

QA:L

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

SUPPLIER AUDIT REPORT

OF

PACIFIC NORTHWEST NATIONAL LABORATORY

RICHLAND, WASHINGTON

**REPORT NUMBER OQA-SA-97-011
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Enclosure

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Pacific Northwest National Laboratory (PNNL) revealed unsatisfactory conditions resulting in the issuance of a Corrective Action Request (CAR) YM-97-C-002 to the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) for action which relates to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. The CAR addresses ineffective implementation of PNNL's QA program. The ineffectiveness of implementation of PNNL's QA program was supported by the following: (1) PNNL's QA plan was significantly out of date; (2) the QA organization does not have the freedom of access for purposes of evaluation and to identify quality problems; (3) no evidence of training to the current implementing procedures; (4) technical instructions do not have a documented independent review; (5) revisions to electronic procedures do not require documented review and approval; (6) significant condition adverse to quality identified, but not documented until 5 months later; and (7) no evidence of internal audits of implementation of PNNL's QA program for the past 3 years.

A second condition adverse to quality relates to a breakdown in the procurement process between CRWMS M&O, Lawrence Livermore National Laboratory (LLNL) and PNNL. This adverse condition is being addressed by CAR YM-97-C-001 which was issued to the CRWMS M&O.

The unsatisfactory conditions identified during the audit were discussed with the Project Manager, PNNL, who agreed to work with CRWMS M&O in the resolution of the unsatisfactory conditions.

The results of the audit warrant a recommendation that the use of PNNL be suspended until a full evaluation of the impact of the deficiencies on testing performed by PNNL has been performed and a determination that PNNL has a fully supported Quality Assurance (QA) Program and it is in full compliance with its updated PNNL QA Plan.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation and effectiveness of PNNL's QA program. This was accomplished by determining if PNNL's program implements the applicable portions of OCRWM's Quality Assurance Requirements and Description (QARD); satisfies the applicable QA requirements specified in CRWMS M&O Memorandum Purchase Order (MPO) DX1468RT3X; and satisfactorily implements PNNL's QA Plan WTC-018, Revision 8. As a result of the audit, it was determined that CRWMS M&O had not yet issued a procurement document to define the QA requirements since LLNL had withdrawn LLNL's Quality Assurance Requirements Specification (QARS) in May 1996. Subsequently, PNNL had elected to continue to reference LLNL's QARS in PNNL's QA plan. The QARS was the basis used to evaluate the implementation of PNNL's QA program. The QA program elements

determined to be applicable are: Organization; QA Program: Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Inspection; Test Control; Control of Measuring and Test Equipment; Storage, Shipping, and Handling; Inspection, Test, and Operating Status; Nonconformance Control; Corrective Action; QA Records and Audits; Software Control; Sample Control; and Scientific Investigation.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance (OQA)
James Blaylock, Audit Team Member, OQA
David Stahl, Observer, CRWMS M&O

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

S. C. Marschman, Project Manager, PNNL
Orie Barnes, QA Engineer, PNNL
W.J. Gray, Senior Scientist, PNNL
B.D. Hanson, Graduate Student Research, PNNL
R.E. Einziger, Technology Development Manager, PNNL
H.C. Buchanan, Technical Specialist, PNNL
M.W. Urie, Staff Scientist, PNNL
Bobbi Romine, Secretary, PNNL

5.0 SUMMARY OF AUDIT RESULTS

As of the date of the audit, PNNL is continuing to work to LLNL's QARS, Revision 0, dated February 13, 1989. The details of CRWMS M&O Statement of Work, which contains the QA requirements, as referenced by the MPO have not been worked out with PNNL management. PNNL's QA Plan, Revision 8, and referenced LLNL's QARS have not been updated to adequately address the applicable elements of OCRWM QARD for the intended scope of work. The results of the audit revealed ineffective implementation of PNNL's QA Plan and LLNL's QARS. Evidence clearly established PNNL QA's absence in oversight activities was directly related to cost and schedule. This appeared to be due to PNNL directing funding towards the technical work and providing PNNL QA with no funding. Implementation of the applicable elements of QARD by PNNL is considered unsatisfactory as noted by the conditions described in Section 6.0 of this report, "Deficiencies/ Recommendations."

The details of the audit, along with the objective evidence reviewed, are contained within the audit checklist, which is available from the OQA's supplier evaluation files.

6.0 DEFICIENCIES/RECOMMENDATIONS

The unsatisfactory conditions have been documented on the respective corrective action

document and submitted to CRWMS M&O for action and resolution.

DEFICIENCIES

CAR YM-97-C-002, LLNL's QARS, Section 2.0, Subsection 2.1, requires a Quality Assurance Program Plan (QAPP) to be developed and include a description of the organization's QA program and indicate the applicable QA requirements. LLNL's QARS, Section 1.0, Subsection 1.2, requires the persons performing QA functions to have sufficient authority, access to work areas, and organizational freedom to identify quality problems. LLNL's QARS, Section 2.0, Subsection 2.6.4, requires personnel performing quality affecting activities to be indoctrinated as to the purpose, scope, methods of implementation, and applicability documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. LLNL's QARS, Section 5.0, Subsection 5.2, requires independent reviews of all instructions and procedures, and is to be performed by the originating organization to assure the technical adequacy and inclusion of appropriate quality requirements. LLNL's QARS, Section 6.0, Subsection 6.1, requires that a document control system be established. Implementation of document control shall provide for a review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance. LLNL's QARS, Section 16.0, Subsection 16.1, requires a corrective action system which insures that conditions adverse to quality or potentially adverse to quality are identified promptly and corrected as soon as practical. LLNL's QARS, Section 18.0, Subsection 18.3.1, requires that applicable elements of the organization's QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. Surveillances may be performed in lieu of an annual audit provided that all applicable QA programmatic elements have been included within the scope of surveillances.

Contrary to the above requirements, PNNL has not implemented an effective quality program as follows:

- A. PNNL's QA plan has not been kept current. The organizational structure as noted in the current PNNL's QA plan is not up to date with changes that have occurred in the organization. Also, the reference to the QA implementing procedures in PNNL's QA plan is significantly out of date in that references are made to procedures which have been deleted from PNNL's QA program and replaced by others.
- B. The QA organization does not have the freedom of access for the purposes of evaluation and to identify quality problems. There has been minimal to no independent QA involvement in PNNL activities since 1994 due to no funding provided for QA activities by PNNL's Project Management.
- C. There is no objective evidence to support that PNNL's project personnel have

- B. The QA organization does not have the freedom of access for the purposes of evaluation and to identify quality problems. There has been minimal to no independent QA involvement in PNNL activities since 1994 due to no funding provided for QA activities by PNNL's Project Management.
- C. There is no objective evidence to support that PNNL's project personnel have received training on the latest revision to the implementing quality procedures that were revised on 07/30/96.
- D. Technical instructions, which supplemented the analytical procedures, provided detailed steps for sample preparation prior to analysis. These technical instructions did not receive an independent technical review.
- E. PNNL has implemented a new electronic procedure system which does not provide for documented evidence of review and approval of changes to quality implementing procedures.
- F. Documented evidence substantiated that PNNL's personnel were aware of a significant condition adverse to quality approximately 5 months prior (07/96) to documenting this condition on PNNL's Deficiency Report (DR)-96-012 in 11/96. Also, completion of corrective action to the significant DR was to have been completed by 12/31/96, but to date there is no evidence to indicate any actions have been taken to follow-up and/or close the deficiency.
- G. There was no objective evidence to support that an audit of PNNL's activities has occurred since 1994. It should be noted that in 1995 two readiness review surveillances were performed, but they did not cover all aspects of the PNNL's QA program. There have not been any PNNL surveillances performed of PNNL's project activities since 1995.