U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT 95-05

OF THE U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AUDIT YM-ARC-95-07

OF

LAWRENCE LIVERMORE NATIONAL LABORATORY

Virginia Colten-Bradley for 03/21/95
English Pearcy (per telephone)
Center for Nuclear Waste
Regulatory Analyses

Virginia Colten-Bradley 03/21/95
Virginia Colten-Bradley
Hydrology & Transport
Section
Performance Assessment and
Hydrology Branch
Division of Waste Management

J G Spraul for 03/21/95
Robert Brient (per telephone)
Center for Nuclear Waste
Regulatory Analyses

J G Spraul 03/21/95
John G. Spraul
High-Level Waste Projects and
Quality Assurance Section
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management

Reviewed and approved by:

John O. Thoma 03/28/95
John Thoma, Section Leader
High-Level Waste Projects and
Quality Assurance Section
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management

ENCLOSURE

1.0 INTRODUCTION

During March 6-10, 1995, 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), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) audit of the QA program of Lawrence Livermore National Laboratory (LLNL). The audit, YM-ARC-95-07, was conducted at the LLNL offices and laboratories in Livermore, California.

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

The NRC staff's objective was to gain confidence that YMQAD and LLNL are properly implementing the requirements of their QA programs 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).

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

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that YMQAD Audit YM-ARC-95-07 was useful and effective. The audit was organized and conducted in a thorough and professional manner and was generally effective. However, the technical portion of the audit was marginally effective. The Technical Specialist on the audit team was replaced just prior to the audit, and tthe replacement's familiarity with the High-Level Waste program, with LLNL activities, and with the DOE auditing process was less than it should have been. In addition, the scope of technical activities audited was beyond the areas of specialization of most Technical Specialists.

Audit team members,the auditors and the Technical Specialists, were independent of the activities they audited. The auditors were well qualified in the QA discipline, and their assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the YMQAD audit team's preliminary finding that the overall implementation of the LLNL QA program is effective. No Corrective Action Requests (CARs) were identified by the YMQAD audit team. Nine potential CARs were acceptably resolved by the LLNL organization during the audit.

OCRWM should continue to closely monitor implementation of the LLNL QA program to ensure 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 at a later date to assess LLNL implementation of its QA program.

3.0 AUDIT PARTICIPANTS

3.1 NRC

John Spraul	Observer	
Virginia Colten-Bradley	Technical Observer	
Robert Brient	Observer	Center for Nuclear Waste Regulatory Analyses (CNWRA)
English Pearcy	Technical Observer	CNWRA

3.2 DOE/YMQAD

Thomas Rodgers	Audit Team Leader (ATL)	YMQAD/Quality Assurance Technical and Support Services Contractor (QATSS)
James Clark	Auditor	YMQAD/QATSS
Robert Harpster	Lead Technical Specialist	YMQAD/QATSS
Kristi Hodges	Auditor	YMQAD/QATSS
Stephen Harris	Auditor	YMQAD/QATSS
John Matras	Auditor	YMQAD/QATSS
Emily Reiter	Auditor	Headquarters Quality Assurance Division/QATSS
Van Ekambaram	Technical Specialist	Management and Operating Contractor/Woodward Clyde

4.0 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" and QAAP 16.1, "Corrective Action." The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

4.1.1 QA Programmatic Elements

The audit scope included the applicable QA programmatic elements and QARD supplements. They are listed below:

1.0 Organization
2.0 Quality Assurance Program
4.0 Procurement Document Control
5.0 Implementing Documents
6.0 Document Control
7.0 Control of Purchased Items and Services
12.0 Control of Measuring and Test Equipment
13.0 Corrective Action
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 Investigations

The other programmatic elements and QARD supplement were determined by the audit team to be not applicable to the current scope of LLNL activities.

This audit concentrated on evaluating the compliance of LLNL activities to applicable requirements. It was also intended to serve as a baseline audit, that is, to determine whether the LLNL QA program adequately addresses the QARD (Revision 0, Change 1, which was recently issued) and whether the LLNL QA program is being implemented satisfactorily.

To determine whether the applicable LLNL procedures adequately address the QARD requirements, the auditors determined whether the procedures they audited adequately reflected these requirements as identified in DOE's Requirements Traceability Network matrix. This was the first item on each section of the checklists, and it constituted a check on the original evaluation of matrix.

4.1.2 Technical Areas

The following technical areas were reviewed by the YMQAD audit team:

Work Breakdown Structure (WBS) No. 1.2.2.5.1, "Metallic Barriers"
WBS No. 1.2.2.4.1, "Spent Fuel Dissolution/Oxidation; Cladding"
WBS No. 1.2.2.4.2, "Glass Testing"
WBS No. 1.2.3.10.3.2, "Thermodynamic Data Determination"
WBS No. 1.2.3.12.4, "Small Block Testing"

Some key technical uncertainties addressed by the work audited are as follows:

WBS Nos. 1.2.2.4.1 and 1.2.2.4.2 -

- Prediction of the releases of non-gaseous radionuclides from waste packages during the containment period and from the engineered barrier system during the post-containment period (Review Plan 5.2, *Assessment of Compliance with the Design Criteria for the Waste Package and its Components*)

WBS No. 1.2.2.5.1 -

- Understanding the effect of groundwater on mode and rate of waste package corrosion (Review Plan 3.2.3.4, *Potentially Adverse Conditions: Groundwater Conditions and the Engineered Barrier System*)

WBS No. 1.2.3.10.3.2 -

- Variability in model parametric values (Review Plan 6.1, *Assessment of Compliance with the Requirement for Cumulative Releases of Radioactive Material*)

WBS No. 1.2.3.12.4 -

- Experimental confirmation of the basic physical concepts of groundwater flow through unsaturated fractured rock (Review Plan 3.2.2.9, *Potentially Adverse Conditions: Changes to Hydrologic Conditions*)

- Identifying which conceptual models adequately represent isothermal and nonisothermal liquid and vapor phase movement of water through unsaturated fractured rock at Yucca Mountain (Review Plan 3.2.2.9)

4.2 Timing of the Audit

The NRC staff believes the general timing of this audit was appropriate for YMQAD to evaluate the pertinent QA activities of LLNL and for the NRC staff to evaluate the YMQAD audit process and implementation of the LLNL QA program. The last full scope audit was conducted in September 1994.

4.3 Conduct Of Audit

The programmatic portion of the audit was performed in a professional manner. The auditors were well prepared and demonstrated a sound knowledge of the LLNL QA program. The interview method of auditing, combined with periodic checking of objective evidence, allowed for thorough responses to the questions and permitted additional questions to be answered. The auditors were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. A caucus of the audit team and the NRC observers was held at the close of each work day, and a meeting of the ATL and LLNL management (with an NRC observer present) was held each morning to discuss the audit status and preliminary findings.

The technical portion of the audit was adversely affected by a late change in the assigned Technical Specialist. As a result, the Technical Specialist conducting the audit was not well acquainted with the checklist (which was prepared by the original Technical Specialist), was not experienced with the DOE auditing process, and was not particularly familiar with the high-level waste program and the Yucca Mountain project. In addition, the range of technical activities audited was beyond the Technical Specialist's range of expertise (and may have been beyond the range of any one Technical Specialist).

The technical checklist was limited to items relating to Scientific Investigation Plans, so it was not helpful guidance in the evaluation of scientific investigation methods and results. As a result, methods and results received much less attention than was expected. Also, the checklist was not generally used to guide the discussions with LLNL technical staff. The checklist items were treated as a separate portion of the audit, albeit with much redundancy with other technical discussions.

4.4 Examination of QA Programmatic Elements

The NRC staff concentrated its observations on the audit of Supplement I, "Software." Only this QA programmatic area is discussed in detail in this report.

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 3, and the QARD. The auditor of software QA evaluated the controls and implementation of the above LLNL procedure. The following scientific and engineering software (SES) computer codes at LLNL were identified as quality affecting: EQ-3/6, V-TOUGH, GEMBOCHS, and a portion of CNGBOCHS. EQ-3/6, GEMBOCHS, and CNGBOCHS were developed by LLNL; V-TOUGH was procured as "TOUGH" and then modified (vectorized) by LLNL to become V-TOUGH. LLNL expects to have the V-Tough code "qualified" by the end of March, 1995. Although not currently considered to be quality affecting, additional SES computer codes being developed by LLNL (YMIM, PANDORA, PIGS, and NUFT) were also audited to a lesser extent.

The software auditor first met with LLNL lead engineers involved in software development to determine what had transpired in the area of software since the DOE audit of September, 1994. The auditor continued his audit of software principally by interviewing appropriate personnel and reviewing documentation involved with the codes listed above. Little time was spent auditing EQ-3/6 since it had been audited in detail during the previous audit and little had transpired on the code since that audit.

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, and each was individually interviewed. The auditor reviewed the software controls that had been applied at LLNL and the results of that process.

The staff observed the majority of the audit of the GEMBOCHS and CNGBOCHS software codes. GEMBOCHS (Geologic and Engineering Materials: Bibliography of Chemical Species) is a database that provides input for EQ-3/6. CNGBOCHS (Change Bibliography of Chemical Species) is used to change the database. GEMBOCHS currently has seven different files for the Yucca Mountain Project. An estimate was provided that about 97% of the data in GEMBOCHS came from handbooks or peer-reviewed journals and was not "qualified" for use on the Yucca Mountain Project. A recommendation by the audit team, supported strongly by the staff, was that, project-wide, emphasis should be placed on the qualification of existing data so that the data can be used in a timely manner to support ongoing work related to site suitability and licensing application.

The auditor reviewed the Individual Software Plans and the documentation packages for GEMBOCHS and CNGBOCHS. The auditor found the information adequate.

The auditor also reviewed the requirements and design information to ensure the documentation sufficiently addressed the ability of GEMBOCHS and CNGBOCHS to meet the needs of the organization. The auditor was able to verify all such information by receiving a "walkthrough" by the principal investigator.

Configuration status accounting was verified by the auditor for the GEMBOCHS and CNGBOCHS software codes. Software development logs, configuration identification logs, and the Source Code Control System method of configuration management were audited and determined to be satisfactory.

Several minor procedural discrepancies were identified during this portion of the audit. They were promptly resolved. The evaluation of the implementation of the 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.

4.5 Examination of Technical Areas

All of the technical area auditing was observed by NRC technical and programmatic observers. In each area, the audit team's Technical Specialist discussed the plans for activities, the conduct of the activities, and the results of the activities with the cognizant LLNL technical personnel. In most cases, the LLNL Technical Area Leader also participated. The major portion of the audit of the technical areas involved these discussions and visits to LLNL laboratories for those activities involving LLNL experiments. On two occasions the NRC observers became concerned, and commented to the technical audit sub-team, about the lack of reviews of objective evidence; particularly procedures, scientific notebooks, technical review documentation, and reports. These comments appeared to stimulate the review of some objective evidence.

The NRC staff believes that one of the major contributions of having technical specialists on an audit team is for their evaluation of technical products and the technical judgements that contribute to those products. The NRC staff believes that the unavoidably inadequate preparation of the Technical Specialist adversely affected the technical portion of the audit.

The LLNL technical staff involved with the audited activities were well qualified and sufficiently experienced to perform their assigned tasks. They were knowledgeable of the QA requirements associated with their work. The low level of quality affecting work in past years did not appear to have adversely affect LLNL's readiness to begin quality affecting activities.

4.5.1 Metallic Barriers (WBS No. 1.2.2.5.1)

Preliminary, non-quality affecting corrosion experiments were underway on eight alloys under a range of compositions and conditions chosen to bound likely Yucca Mountain conditions. Simulated J-13 water, 100X concentrated J-13 water, low pH (≈2), and high pH (≈10) fluids were being used.

4.5.2 Spent Fuel Dissolution/Oxidation; Cladding (WBS No. 1.2.2.4.1)

A range of spent fuel oxidation and dissolution experiments was being managed by LLNL with work being conducted by Pacific Northwest Laboratory (PNL) and Argonne National Laboratory (ANL). At LLNL, un-irradiated UO_2 (and higher oxide) powders were undergoing controlled dissolution test in flow-through vessels. This work, and the spent fuel experiments, follow many years of related experiments conducted at PNL and ANL.

4.5.3 Thermodynamic Data Determination (WBS No. 1.2.3.10.3.2)

The Principal Investigator described a six year program, of which LLNL was in the very early stages. Work to date consisted almost entirely of participation in the NEA/OECD effort to develop a standard set of thermodynamic data for important radionuclides. Data for uranium had been published, and a data report for other elements was in draft form. The data had been exposed to peer reviews which LLNL may be able to use for (existing) data qualification. After qualification, these data are to be included in the GEMBOCHS database.

4.5.4 Glass Testing (WBS No. 1.2.2.4.2)

Glass testing activities conducted at ANL are being managed from LLNL. Both saturated and unsaturated experiments are planned. Data interpretation to date had been limited to simple models and rate calculations.

4.5.5 Small Block Testing (WBS 1.2.3.12.4)

Small block tests at LLNL were observed in the laboratory, and discussions were held regarding the large block tests. A block of Topopah Spring tuff approximately 1'x 1'x 2' was cut from a float boulder, which had been collected on Fran Ridge. This "small block" had been mapped in detail and instrumented for preliminary scoping tests (non-quality affecting). Cores and small slabs of Topopah Spring tuff had been prepared for measurements of fracture hydraulic properties, hydrothermal alteration tests, and fracture-healing tests.

4.6 Audit Team Qualification and Independence

The qualifications of the ATL and auditors were found to be acceptable in that each auditor and the ATL met the requirements of QAAP 18.1, "Qualification of Audit Personnel." The background of the Technical Specialist was well-suited to areas of general and analytical chemistry, but a lack of familiarity with radionuclide chemistry and spent fuel chemistry was noted. The range of technical activities audited may have been beyond the expertise of any one Technical Specialist.

The audit team members, the auditors and the Technical Specialists, did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence. The auditors were well

qualified in the QA discipline, and their assignments and checklist items were adequately described in the audit plan.

The auditors 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.

4.7 Review of Previous Audit Findings

One CAR was issued as a result of the last YMQAD audit of LLNL, and one NRC inquiry remained open. The CAR was closed during the audit, and actions were taken so that the NRC inquiry could be closed.

4.8 NRC Staff Findings

The QA programmatic portion of the audit 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 technical portion of the audit was marginally effective due to the late substitution of the Technical Specialist, and his lack of training and experience in auditing and with the high-level waste program.

The NRC staff agrees with the preliminary YMQAD audit team finding that implementation of the LLNL QA program is adequate in each of the QA programmatic areas audited. The NRC staff did not observe any deficiencies in either the audit process, the LLNL QA program, or its implementation.

Recognizing the effects of the unavoidable last-minute change of the audit team's Technical Specialist, the NRC presents the following points for DOE's consideration when planning future audits:

- Technical Specialists should be carefully matched to the technical activities being audited. Several Technical Specialists may be necessary to cover the variety of activities as encountered in this audit.

- Technical checklists should be prepared and utilized such that personnel, plans, methods, review documentation, and results are evaluated and so that the objectives of the technical portion of the audit, described in the audit plan, are adequately addressed.

- Technical Specialists should be provided with adequate training and time for preparation. The Audit Team Leader and Lead Technical Specialist should provide appropriate guidance to first-time Technical Specialists to ensure that the objectives of the technical portion of the audit can be met.

4.9 Summary of YMQAD Audit Findings

No deficiencies were reported regarding whether the applicable LLNL procedures adequately address the QARD requirements as identified in DOE's RTN matrix.

Within the scope of this audit, the audit team concluded that LLNL procedures are adequate to address the recent revision of the OCRWM QARD (baseline) and that LLNL's QA program implementation is satisfactory. The NRC staff agrees with these conclusions. No CARs were identified as a result of the audit. Nine potential CARs requiring only remedial action were acceptably resolved by the LLNL organization prior to the post-audit meeting. In addition, the audit team provided eleven recommendations to LLNL for improving its QA program and two positive comments for good practices.