP-93-14 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. Audit team members were independent of the activities that they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team findings that the LLNL-YMP QA program has adequate procedural controls in place and that program implementation in the areas audited is generally satisfactory. The only exception to satisfactory program implementation is in the areas of nonconformance control and software QA where there has been insufficient implementation since the last audit of these areas to judge their effectiveness. The classification of software controls continues as unsatisfactory from a previous YMQAD audit of that area because there has been inadequate activity in that area to change the classification.

The audit team provided six recommendations to improve the LLNL-YMP QA program, and six preliminary Corrective Action Requests (CARs) were generated

by the audit team during the audit: five of the six preliminary CARs were acceptably resolved by LLNL-YMP during the audit. The preliminary CARs identified by the YMQAD audit team are not significant in terms of the overall implementation of the LLNL-YMP QA program.

OCRWM should continue to closely monitor LLNL-YMP implementation of its QA program to ensure that the deficiency identified during this audit is corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits later to assess LLNL-YMP implementation of its QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observer	
Tae M. Ahn	Observer	
Robert D. Brient	Observer	Center for Nuclear Waste Regulatory Analyses (CNWRA)
Rodney M. Weber	Observer Trainee	CNWRA

4.2 DOE

Richard L. Weeks	Audit Team Leader (ATL)	YMQAD - Science Applications International Corp. (SAIC)
Mario R. Diaz	Auditor	YMQAD
Thomas J. Higgins	Auditor	YMQAD - SAIC
John E. Therien	Auditor	YMQAD - SAIC
Kenneth T. McFall	Lead Technical Specialist	YMQAD - SAIC
David Stahl	Technical Specialist	YMQAD - Management and Operating Contractor/B&W Fuel Company (M&O/B&W)
J. Kevin McCoy	Technical Specialist	YMQAD - M&O/B&W

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The YMQAD audit of LLNL-YMP was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 5 plus Interim Change Notice 1) and QAAP 16.1, "Corrective Action" (Revision 4). The NRC observation audit of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of Audit

The audit scope included the applicable QA programmatic elements and scientific investigations listed below:

5.1.1 QA Programmatic Elements

- 3 Scientific Investigation Control and Design Control¹
- 4 Procurement Document Control
- 7 Control of Purchased Items and Services
- 8 Identification and Control of Items, Samples, and Data
- 13 Handling, Storage, and Shipping
- 15 Control of Nonconforming Items

Before the audit, QA Programmatic Elements 10, "Inspection," 11, "Test Control", and 14, "Inspection, Test, and Operating Status," were determined by YMQAD to be not applicable at LLNL-YMP because LLNL-YMP has no current activities to which these elements apply.

5.1.2 Scientific Investigations

- D-20-27 Unsaturated Testing of WVDP (West Valley) and DWPF (Savannah River) Glass
- D-20-45 Low-Temperature Oven Method for Spent Fuel Oxidation Testing
- D-20-53A Flow-Through Dissolution Tests on UO₂
- D-20-53B Flow-Through Dissolution Tests on Spent Fuel

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate for YMQAD to audit the pertinent QA activities of LLNL-YMP and for the staff to evaluate the YMQAD audit process and LLNL-YMP's implementation of its QA program. Quality affecting activities are in progress. This audit was scheduled in conformance with YMQAD's current practice of auditing LLNL-YMP approximately semi-annually with each applicable QA programmatic element audited at least annually.

5.3 Examination of QA Programmatic Elements and Scientific Investigations

Before the audit, the audit team developed and utilized checklists based on the requirements in the pertinent implementing procedures and activity plans as they are listed in Table 1 at the end of this report. Auditing of QA Programmatic Element 4, "Procurement Document Control," was conducted simultaneously with auditing of QA Programmatic Element 7, "Control of Purchased Items and Services." Similarly, Programmatic Element 8, "Identification and Control of Items, Samples, and Data," and Programmatic Element 13, "Handling, Storage, and Shipping," were also audited simultaneously. Specific audit team members were assigned to audit compliance with the specific LLNL-YMP procedures and activity plans listed in Table 1.

¹ LLNL-YMP has no responsibility for design control at this time. QA Program Elements 19, "Computer Software," and 20, "Scientific Investigations," are included in QA Program Element 3 in accordance with the LLNL-YMP QA Program Plan.

During the audit, the checklists were used by the audit team members to guide their interviews with LLNL-YMP and LLNL-YMP contractor personnel. It was found that insufficient activity had occurred under QA Programmatic Elements 15, "Control of Nonconforming Items," and 19, "Computer Software," to allow an assessment of their effectiveness.

The NRC staff observed the YMQAD audit team's evaluation of each of the scientific investigations and QA programmatic elements. The NRC staff observed all or a portion of the YMQAD audit covering the activity plans and implementing procedures listed in Table 1.

The NRC staff observed that each of the audit team members reviewed related documentation and interviewed at least a representative sample of LLNL-YMP and LLNL-YMP contractor personnel to determine their understanding and degree of implementation of the activity plans and procedures. The audit team members were well prepared and knowledgeable of the QA program requirements. They used their checklists effectively and pursued issues beyond the checklists when appropriate. They solicited comments and questions from the NRC observers in an acceptable manner. The NRC staff observations regarding the audit and the implementation of each QA programmatic element and the scientific investigations are discussed below.

5.3.1 QA Programmatic Elements

- Scientific Investigation Control and Design Control (Programmatic Element 3)

Computer software and scientific investigations were audited under Programmatic Element 3. Regarding computer software, LLNL-YMP has two codes identified in its Software Master Log as being quality-affecting: EQ3/6 and VTOUGH. Both of these codes are cited as being developmental versions, not certified for quality-affecting work. Software development was described in Individual Software Plans, three of which are associated with EQ3/6, one with VTOUGH, and five additional associated with other codes. The portion of the software QA audit observed concentrated on control of EQ3/6 and VTOUGH. Discussions were held with the respective Principal Investigators, and software documentation was examined. A minor discrepancy was identified by the auditor in a file which was required by procedure to contain certain documentation. The documentation was located, and remedial action was taken during the audit. While this audit identified no significant deficiencies regarding computer software, a previous YMQAD audit² had concluded that software controls were unsatisfactory due to software problems noted in LLNL-YMP CARs. The audit team concluded that insufficient implementation has occurred in this area since that determination to change the status. Thus the status of software controls is to remain unsatisfactory.

² See the letter of September 30, 1992, from Horton (DOE) to Clarke (LLNL-YMP) that includes Audit Report YMP-92-21 as an enclosure (NRC RIDS Accession Number 9210090421).

The audit of computer software was effective. The NRC staff does not disagree with the audit team's preliminary finding that software control continues to be classified as unsatisfactory.

The results of the audit of scientific investigations and the related NRC staff observations of this portion of the audit are discussed in Section 5.3.2 below.

- Procurement Document Control and Control of Purchased Items and Services (Programmatic Elements 4 and 7)

Programmatic Elements 4 and 7 were audited simultaneously. LLNL had only two quality-affecting procurement activities: the interagency type agreements with Argonne National Laboratory (ANL) and Pacific Northwest Laboratory (PNL). This special type of procurement is covered in appropriate procedures, and the procurement documents include appropriate QA requirements. ANL and PNL were last audited by LLNL-YMP in 1991, and the auditor found that annual evaluations to determine whether annual audits are necessary had not been performed. This resulted in the one preliminary CAR that remained open at the end of the audit.

LLNL may also procure items and services internally; for example, calibration of balances. No internal procurement activities have occurred during the past year since calibrations have been performed "before use" using mass standards with a five year calibration interval. When the calibration of mass standards expires, the internal procurement practices are expected to be used.

The auditor was thorough in his evaluations, and the audit of these programmatic elements was effective. The NRC staff agrees with the audit team's assessment that implementation of Programmatic Elements 4 and 7 was adequate.

- Identification and Control of Items, Samples, and Data and Handling, Storage, and Shipping (Programmatic Elements 8 and 13)

Programmatic Elements 8 and 13 were also audited simultaneously, and the audit of these elements focused on their application to samples. The portion observed was conducted in the chemistry laboratory where the flow-through dissolution tests on UO_2 were being conducted. Samples were appropriately labeled and stored. However, the auditor identified that the location of the samples and the storage environment were not documented. This condition was corrected during the audit with appropriate entries in the scientific notebook.

The audit of these programmatic elements was effective. The NRC staff agrees with the audit team that LLNL-YMP implementation of these programmatic elements is adequate.

- Control of Nonconforming Items (Programmatic Element 15)

Insufficient activity had occurred under Programmatic Elements 15 to allow an assessment of its effectiveness.

5.3.2 Scientific Investigations

The following is a summary of the NRC staff's observations of the audit of the scientific investigations. Four areas were audited: (a) unsaturated testing of WVDP and DWPF glass by ANL, (b) low-temperature oven method for spent fuel oxidation testing by PNL, (c) flow-through dissolution tests on UO_2 by LLNL-YMP, and (d) flow-through dissolution tests on spent fuel by PNL. PNL and ANL are sub-contractors of LLNL-YMP. The checklist for this portion of the audit focused primarily on personnel qualifications, test procedures, and test variables.

The study plans listed in Table 1 were used as the source of technical questions during this portion of the audit. Applicable LLNL-YMP laboratory notebooks were reviewed and found to be acceptable. Involved LLNL-YMP technical personnel were interviewed. These individuals appeared well qualified for their work assignments and, in general, were properly trained and had an overall understanding of the QA requirements. They were very familiar with the activities being performed at ANL and PNL. No problems were identified during this portion of the audit.

The audit of this portion of the LLNL-YMP QA program was effective. The Lead Technical Specialist and the Technical Specialists working together as a team were involved in all of the technical activity evaluations observed by the NRC staff. This team of technical specialists that performed the technical portion of the audit appeared to be well qualified to do its assigned work. The audit process allowed for thorough responses to the questions, even though the questions were general in nature. The team's familiarity with ongoing LLNL-YMP activities and the related activities being performed by ANL and PNL was particularly beneficial in follow-up questioning. The NRC staff agrees with the audit team finding that QA program implementation for the four scientific investigations audited is adequate.

5.3.3 Conclusions

The audit of the LLNL-YMP QA program evaluated the adequacy of implementing procedures and the effectiveness of implementation of the QA program and scientific investigations. The audit team members used appropriate checklists, interviewed LLNL-YMP and LLNL-YMP contractor personnel, and reviewed pertinent documentation. The audit was effective, and the NRC staff agrees with the audit team that LLNL-YMP is adequately implementing its QA program in the areas audited.

5.4 Conduct of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the LLNL-YMP QA program. In general the audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. Daily caucuses were held between audit team members and observers, and daily audit status meetings were held between LLNL-YMP management and the ATL (with an NRC observer present) to discuss the preliminary findings.

5.5 Qualification of Audit Team Members

The qualifications of the YMQAD ATL and audit team members were reviewed by the NRC observers during the course of the audit and found to be acceptable.

5.6 Audit Team Preparation

The audit team members were prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The audit plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, a list of the activities to be audited, and audit checklist references.

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they audited. Members of the team had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence.

5.8 Summary of NRC Staff Findings

The NRC staff did not identify any observations relating to deficiencies in either the OCRWM audit process or the implementation of the LLNL-YMP QA program.

5.9 Summary of YMQAD Audit Findings

Within the scope of this audit, the audit team concluded that the LLNL-YMP QA procedures are adequate and that LLNL-YMP's QA program implementation in the areas audited is adequate except for software control. While this audit identified no significant deficiencies regarding computer software, a previous YMQAD audit had concluded that software controls were unsatisfactory due to software problems noted in LLNL-YMP CARs. The audit team concluded that insufficient implementation has occurred in this area since that determination to change the status. Thus the status of software controls is to remain unsatisfactory.

The audit team provided six recommendations to improve the LLNL-YMP QA program, and six preliminary CARs, were generated by the audit team during the audit: five of the six preliminary CARs were acceptably resolved by LLNL-YMP during the audit. The preliminary CAR which was not closed during the audit addressed the lack of audit/documented evaluation of ANL and PNL since September 1991. The recommendations and preliminary CARs do not indicate any significant shortcoming in the QA program of LLNL-YMP.

Table 1 - Procedures and Activity Plans Used for Audit YMP-93-14

PROCEDURE/ACTIVITY PLAN TITLE	NUMBER	REVISION
Quality Assurance Grading	QP 2.8	3
Scientific Investigation Control	QP 3.0	2
Review of Technical Publications and Data	QP 3.3	2
Scientific Notebooks	QP 3.4	2
Procurement Document Control	QP 4.0	3 w/CN 4.0-3-1
Preparation of Quality Assurance Requirements Specifications and Approval of Subcontractor QA Programs	QP 4.1	2 w/CN 4.1-2-1
Identification and Control of Items, Samples, and Data	QP 8.0	1
Handling, Storage, and Shipping	QP 13.0	1
Nonconforming Items	QP 15.0	3
LLNL-YMP Software Quality Assurance Plan, Section 4.3.1	-	0 w/CN 1
Software Quality Assurance	QP 3.2	0
Software Configuration Management	TIP-YM-11	0
Requirements for Computer Software used to support a High-Level Nuclear Waste Repository License	033-YM-R, Appendix H	0
Unsaturated Testing of WVDP and DWPF Glass	D-20-27	-
Low-Temperature Oven Method for Spent Fuel Oxidation Testing	D-20-45	-
Flow-Through Dissolution Tests on UO ₂	D-20-53A	-
Flow-Through Dissolution Tests on Spent Fuel	D-20-53B	-