U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT 94-12

OF THE

U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AUDIT YMP-94-10

OF

LAWRENCE LIVERMORE NATIONAL LABORATORY

J G Spraul for 01/12/95
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ENCLOSURE 1

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1.0 INTRODUCTION

During September 19-23, 1994, members of the U.S. Nuclear Regulatory Commission Division of Waste Management Quality Assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) audit of the QA program of Lawrence Livermore National Laboratory (LLNL). The audit, YMP-94-10, was conducted at the LLNL facility in Livermore, California. The audit evaluated the adequacy and effectiveness of the LLNL QA program in all applicable QA programmatic areas and in selected technical elements. The State of Nevada did not observe this audit.

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

2.0 OBJECTIVES

The objectives of the audit by YMQAD were to determine whether the LLNL QA program and its implementation meet the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and LLNL implementing procedures.

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

3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that YMQAD Audit YMP-94-10 was useful and effective. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities 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 team was augmented with a technical specialist whose qualifications had been previously verified.

The NRC staff agrees with the preliminary audit team finding that the overall implementation of the LLNL QA program is adequate in all applicable QA programmatic elements and in the technical areas audited. One preliminary Corrective Action Request (CAR), regarding incomplete documentation of a management assessment, was discussed by the audit team at the post-audit meeting. Seven other potential CARs were acceptably resolved by LLNL during the audit. Neither the preliminary CAR nor those corrected during the audit were significant in terms of the overall implementation of the LLNL QA program.

One NRC Audit Observer Inquiry was not fully responded to during the LLNL audit, and this is being held as an NRC Open Item as noted in Enclosure 2 until an acceptable LLNL response is received through the DOE. The open item involves electronic record keeping at LLNL as described in an LLNL Yucca Mountain Project procedure.

The LLNL QA program should continue to be monitored to ensure that the deficiencies identified during this audit and previous audits are corrected in a timely manner and that future QA program implementation is adequate. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the LLNL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Thomas E. Rodgers	Audit Team Leader (ATL)	YMQAD/Quality Assurance Technical and Support Services Contractor (QATSS)
Cynthia Humphries	ATL-In-Training	YMQAD/QATSS
Kevin McCoy	Technical Specialist	Management & Operations Contractor
Vance Cannady	Auditor	Headquarters Quality Assurance Division (HQAD)/QATSS
Hugh Lentz	Auditor	HQAD/QATSS
Amelia Arceo	Auditor	YMQAD/QATSS
Sandra Bates	Auditor	YMQAD/QATSS
John Gray	Auditor	YMQAD/QATSS
Thomas Higgins	Auditor	YMQAD/QATSS
Mario Diaz	Auditor	DOE/YMQAD

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This audit of LLNL was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 6) and QAAP 16.1, "Corrective Action" (Revision 6). The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of the YMQAD Audit and NRC Observations

5.1.1 QA Programmatic Elements

Audit YMP-94-10 was a full scope audit, addressing all programmatic elements applicable to LLNL, which are listed below, including the QARD Supplements:

1.0 Organization
2.0 Quality Assurance Program
4.0 Procurement Document Control
5.0 Instructions, Procedures,and Drawings
6.0 Document Control
7.0 Control of Purchased Items and Services

12.0 Control of Measuring and Test Equipment
13.0 Handling, Storage, and Shipping
15.0 Nonconformances
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits
Supplement I, Software
Supplement II, Sample Control
Supplement III, Scientific Investigation

5.1.2 Technical Areas

The audit of the LLNL included a technical evaluation of the following selected technical elements:

Oven Dry Bath Oxidation - Work Breakdown Structure (WBS) 1.2.2.3.1.1
Spent Fuel/UO2 Flow Thru Saturated Dissolution Testing - WBS 1.2.2.3.1.1
HLW (High-Level Waste) Glass Unsaturated Testing - WBS 1.2.2.3.1.2

5.1.3 Observations

The NRC staff observed all or parts of the audit of QA Programmatic Element 17 and Supplements I and III; only these are discussed in detail in this report. The NRC Observation Team did not include a technical observer.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate for YMQAD to evaluate the pertinent QA activities of LLNL and for the NRC staff to evaluate the OCRWM audit process and implementation of the LLNL QA program. A previous QA audit of LLNL occurred July 19-23, 1993.

5.3 Examination of QA Programmatic Elements

The NRC staff observed that the auditors reviewed related documentation and interviewed a representative sample of LLNL personnel who were involved with the pertinent programmatic and technical areas. The auditors observed were well prepared and knowledgeable of the QA program requirements. Checklists, based primarily on LLNL implementing procedures, were used effectively; and auditors pursued issues beyond the checklists when appropriate. Comments and questions were solicited from the NRC observers in an appropriate manner. The audit team was divided into numerous sub-teams, evaluating technical activities and associated QA programmatic elements. The NRC staff observations regarding the audit and the implementation of the QA programmatic elements and supplements observed are discussed below.

5.3.1 Quality Assurance Records (QA Programmatic Element 17.0)

The audit of this element included discussions with the LLNL Local Records Center (LRC) staff and detailed review of records to provide the objective evidence required to determine adequate implementation of the LLNL procedures. For the QA record packages audited, the auditor noted each document number on

an "Objective Evidence Reviewed" sheet, along with the name of the person who authenticated the document and the date it was entered into the QA records system. The records packages audited included Scientific Investigation Plans, QA audits, QA surveillances, and scientific notebooks. Adequate sampling was utilized throughout this portion of the audit to ensure thorough coverage of documents in the LRC. In one case record legibility was a problem, and this was corrected during the course of the audit.

The LRC staff members were aware of their responsibilities, knew their individual roles in the organization, and performed their tasks adequately. In all cases, they were able to supply the auditor with the requested records promptly.

In addition to evaluating retained records, the auditor verified the rating on the fire-resistant containers, the access lists to the records, and the functioning of the computer-based document logging system. The LRC has been operating as a integral unit at LLNL for several years, and the staff members professionally responded to the auditor's questions and provided the objective evidence needed to the auditor.

The audit process was effective, the LRC staff had a clear understanding of the procedures under which they operate, and the implementation of this programmatic element is adequate.

5.3.2 Software Quality Assurance (QARD Supplement I)

The checklist questions for auditing LLNL's computer software controls were developed by the auditor based on LLNL procedure 033-YMP-QP 3.2, "Software Quality Assurance," Revision 2, and the QARD.

The auditor of software QA evaluated the controls and implementation of the above LLNL procedure. Three scientific and engineering software (SES) computer codes at LLNL were identified as quality-affecting: EQ3/6, YMIM, and V-TOUGH. EQ3/6 and YMIM were developed by LLNL; V-TOUGH was procured.

Before asking checklist questions of the cognizant software engineer or task leader, the auditor had the auditee describe the functions of the software being audited, its general parameters and history, and the status of the software in its life cycle. A different person was responsible for each computer code. Each was individually interviewed and responses to the checklist questions were recorded after each response. The auditor, who on a previous audit was the technical specialist for QARD Supplement I, reviewed the software controls that had been applied at LLNL and the results of that process.

The Individual Software Plans for the development of EQ3/6 and YMIM and for the initial qualification of V-TOUGH were reviewed and each Software Plan became the basis of audit evaluation, both within the checklist and beyond the checklist.

Documentation packages on each of the SES codes were reviewed. They provided the following information:

- a description of how to use the software (including input and output options, data files, input and output data, defaults, file formats, anticipated errors and how the user can respond, the hardware and software environments, and a description of the allowable and tolerable ranges for inputs and outputs),
- available sample problems,
- changes since the last release that affected the user, and
- available installation procedures.

This information was provided for each of the SES codes, and the auditor found the information adequate considering the state of development of each code.

The auditor also reviewed the requirements and design information to ensure the documentation sufficiently addressed the ability of the software to meet the needs of the organization. Included in this review were checks for the following information:

- functional requirements,
- performance requirements and design constraints,
- interfaces with external data, hardware, or other software,
- applicable software and hardware operation issues including programming languages and versions, portability, maintainability, reliability, and efficiency,
- a description of the major software items as they relate to the functional requirements,
- a description of the software structure including software internal interfaces, control logic, and data structure and flow, and
- a description of models and numerical methods.

The auditor was able to verify this information by either reviewing published documents and text files, such as in the case of EQ3/6, or by receiving a "walkthrough" by the principal investigator as in the case of V-TOUGH.

Configuration status accounting was verified by the auditor for each of the software codes to include:

- a list of the approved baseline elements and unique identifiers,
- the status of proposed and approved changes to the baseline elements, and
- a brief chronology of the software items, including descriptions of the changes made between versions of the software items.

Software development logs, configuration identification logs, and the Source Code Control System method of configuration management were audited and determined to be satisfactory for each of the three SES computer codes.

Several minor procedural discrepancies were identified during this portion of the audit. They were promptly resolved by the involved LLNL personnel who also answered the auditor's questions. The evaluation of the implementation of the SES-related requirements was thorough, and overall, implementation of the QARD Supplement I was adequate. Software QA was judged by the audit team to be satisfactorily implemented and the audit of this area was effective.

5.3.3 Scientific Investigations (QARD Supplement III)

The auditing of QA Supplement III was done by an audit sub-team of an auditor and the technical specialist. The sub-team's primary interface was with the Technical Area Leader for Waste Form Characterization. This individual was knowledgeable of the programs, activities, progress, and results to date of the three items of WBS that were audited. The checklist for this portion of the audit was based on the WBS documents, the corresponding Scientific Investigation Plans, and the technical specialist's knowledge of what is being done.

The sub-team audited pertinent documents, such as the scientific notebooks, activity plans, procedures, letter reports, and formal (peer reviewed) reports. A portion of the laboratory work, including all the work with radiated samples, is being done at other national laboratories under the direction of LLNL. The scientific notebooks for that work were not available to the audit sub-team. Other members of the audit team reviewed the reports of LLNL audits of the work in question, and the sub-team audited reports and other related correspondence. LLNL's Technical Area Leader was able to answer the remaining questions from the audit sub-team to its satisfaction.

The sub-team audited the laboratory where the testing at LLNL was being done and interviewed the testing personnel. The personnel were knowledgeable of the controlling procedures and appeared to be working in accordance with them. No discrepancies were found.

5.3.4 Conclusions

Overall, Audit YMP-94-10 was conducted in a professional manner, and the auditors adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the LLNL QA program. The NRC staff concludes that the audit of Programmatic Element 17.0 and Supplements I and III was effective and that LLNL's QA program implementation in these areas was adequate.

5.4 Qualification Of Auditors

The qualifications of the ATL and auditors were reviewed and found to be acceptable in that each auditor, the ATL, and the ATL-In-Training met the requirements of QAAP 18.1, "Qualification of Audit Personnel." The technical specialist was experienced and performed his task well.

5.5 Audit Team Independence

The audit team was composed of QATSS personnel who support YMQAD and HQAD, plus a technical specialist from the Management & Operations Contractor. The HQAD/QATSS auditors were specifically assigned to areas where they did not have prior responsibility or involvement. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

5.6 Review of Previous Audit Findings

The ATL-in-Training assigned each of the audit sub-teams to follow-up on previously issued CARs in their particular areas. The auditors verified that corrective actions had been appropriately completed.

5.7 Summary of NRC Staff Findings

Based on the scope of the NRC observations, the NRC staff agrees with the preliminary YMQAD audit team finding that the applicable QA programmatic elements and the overall implementation of the LLNL QA program are adequate. The NRC staff did not observe any deficiencies in the audit process or in the LLNL QA program, except as found by the YMQAD audit team and as noted in Section 5.7.2 below.

5.7.1 Good Practice

A good practice was noted during this audit of maintaining a computerized daily status sheet of all segments of the audit which identified the QA program element, the implementing procedures for the element, and the status of each.

5.7.2 Weakness/Open Item

LLNL procedure TIP-YM-12, "Electronic Record Keeping," indicates that electronic records can be used instead of hard copy records generated in scientific notebooks. An "Audit Observer Inquiry" generated by the NRC questioned whether the controls in the procedure were specific enough and whether activities in accordance with the procedure could be audited. The thrust of the inquiry was to ascertain whether controls are in place to prevent changes of the text in the electronic record keeping media just before the hard copy is printed for submittal to the local records center. After some discussion, there was a commitment by LLNL management to respond, through the DOE, with an expanded response to the inquiry. DOE should follow-up to ensure that LLNL adequately addresses the inquiry. The NRC staff will carry this Audit Observer Inquiry as an Open Item until a satisfactory response is received through the DOE.

5.8 Summary of YMQAD Audit Findings

Within the scope of this audit, the YMQAD audit team concluded that the LLNL procedures and the LLNL implementation of the procedures are adequate. At the post-audit meeting, the ATL-In-Training explained the areas of concern and the

one preliminary CAR. The CAR addressed LLNL's Management Assessment 93-01 which was identified as having incomplete documentation. The adverse condition was identified that the associated sources of information (i.e., interviews and documents reviewed), assessment criteria, and the resultant observations and/or recommendations were not documented on Management Assessment Worksheets as required in LLNL 033-YMP-QP 2.3.

Seven other deficiencies requiring only remedial corrective action were acceptably resolved by the LLNL organization prior to the post-audit meeting. In addition, the audit team provided eight recommendations to improve the LLNL QA program.

OPEN ITEM

COMMENT

LLNL procedure TIP-YM-12, "Electronic Record Keeping," indicates that electronic records can be used instead of hard copy records generated in scientific notebooks. An "Audit Observer Inquiry" generated by the NRC questioned whether the controls in the procedure were specific enough and whether activities in accordance with the procedure could be audited. After some discussion, there was a commitment by LLNL management to respond, through the DOE, with an expanded response to the inquiry. The NRC staff will carry this Audit Observer Inquiry as an Open Item until a satisfactory response is received through the DOE.

Basis

The thrust of the inquiry was to ascertain whether controls are in place to prevent changes of the text in electronic record keeping media just before the hard copy is printed and made a QA record for submittal to the local records center.

Recommendation

DOE should follow-up to ensure that LLNL adequately addresses the inquiry.