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U.S. Nuclear Regulatory Commission

Observation Audit Report

for the Joint

Department of Energy - Headquarters/

Department of Energy - Richland

Audit (8801) of the

Pacific Northwest Laboratory-Materials

Characterization Center

Nancy-Ann Voltura
Operations Branch-QA Section
Division of High-Level Waste
Management

Summary

From February 22-26, 1988, the Nuclear Regulatory Commission (NRC) staff observed the joint Department of Energy-Headquarters/Department of Energy-Richland (DOE-HQ/DOE-RL) audit #8801 of Pacific Northwest Laboratory-Materials Characterization Center (PNL-MCC). The objectives for the audit were to: (a) verify that PNL had, in place, an approved QA program applicable to the activities within the scope of the audit; (b) verify that the implementation of the QA program criteria applicable to the audit is achieving the intended purpose; and, (c) assess the technical adequacy of selected activities using technical advisors from DOE and other sources.

The NRC observation audit assessed the effectiveness of the audit in meeting its stated objectives. The NRC staff conclusions are based on review of the audit team's checklists and findings, direct observation of the auditors and the audit process, and discussions with members of the audit team. The following is provided with respect to DOE accomplishing its three (3) audit objectives as stated above:

(a) PNL's QA program, "QA Manual for License-Related Programs," PNL-MA-60, and the "Interim QA Plan for LLNL Tuff Repository Waste Package Development Program," QAP No. WTC-018, Rev. 1 (July 27, 1987) were used by the audit team in the development of the checklist questions. Verification that these approved programs were being implemented was evidenced by the conduct of specific audit activities and is related to objective (b);

(b) The three (3) audit subteams were assigned various aspects of the PNL-MCC program to review. Where implementation could not be verified as achieving the intended purpose, the respective audit subteams identified program deficiencies (See Attachment C).

The staff observed that 3 of the 18 criteria affecting Tuff Program activities could not be audited due to time constraints. In these areas, (Identification and Control of Material, Parts and Services; Inspection; and Test Control) implementation of the PNL QA program criteria was not verified.

(c) The NRC observer believes that the technical specialists/advisors were knowledgeable in their assigned areas and conducted thorough investigations by which to base their conclusions (e.g. spent fuel and gas sampling techniques).

It should be noted that the NRC staff did not formally assess the adequacy of the PNL QA Plan and procedures as part of this audit. This review will be conducted separately once the QA Plan has been formally submitted by DOE-HQ.

Several areas where the DOE-HQ/DOE-RL audit process needs improvement include: (a) clarifying rights of access between Lawrence Livermore National Laboratory (LLNL) and its subcontractor PNL (as currently structured, LLNL's access to PNL appears contingent upon those times when an audit is planned by either DOE-HQ or DOE-RL and LLNL may be asked to participate); (b) providing adequate audit team training; (c) improving development of audit checklists to include technical input on a timely basis; (d) assuring that DOE QA program documents are consistent with its endorsed consensus standard, are subject to document control measures, and describe the audit process, program criteria and audit team responsibilities as reflected in the implementation of the audit.

FRONT

1.0 Introduction

The NRC staff conducted an observation audit of the DOE-HQ/DOE-RL audit #8801 from February 22, 1988 through February 26, 1988. The DOE audit was conducted at Pacific Northwest Laboratory-Materials Characterization Center (PNL-MCC) in Richland, Washington. The audit team consisted of twelve (12) members who were divided into three (3) subteams and assigned different program areas to audit. The team was organized as follows:

Audit team leader - T.K. Subramanian (DOE-RL)

Subteam A - Responsible for: Material Characterization Center (MCC) Activities

Audit Personnel:
D. Brown (DOE-HQ/Weston) - Subteam Lead Auditor
H. Litz (DOE-RL) - Auditor

S. Gomberg (DOE-HQ) - Technical Advisor
C. Pescatore (Brookhaven Nat'l Lab) - Technical Advisor
D. van Rooyen (Brookhaven Nat'l Lab) - Technical Advisor

Subteam B - Responsible for: Tuff Program Activities

Audit Personnel:
J. Dronkers (LLNL) - Subteam Lead Auditor
H. Shaw (LLNL) - Technical Advisor

Subteam C - Responsible for: PNL Generic Program Activities

Audit Personnel:
C. K. Kasch (DOE-RL) - Subteam Lead Auditor
K. Vadlamani (DOE-RL) - Auditor
W. Camp (DOE-RL/MACTEC) - Auditor
P. E. Lamont (DOE-RL) Technical Advisor

In addition, there were three (3) observers from different DOE offices:

- J. C. Haugen (DOE-CH/MIO)
- S. P. Mathur (DOE-HW/DP)
- D. Langstaff (DOE-RL)

The objectives of the DOE-HQ/DOE-RL audit #8801 were to:

(a) verify that PNL had, in place, an approved QA program applicable to the activities within the scope of the audit;

(b) verify that implementation of the QA program criteria applicable to the audit is achieving the intended purpose;

(c) assess the technical adequacy of selected activities using technical advisors from DOE and other sources.

The primary objective of the Nuclear Regulatory Commission's (NRC) observation audit program is to gain confidence that the DOE is meeting the NRC's QA program requirements. Recommendations for improving the DOE audit program are made by the staff. Observation audits by the staff will enable them to give guidance to the DOE on QA programs that are being developed and should help to provide confidence that DOE is meeting the NRC's QA program requirements.

The NRC staff conclusions concerning this audit are based on review of the audit checklist and findings, direct observation of the auditors and the audit process, and discussions with members of the audit team. The criteria for the staff's review are established in the NRC's QA Procedure for Auditing DOE High Level Waste Repository Program QA Audits.

2.0 Scope of the Audit

Based on the DOE-HQ/DOE-RL Final Audit Plan dated February 22, 1988, audit #8801 "...was intended to cover the QA program activities referenced in Battelle-Pacific Northwest Laboratories (PNL) QA Manual and in ANSI/ASME NQA-1, 1986, as they relate to the activities of the Materials Characterization Center and Tuff Program activities now being performed at PNL." "...The objective of the MCC is to assist DOE's waste-form producing and repository development projects and includes: providing reference and testing materials, standardizing test methods, and characterizing spent fuel (approved test materials)." "...The Tuff project, Nevada Nuclear Waste Storage Investigations (NNWSI)-DOE Nevada Project Office has assigned the responsibilities of design and performance verification of the waste package to LLNL." PNL-MCC is conducting research activities related to these tasks for LLNL.

A summary of the responsibilities and program areas that were planned to be audited are as follows:

Appendix B Criterion/Title		Responsibilities for Conducting These Audit Activities:		
		Team A (MCC)	Team B (Tuff)	Team C (PNL Generic Program Activities)
I	Organization	X	X	
II	QA Program	X	X	
III	Design Control	X	X	
IV	Procurement Document Control			X

V	Instructions, Procedures & Drawings			X
VI	Document Control			X
VII	Control of Purchased Material, Equipment & Services			X
*VIII	Identification & Control of Material, Parts and Components	X	X	
IX	Control of Special Processes	X	X	
*X	Inspection	X	X	
*XI	Test Control	X	X	
XII	Control of Measuring & Test Equipment	X	X	
XIII	Handling, Storage & Shipping	X	X	
XIV	Inspection, Test & Operating Status	X	X	
XV	Nonconforming Materials, Parts and Components			X
XVI	Corrective Action			X
XVII	QA Records			X
XVIII	Audits			X

The DOE Final Audit Plan and the audit agenda are included as Appendix B to this report. As noted above (*), some areas were not audited for the Tuff Program due to lack of time; see Staff Observation in Section 3.0, item C.

3.0 NRC Staff Observations

A. Qualifications of Auditors:

° Nuclear licensing experience; Nuclear QA experience; Years of experience; Technical expertise:

The overall experience and qualifications of the audit team appeared adequate for conducting the QA programmatic audit of PNL-MCC. Based on a very general review of those auditor qualification records that were on file at DOE-RL, several members of the audit team had over 20 years experience in nuclear QA/QC programs and others ranged between approximately 5 and 10 years of related experience. The audit team leader has approximately 28 years of nuclear experience including nuclear fuels research and the development, manufacture and quality assurance of power reactor components.

The qualifications of the technical advisors appeared to be appropriate for the areas investigated, as their education and experience included advanced degrees in nuclear engineering, chemical engineering, metallurgy, and geology.

° Communication Skills

The communication skills of the audit team were good. During the audit entrance/exit meetings, the daily audit activity and the daily team caucus meetings, audit team members clearly expressed the respective audit topics, questions and related results to PNL.

The NRC observer reviewed selected activities of Subteam A (Section 2.0), at various times on Tuesday, February 23, 1988 and Wednesday, February 24, 1988. The investigations into such areas as spent fuel identification and control, fuel rod scanning, and fission gas sampling were pursued using a thorough process of discussion, review of related activities, review of documentation and detailed follow-up. This Subteam exhibited very good communication skills during the conduct of their activities. Their investigations resulted in identifying deficient program areas as detailed in Quality Audit Concerns 8801-01, 8801-03 and Audit Observation 8801-01.

The review of QA administrative activities by one member of Subteam B (Section 2.0) was observed on Thursday, February 25, 1988. These activities included review of document controls/document change controls for technical instructions, administrative procedures and other documents. The communications skills of the audit team member were very good, follow-up questions were pursued and documentation was reviewed to assist in evaluating program implementation. This investigation resulted in issuing Audit Observations 8801-03, 8801-04 and 8801-05.

The activities of Subteam C were not observed.

° Conformance with NQA-1 Requirements for Auditors and Lead Auditors

The staff reviewed DOE-RL QA Procedure BP 18-4, Auditor Qualification Rev. 1, 3/9/87 and identified some inconsistencies with its referenced industry

standard, ANSI/ASME NQA-1, 1986. Per this standard, Supplement 2S-3, Section 5.2, "Qualification Examination" establishes that the development and administration of the Lead Auditor examination is the responsibility of the employer. Although this responsibility may be delegated, the employer retains responsibility for the exam to conform to NQA-1, 1986. However, review of the QA Lead Auditor Qualification Record for the Lead Auditor on this audit (8801), revealed a cross reference note to the results of the examination administered when the individual was employed by an Architect/Engineering (A/E) company in 1981. Similar notes, which referenced a previous employer's management approval signatures and results, were used in the following qualification areas: Management and Justification, Audit Communication Skills, Audit Participation, Examination Results and Annual Evaluation. NQA-1, 1986 Supplement 2S-3 clearly establishes that attesting to satisfying these requirements is the responsibility of the Lead Auditor's employer, in this case, DOE-RL. While NQA-1, 1986 allows for these activities to be delegated to a certifying agency, NRC staff established that DOE-RL had not contracted the services of the referenced A/E to develop and administer the examination whose results are referenced and used as the basis for certification. Since the basis for the development of this exam was not established by DOE-RL, either by internal or external means, the extent to which specific lead auditor skills and knowledge were evaluated may or may not have been consistent with DOE repository program requirements. Based on staff observations of the lead auditor's performance during the audit, strengthening such lead auditor skills as planning, organizing, and directing an audit would assist in improving the existing skills of the lead auditor.

The overall qualifications and auditing skills of the audit team appeared adequate for this audit. Records of several audit team member's qualifications were briefly reviewed and identified an average of 10-15 years of nuclear QA/QC experience.

- Training in Auditing Techniques

The audit team was familiar with the basic techniques of auditing and utilized these skills to conduct the audit. However, since the audit team included individuals arriving from various DOE organizations at different times, the audit team leader was placed in the position of conducting audit specific training at different intervals during the week. This may have contributed to the fact that differences occurred in the scope of material that was presented to team members. One of the possible effects of this could have been the observed lack of understanding by one of the technical advisors on the use of the audit checklist during the conduct of his activities. Improvements in coordinating audit team training to assure consistency in the material presented and in attaining a consistent level of understanding by all members of the audit team would assist the overall effectiveness of future DOE audits.

B. Audit Team Preparation

° Content of Audit Plan and Checklist

The checklist addressed the scope of activities that was identified by the audit plan. However, from staff observations, the system for providing technical input into the development of the final audit checklist needs to be improved so that appropriate technical areas are included as part of the formal checklist development and approval process. Based on observations and discussions, it was not clear whether all technical portions of the checklist had been submitted for review by the audit team leader prior to use. The checklist appeared comprehensive in its scope and content.

° Knowledge of Audited Organization's, Procedures, Policies, Standards, etc.

The audit team seemed knowledgeable with the scope of activities conducted by PNL-MCC.

C. Selection of Areas to be Audited

Based on the information provided in the 8801 Audit Plan, the selection of areas to be audited (reference Section 2.0, Scope) were relevant to the scope of activities being conducted by PNL-MCC for the high-level waste repository program.

However, there is an NRC observation with respect to this topic. It was observed that time constraints, imposed by a lack of sufficient advance planning, affected the conduct of the Tuff Program portion of the audit. With members of Subteam B arriving at different times during the week to begin their respective audit activities, this resulted in insufficient time being available for the completion of approximately ten or twelve criteria which Subteam B had to investigate in a 2-day time frame. As a result, audit activities for several Tuff Program areas, Criteria 8, 10, and 11, could not be completed. Since the original audit plan was to review all 18 criteria of Appendix B to assess that PNL's QA program was in place and implemented, omission of these three criteria appears to affect fulfilling that plan.

Upon receipt of the DOE audit report (8801), dated May 5, 1988, the staff conducted a brief review which identified an inconsistency in the areas noted as not having been audited for Tuff (NNWSI) activities. The audit report (Page 12) states that criteria 8, 9, and 11 were not audited for Tuff activities; however, discussions with audit personnel and observations made during the audit indicate that inspection activities (criterion 10) were also not evaluated. Clarification should be provided within DOE's documentation for this audit.

° Known Problem Areas Including Follow-Up from Previous Audits

Since this was the first audit of PNL-MCC by the DOE, there were no previous problem areas identified for follow-up.

D. Conduct of entrance/exit meetings

° Scope of the Audit Discussed with Audited Organization

The audit team conducted the entrance and exit meetings as scheduled in the audit plan. At the entrance meeting on February 23, 1988, the scope of the audit was clearly defined, the requirements documents were identified and initial contacts between the audit team and PNL-MCC were established. In addition, audit team introductions were made and any questions and comments were encouraged.

° Audit Results Presented to Audited Organization

The audit team exit meeting was held on February 26, 1988 and the audit team presented a summary of the audit concerns and observations generated as a result of their activities. PNL-MCC was afforded the opportunity to present additional information or request clarification on the audit results. The audit team leader provided PNL-MCC with draft copies of the audit results. Commitments were obtained from PNL-MCC management to evaluate the discrepancies and provide DOE-RL with a documented response.

It should be noted that daily briefings were provided to PNL-MCC management on the results of each day's activity. These briefings provided a detailed review of the activities investigated and afforded PNL-MCC management the opportunity to discuss any potential audit concerns or observations with the audit team.

The four DOE observers and the NRC observer were also afforded the opportunity to express their concerns and/or comments at the audit entrance, exit and daily team caucus meetings.

E. Coverage and Conduct of the Audit

In observing the audit subteams conduct their evaluations of selected PNL-MCC program areas, the staff concluded that these evaluations were conducted adequately. In particular, the technical advisors conducted comprehensive investigations and were thorough in their review of spent fuel and gas sampling activities. Their conclusions were based on a careful review and consideration of several associated areas. In total, there were seven(7) and six(6) observations identified by the audit team; these are included as Appendix C.

As stated in Section C, three of the 18 criteria were not audited by Subteam B. The NRC observer believes that sufficient planning and use of resources could help mitigate this situation during future audits.

With respect to the conduct of the audit, there are two additional staff observations:

° Audit 8801 was conducted using an uncontrolled QA Procedure - BP-18.6, QA Audits, Rev. 0 dated March 18, 1987. Per DOE-RL memorandum 88-QSD-044, dated February 12, 1988, the maintenance of controlled documents would no

longer be updated. Per direction of the memorandum, "... BWIP does not require you to return any of these controlled documents; however, they should be either destroyed or, as a minimum, identified as uncontrolled."

- The criteria for determining whether audit deficiencies would be classified as either a finding, concern or observation were not defined in approved DOE-RL QA program documents, but were distributed to the audit team as part of the pre-audit briefing hand-out on February 22, 1988. In addition the DOE-RL QA program does not specify the use, role and responsibilities of the Subteam Lead Auditor.

Since the procedure for conducting audits should clearly be a controlled document that describes the audit program and the criteria for defining program deficiencies, DOE-HQ/DOE-RL should provide measures for resolving these observations so that future audits would not be similarly affected.

F. Evaluations of Technical Products

As previously stated, the NRC observer believes that adequate investigations were conducted to review the spent fuel and gas sampling activities. Although the coordination effort for generating the technical audit checklist questions could be greatly improved, the technical advisors provided in-depth reviews in their respective areas which supported the conclusions reached and evidenced by Audit Concern 8801-01.

G. Audit Team Coordination

The overall coordination of the audit team could be improved with respect to the areas referenced in A, B, C, and E above. Consideration should be given to more detailed advance planning and improved use of audit team personnel for future joint audits of this nature and scope.

The audit team members interacted well and provided support to other members when necessary. The technical advisors complemented the scope of the audit team's activities.

H. Additional Area for Discussion:

NRC staff discussed Lawrence Livermore National Laboratory's (LLNL) "Right of Access" to perform independent audits of the work conducted by its subcontractor, PNL. NRC staff tried to establish whether past audits of PNL had been conducted by LLNL and was informed that LLNL has limited access to PNL because they are a contractor of DOE-RL. As such, LLNL's access to PNL appears limited to those times when an audit has been planned by either DOE-HQ or DOE-RL, at which time, LLNL may be asked to participate. It would appear that this does not meet the Tuff Program's "Right of Access" requirements per NQA-1, Supplement 4S-1. Clarification of these relationships, their interfaces and the appropriate rights of access between LLNL and PNL need to be addressed.

Although this observation was discussed with the Subteam B Lead Auditor for Tuff Program Activities and was not discussed with DOE-RL QA management, it is an area that needs to be addressed and clarified by DOE.

4.0 Conclusions:

A brief listing of concerns with respect to the conduct of the audit are provided as Appendix A.

Appendix A

Concerns With Respect to the Conduct of the Joint DOE-HQ/DOE-RL Audit

As discussed in the text of this report, the following concerns represent areas where the NRC observer believes the DOE-HQ/DOE-RL audit program can be improved:

(1) Clarifying the rights of access between Lawrence Livermore National Laboratory and its subcontractor Pacific Northwest Laboratory. As currently structured, LLNL's access to PNL appears limited to those times when an audit is planned by either DOE-HQ or DOE-RL and LLNL may be asked to participate;

(2) Planning and coordinating the audit in such a manner as to provide a more effective audit process;

(3) Coordinating the overall audit-related training program to provide consistency in the topics presented so as to achieve a consistent level of understanding of the audit process;

(4) Coordinating the development of the audit checklist with sufficient time to review and incorporate the technical program areas that are to be addressed;

(5) Reviewing QA program documents for consistency with program endorsed consensus standards prior to implementation;

(6) Assuring that DOE program documents (i.e audit procedures) are subject to appropriate document control measures;

(7) Ensuring that approved QA program documents describe the audit process, the roles and responsibilities of audit team members and any audit program criteria or definitions which are to be implemented in conducting and documenting the audit activity.

APPENDIX B

DEPARTMENT OF ENERGY

DOE-RL/DOE-HQ JOINT QA AUDIT 88-01

OF PACIFIC NORTHWEST LABORATORY (PNL)

FINAL QUALITY ASSURANCE AUDIT PLAN

SELECTED QA PROGRAM ELEMENTS

FEBRUARY 23 - 26, 1988

T. K. Subramanian
Audit Team Leader

2.22.'88
Date

W. S. Gibbons
MACTEC

2/22/88
Date

R. P. Saget
Director, Quality Systems Division

2/22/88
Date

FINAL AUDIT PLAN
PACIFIC NORTHWEST LABORATORY (PNL)
AUDIT 8801
February 23-26, 1988

SCOPE

This audit is intended to cover the QA program activities referenced in Battelle Pacific Northwest Laboratories (PNL) QA Manual and in ANSI/ASME NQA-1, 1986, as they relate to the activities of the Material Characterization Center and Tuff Program activities now being performed at PNL.

This audit will be a joint audit with auditors and technical advisors from DOE-HQ, DOE-RL, Lawrence Livermore National Laboratory (LLNL) and Brookhaven National Laboratory (BNL).

AUDIT TEAM

The audit team is to be led by T. K. Subramanian of DOE-RL's BWIP Quality Systems Division. The three subteams, their responsibilities and the observers are shown in Attachment A.

BACKGROUND

The Nuclear Waste Materials Characterization Center (MCC) was created by DOE at the Pacific Northwest Laboratory (PNL) in FY-1980 to coordinate the collection of a defensible materials property data base, supported by well-documented test methods, statistics, and quality assurance, that can be used as a recognized, authoritative source of data for waste management systems, design, integration, and licensing. These activities are funded by and support the Office of Geologic Repositories (OGR), the Office of Nuclear Energy (NE), and the Office of Defense Waste and Byproducts Management (DP).

The Materials Integration Office (MIO) at the DOE Chicago Operations Office has programmatic responsibility for the activities of the MCC and of the Materials Review Board (MRB), an independent peer-review panel that was created at the same time as the MCC.

The objective of the MCC is to assist DOE's waste-form producing and repository development projects and it includes: providing reference and testing materials, standardizing test methods, and characterizing spent fuel (approved test materials.)

Support provided by the MCC to the Office of Geologic Repositories will include characterization and distribution of approved testing materials for use by repository projects in their site characterization activities.

Spent fuel characterization involves radiochemical and ceramographic/metallographic evaluation of fuel pellets, cladding and assembly hardware. MCC also coordinates analytical methods workshops and continues test method development and collection of waste glass data for incorporation into the Nuclear Waste Materials Handbook.

Currently major MCC activities of interest to OGR are in the spent fuel operations and spent fuel characterization groups (Tasks 04 & 03), for example, Gamma scanning, fission gas sampling and required radiochemical and ceramographic/metallographic analysis of approved test materials.

Tuff - The Nevada Nuclear Waste Storage Investigations (NNWSI) project assigned the design and performance verification of waste packages to Lawrence Livermore National Laboratory (LLNL). LLNL assigned research tasks designed to investigate 1) the leaching/dissolution behavior of spent fuel, 2) the corrosion behavior of spent fuel cladding, and 3) the oxidation characteristics of spent fuel to Westinghouse Hanford Company (WHC) during 1983.

The research tasks were performed by WHC until consolidation occurred at Hanford on June 29, 1987. As a result of consolidation, research work and personnel performing the research activities were transferred to Pacific Northwest Laboratories (PNL) for the program. As there were no continuing tests in progress when the work was transferred, records for work performed prior to June 29, 1987, were completed under WHC's management responsibility. The WHC technical procedures for the oxidation characteristics activities, the only quality level 1 work, were modified to comply with the requirements of PNL's approved QA Program - MA-60. The other two tasks have been designated quality level 3 which is governed by PNL's Good Practices Standard. Dr. S. C. Marschman is assigned the management responsibility for the program.

Quality Level 1 work performed by PNL since consolidation includes indoctrination of new PNL employees assigned to the Tuff activities in the PNL QA program, revision of test plans to include BWR fuel and performance of drybath interim and post test examinations.

Based on the background information provided for MCC and Tuff activities at PNL, the current audit will address 18 Quality Assurance Criterion as they relate to the MCC and Tuff programs.

AUDIT OBJECTIVES

1. To verify that PNL has, in place, an approved QA program applicable to the activities within the scope of this audit.

2. To verify that the implementation of the QA program criteria applicable to this audit, is achieving the intended purpose(s), and

3. To assess the technical adequacy of selected activities using technical advisors from DOE and other sources.

AUDIT FINDINGS/CONCERNS/OBSERVATIONS

In view of the wide variation in the "definition" of audit findings and the treatment of "concerns" and "observations" it is felt that a brief explanation of "findings", "concerns", and "observations" will be in order. Attachment B presents the details of what constitutes a "finding", "concern", and "observation" which will be utilized during Audit 8801.

SCHEDULE OF AUDIT ACTIVITIES

Table 1 shows the planned schedule of audit activities.

CHECKLIST

The Checklist for the audit is shown as Attachment C to this plan. The auditors are authorized to pursue additional investigation if defective evidence demands further scrutiny. The completed checklist will contain any additional areas investigated.

NOTE: Final audit plan distributed to the audited organization will not include Attachment C (Audit Checklist.)

ATTACHMENT A
DOE-RL/DOE-HQ JOINT QA AUDIT 8801
OF PACIFIC NORTHWEST LABORATORY (PNL)

Audit Scope and Team Responsibilities

NQA-1 CRITERION	Subteam A	B	C
1, 2, 3, 8, 9, 10, 11, 12, 13, & 14	X	X	
4, 5, 6, 7, 15, 16, 17 & 18			X

SUB-TEAM RESPONSIBILITIES	MATERIAL CHARACTERIZATION CENTER ACTIVITIES	TUFF PROGRAM ACTIVITIES	PNL GENERIC PROGRAM ACTIVITIES (TRAINING, PROCUREMENT, ETC.)
AUDIT PERSONNEL			
SUB-TEAM LEAD AUDITOR(S)	D. BROWN (DOE-HQ WESTON) H. LITZ (DOE-RL)	J. DRONKERS (LLNL)	C. K. KASCH (DOE-RL) K. VADLAMANI (DOE-RL) W. CAMP (DOE-RL MACTEC)
TECHNICAL ADVISOR	S. GOMBERG (DOE-HQ) C. PESCATORE (BNL) D. VAN ROOYEN (BNL)	H. SHAW (LLNL)	P. E. LAMONT (DOE-RL) (FOR ALL ACTIVITIES)

OBSERVER(S) * N. VOLTURA, (NRC); J. MATHUR, (DOE-HQ); D. LANGSTAFF, (DOE-RL) (FOR ALL ACTIVITIES)

* Audit Team Leader T. K. Subramanian, in consultation with the sub-team leads and PNL, will accommodate observer's requests to join different sub-teams on a daily basis.

[QA25B8.WC1]

AUDIT 8801 OBJECTIVES

1. TO VERIFY THAT PNL HAS, IN PLACE, AN APPROVED QA PROGRAM APPLICABLE TO THE ACTIVITIES WITHIN THE SCOPE OF THIS AUDIT.

2. TO VERIFY THAT THE IMPLEMENTATION OF THE QA PROGRAM CRITERIA APPLICABLE TO THIS AUDIT, IS ACHIEVING THE INTENDED PURPOSE(S), AND

3. TO ASSESS THE TECHNICAL ADEQUACY OF SELECTED ACTIVITIES USING TECHNICAL ADVISORS FROM DOE AND OTHER SOURCES.

ATTACHMENT B

AUDIT: **FINDING** CONCERN OBSERVATION

- RESULTS FROM OBJECTIVE EVIDENCE EXAMINATION
- EVALUATION ESTABLISHES SIGNIFICANT CONDITION ADVERSE TO QUALITY (NQA-1, SUPP. S-1)
- OR, FAILURE OF A CONTROL SYSTEM TO ACHIEVE THE INTENDED PURPOSE i.e., VIOLATION OF REQUIREMENTS WHICH COULD LEAD TO REDUCED PRODUCT QUALITY
- MAY SUMMARIZE NUMEROUS SMALL ANOMALIES
- REQUIRES RESPONSE INCLUDING ROOT CAUSE, ACTION TO PREVENT RECURRENCE, IMPACT ON COMPLETED WORK BESIDES CORRECTIVE ACTION

AUDIT: FINDING CONCERN OBSERVATION

- RESULTS FROM OBJECTIVE EVIDENCE EXAMINATION
- IS NONCOMPLIANCE TO REQUIREMENT(S) WHICH WOULD NOT LEAD TO REDUCED PRODUCT QUALITY
- REQUIRES DOCUMENTATION OF CORRECTIVE ACTION (RESPONSE FROM AUDITED ORGANIZATIONS IS ONE FORM OF CORRECTIVE ACTION DOCUMENTATION)
- EXAMPLES: MISSING ENTRY ON A TRAINING RECORD WHERE TRAINING CAN BE VERIFIED IN ANOTHER WAY

AUDIT: FINDING CONCERN OBSERVATION

- IS A WRITTEN EXPRESSION OF AN AUDITOR'S OPINION ON A PERCEIVED QUALITY-AFFECTING CONDITION.
- MAY REFLECT INSUFFICIENT INVESTIGATION OF A CONDITION TO IDENTIFY IT AS A FINDING OR CONCERN.
- NEED NOT BE RESPONDED TO
- LEAD AUDITOR IN CONJUNCTION WITH AUDIT TEAM AND AUDITED ORGANIZATION DETERMINES THE PROPER CLASSIFICATION OF EACH OF THE AUDIT RESULTS I.e., FINDINGS/CONCERNS/OBSERVATIONS

TABLE 1

DOE-RL/DOE-HQ JOINT QA AUDIT 8801 OF PACIFIC NORTHWEST LABORATORY (PNL)

SCHEDULE OF AUDIT ACTIVITIES

DAY	DATE	SUBTEAM A CRITERION	SUBTEAM B CRITERION	SUBTEAM C CRITERION
TUESDAY	2/23	1, 2, 8, 9, 10	-	4, 7, 15, 16, 17 AND 18
WEDNESDAY	2/24	3, 11, 12, 14	1, 2, 3, 5, 6, 8, 9	4, 5, 6, 7, 15, 16 17 AND 18
THURSDAY	2/25	3, 8, 9, AND WRAP UP	10, 11, 12, 13, 14, 15 AND WRAP UP	4, 5, 6, 7, 15, 16 17, 18 AND WRAP UP
FRIDAY	2/26	DRAFT AUDIT RESULTS AND EXIT MEETING		

[QA25B8.WC1]

APPENDIX C

Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

88-QSD-052

MAR 03 1988

Director
Pacific Northwest Laboratory
Richland, Washington

Dear Sir:

DOE-RL/DOE-HQ JOINT QUALITY ASSURANCE AUDIT 8801 OF SELECTED PACIFIC NORTHWEST LABORATORY (PNL) ACTIVITIES

The DOE-RL/DOE-HQ Joint Audit 8801 completed on February 26, 1988, resulted in the attached seven (7) concerns and six (6) observations. These concerns and observations were discussed with the cognizant manager of the audited departments (Quality Assurance (QA), Materials Characterization Center (MCC) and TUFF Project) during the audit exit meeting held on February 26, 1988.

Response to these seven (7) concerns is required within 30 days from the date of receipt of this transmittal.

Should you have any questions regarding the Audit 8801, please contact me or T. K. Subramanian of my staff.

Sincerely,

R. P. Saget

R. P. Saget, Director
Quality Systems Division

QSD:TKS

Enclosure

cc w/encl:
G. Faust, Weston
N. Montgomery, EEI
R. Stein, DOE-HQ
J. J. Linehan, NRC
J. C. Haugen, MIO, CH
S. P. Mathur, DP-HQ

cc w/o encl:
R. Cook, NRC
J. Morris, DOE-HQ

102.7
NHO2

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO. 8801-01

1. TO: Name	Title	3. Location
M. KREITER	MCC PROJECT MANAGER	PNL - Richland, WA

4. Reference/Requirements

PAP 901, Rev. 1, Control of Processes, Section 4.1 "The PM shall assure that controlled processes to be performed by his project and shall determine whether or not specific qualification is ... required."

5. Audit No. 8801

6. Potential Reportability Under 10 CFR 60.73

☐ Yes ☒ No

7. Description

Attached are several procedural concerns which collectively indicate the need for qualification of technical procedures addressing the spent fuel operations.

8. Lead Auditor (Signature)	9. Issue Date	10. Response Due Date
T K Subramanian	3.3.'88	4.4.'88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)	13. Date	14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)	16. Date

18. Final Distribution

ORIGINAL–Audit Report File

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17. Final Review and Approval (Audit Concern Closed)

DIRECTOR – Quality Systems Division _____ Date _____

MCC-TP-8, Spent Fuel Identification and Control

1. Means to prevent loss of fuel from segmented rods during handling and storage were not apparent in this procedure. Such means should be devised (e.g., capping the ends) and appropriate steps be incorporated into the procedure.

2. The procedure does not specify the maximum length of time during which fuel samples can be exposed to the hot cell atmosphere. A concern exists that the fuel may partially oxidize under these conditions and thereby undergo a change in its chemical characteristics. This concern also extends to cutting operations whereby oxidation could be accelerated as a result of higher temperatures generated during cutting. (This effect has been reported in the Canadian Waste Management Program.) The procedure should at least specify a maximum length of time that fuel samples may remain in the hot cell atmosphere, and inerting the cutting operations should be evaluated.

MCC-TP-9, Fuel Rod Scanning Procedure

1. The procedure should reference a design report for the Fuel Rod Scanning System where the operating limits and requirements are clearly identified. Such a report could serve as a basis for 1) training the operators, 2) maintaining the system, and 3) implementing future upgrades. This report could be critical if the original staff responsible for the design are no longer available.

MCC-TP-10, Fission Gas Sampling

1. The procedure should reference a design report for the Fission Gas Sampling Systems where the operating limits and requirements are clearly identified. Such a report could serve as a basis for 1) training the operators, 2) maintaining the system, and 3) implementing future upgrades. This report could be critical if the original staff responsible for the design are no longer available.

2. The procedure does not provide a method to calibrate the Baritron pressure gauge after it has been installed. It is recommended that the system be modified to permit on-line calibration checks before and after fission gas sampling. The operational limits and vulnerability of the Baritron, e.g., sensitivity to particular gases and temperature, etc., should be identified in the design report. (See preceding concern.)

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY - RICHLAND OPERATIONS

2. QAC CONTROL NO.
8801-02

1. TO: Name / Title
C. E. HUGHEY, / QAD Manager

3. Location
PNL - Richland, WA

4. Reference/Requirements
PAP 201, Revision 2, ICNs 1, 2, 3 and 4 - "Indoctrination and Training"

Section 4.3.2 - "Personnel shall receive the appropriate indoctrination and training".

5. Audit No.
8801

6. Potential Reportability Under 10 CFR 60.73
☐ Yes ☒ No

7. Description

Training to detailed procedures and revisions is considered to be ineffective. Examples of this concern are attached.

8. Lead Auditor (Signature)
R Birbaumer

9. Issue Date
3.3.'88

10. Response Due Date
4.4.'88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)

13. Date

14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)

16. Date

18. Final Distribution

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17. Final Review and Approval (Audit Concern Closed)

DIRECTOR - Quality Systems Division

Date

1. PAP-404, Revision 3, Paragraphs 4.2.1 and 4.2.3b require the Project Manager to include quality levels in SOWs and the QAD Rep. to verify incorporation of quality levels. MCC SOW M28071, Rev. 1, Approved on 12/21/87, does not include a quality level however, QA requirements are included in SOW.

2. PAP-404, Rev. 3, Paragraph 4.2.3e requires that the Project Manager give final approval of SOWs for quality Level 1 services. Tuff SOW M37615, Rev. 0, issued 1/4/88, was approved by Task Leader and not Project Manager.

3. PAP-706, Rev. 1, ICN #PAP-706-R1-1, Paragraph 4.1.3, requires the use of an Inspection/Test Instruction (ITI) when performing receiving inspections. No ITI was completed for an autoclave received on 1/2/88 (PR/PO Q8633.) Documentation in the QC files provides evidence that the item was in fact inspected by QC upon receipt. This discrepancy was corrected during audit by issuance of internal letter (QC-072-GRA) and completion of an ITI.

4. PAP-705, Rev. 1, Paragraph 4.2.1 requires that the QC Rep. review submitted documents, verify applicable material numbers, and record the information. QC Review Plan and Record (RPR) for PR/PO T1713 (cylinders of dry air) received during 1/88, did not reflect verification of cylinder numbers to submitted material certifications. This discrepancy was corrected during audit by issuance of internal letter (QC-073-NWG) and correction to RPR.

[NOTE: Audit concerns 8801-04, 06 & 07 issued independent from this concern.]

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO.
8801-03

1. TO: Name: MAX KREITER
Title: MCC PROJECT MANAGER

3. Location
PNL- Richland, WA

4. Reference/Requirements

PAP 901, Rev. 1, "Control of Processes", Section 4.1 - Processes shall be identified and controlled.

5. Audit No.
8801

6. Potential Reportability Under 10 CFR 60.73
☐ Yes ☒ No

7. Description

The attached concern addresses the reference of a Technical Procedure in several documents. The revision of the TP may not be the same.

8. Lead Auditor (Signature)
R V Brownington

9. Issue Date
3.3.'88

10. Response Due Date
4.4.'88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)

13. Date

14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)

16. Date

18. Final Distribution

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17. Final Review and Approval (Audit Concern Closed)

DIRECTOR – Quality Systems Division

Date

Concern on MCC-TP-5, Rev. 2, MCC-1P, and MCC-3S, "Glass Testing Procedures and Methods".

The Nuclear Waste Handbook and companion document, PNL-3990, is a set of controlled documents which is widely distributed and which includes the 9-30-83 version MCC-1P, Static Leach Test Method. However, there have been several revisions to this method, and it has been further modified by MCC-TP-5, Rev. 2, for use in testing West Valley glass. While PNL/MCC is internally in compliance with MA-60 requirements, holders of the Handbook may not necessarily be aware of the latest technical changes. Furthermore, two systems of technical procedures seem difficult to manage and are likely to result in technical inconsistencies.

It is recognized that recent discussions by DOE may lead to elimination of the programmatic requirement for the Handbook. However, PNL-MCC should also evaluate positive steps to resolve this situation. Actions that should be considered include: 1) Issuing notices to holders of the Handbook apprising them of the situation, 2) incorporating useful test methods directly into the MCC-TP system, and 3) recommending to DOE steps for a controlled termination of the Handbook. This latter could include publishing the latest versions of the test methods as PNL reports and providing copies of these to Handbook holders when the Handbook is recalled.

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO. 8801-04

1. TO: Name MAX KREITER — **Title** MCC PROJECT MANAGER

3. Location PNL- Richland, WA

4. Reference/Requirements

PNL-MA-60 (11/10/86), Section 3.2 "Computer Software Control", SCP 312, Revision 1, ICN# SCP-312-1 (1/16/87), Para. 5.3.2 - "The Project Manager shall assure that an ITR (Independent Technical Review) of the SRF is performed..."

5. Audit No. 8801

6. Potential Reportability Under 10 CFR 60.73

☐ Yes ☒ No

7. Description

No ITR of the two SRF's pertaining to ORIGIN 2/VAX was performed.

8. Lead Auditor (Signature)	9. Issue Date	10. Response Due Date
R V Subramanian	3.3.'88	4.4.'88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)	13. Date	14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)	16. Date

18. Final Distribution

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17. Final Review and Approval (Audit Concern Closed)

DIRECTOR – Quality Systems Division _____ Date _____

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO.
8801-05

1. TO: Name	Title	3. Location
C. E. HUGHEY,	QAD MANAGER	PNL- Richland, WA

4. Reference/Requirements	5. Audit No.
CRITERION 18, NQA-1 (1986), Basic Requirement 18, "Audits" PNL-MA-60, Section 18.1 (11/10/86)	8801 6. Potential Reportability Under 10 CFR 60.73 ☐ Yes ☒ No

7. Description REQUIREMENT – The "scope" portion of Section 18.1 of PNL's QA Manual (PNL-MA-60) states, in part: "This section establishes the requirements for planning, performing and reporting audits to verify compliance with all aspects of the QA program and to determine its effectiveness. This section, together with the applicable documents, is intended to meet NQA-1 Basic Requirement 18, NQA-1 Supplement 18S-1 and 10 CFR 50, Appendix B, Criterion XVIII; and DOE requirements that are applicable to the programs and projects of the Office of Civilian Radioactive Waste Management."

CONCERN - Contrary to the above, no objective evidence was available to indicate that the Quality Control/Quality Engineering activities have been audited as required (PNL Audit files were reviewed for last two years.)

8. Lead Auditor (Signature)	9. Issue Date	10. Response Due Date
R. S. Subramanian	3.3.88	4.4.88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)	13. Date	14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)	16. Date

18. Final Distribution	17. Final Review and Approval (Audit Concern Closed)
ORIGINAL–Audit Report File 1– 2– 3–	DIRECTOR – Quality Systems Division _____ Date _____

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO.
8801-06

1. TO: Name
Steven C. Marschman

Title
Tuff Project Manager

3. Location
PNL - Richland, WA

4. Reference/Requirements
Criterion 17, Quality Assurance Records, NQA-1-1986
Reference: PNL-MA-60 Section 17.1, Paragraph 17.1.2.3
PAP-1704, Rev. 1, ICN #1, Paragraph 4.4.1

5. Audit No.
8801

6. Potential Reportability Under 10 CFR 60.73
☐ Yes ☒ No

7. Description

Requirement

The Project Manager shall assure that all Laboratory Record Books (LRB) are periodically (at least once each month or as directed by the Project Manager) reviewed to confirm correct and adequate recording of significant information related to research project activities in accordance with this procedure.

Concern

Contrary to the above requirement, the NNWSI (Tuff) Laboratory Record Books are not being reviewed as required (e.g., Laboratory Record Book #BNW 52391).

8. Lead Auditor (Signature)
R V Brownewell

9. Issue Date
3.3.88

10. Response Due Date
4.4.'88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)

13. Date

14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)

16. Date

18. Final Distribution

ORIGINAL–Audit Report File
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17. Final Review and Approval (Audit Concern Closed)

DIRECTOR – Quality Systems Division

Date

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO. 8801-07

1. TO: Name	Title	3. Location
Steven C. Marschman	Tuff Project Manager	PNL - Richland, WA

4. Reference/Requirements

Criterion 17, Quality Assurance Records, NQA-1-1986
Reference: PNL-MA-60 Section 17.1, Paragraph 17.1.2.4
PAP-1704 Rev. 2, Paragraph 4.5, Inspection of Completed Records

5. Audit No. 8801

6. Potential Reportability Under 10 CFR 60.73
☐ Yes ☒ No

7. Description

Requirement
Paragraph 4.5.1 of PAP-1701 requires that at least once a month, the Project Records Custodian shall request records from Project Contributors for transfer to the PNL Records Center.

Concern
Contrary to the above requirement...NNWSI (TUFF) Project Records have not been transferred to the PNL Records Center since the Project was transferred to PNL (6/29/87).

Although there is evidence that this subject has been under discussion with the sponsor, neither the QA Plan nor the PAP have been modified to permit deviation from the governing procedure.

8. Lead Auditor (Signature)	9. Issue Date	10. Response Due Date
R V Buhaman	3.3.88	4.4.88

11. Auditee Corrective Action Commitment

12. Responsible Action Manager (Signature)	13. Date	14. Action Completion Due Date

ACTION VERIFIED

15. Lead Auditor (Signature)	16. Date

18. Final Distribution

ORIGINAL–Audit Report File
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17. Final Review and Approval (Audit Concern Closed)

DIRECTOR – Quality Systems Division _____ Date _____

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS

AUDIT OBSERVATION

AUDIT NO. 8801

HOT CELL OPERATIONS

During review of the Hot Cell Processes, several observations were noted:

- During removal of a fuel rod from an assembly, it was established that some scraping, or binding, will occur. This may cause the loss of some of the loose crud which could impact the quantitative calculations.
- High speed cutting of a fuel rod could cause a temperature increase. It is not established if CO_2 formation at this point could lower the residual Carbon-14 in the external crud. In addition, due to the vibration during cutting has not been examined in terms of crud loss.
- It has been established that Hot Cell D is contaminated. It can not be established if this condition could cause cross contamination on spent fuel samples.
- Analysis for Carbon-14 in crud only determines the CO_3 type. Other sources are not included and MCC should investigate to confirm if an improved procedure is needed. The total inventory of Carbon-14 should be subject to further investigation.
- The reversal of two (2) sets of photo negatives was noted (Reference DR 87-127). It is felt that the corrective action was vague. There was not explanation of how the correction was done.
- It appears to be possible that samples could change during preparation and handling. The results of Carbon-14 analysis could be affected.

MCC-TP-7, SPENT FUEL ROD RETRIEVAL AND TRANSFER TO D-CELL

The procedure requires the operators to sign-off completion of individual steps in the procedure itself. This appears to be awkward when the procedure is controlled. It is suggested that the procedure be revised to require operators to sign-off a data sheet for the appropriate procedural steps.

MCC-TP-8 includes a list of applicable SOPs. These SOPs also appear to apply to MCC-TP-7.

The procedure requires the operators to verify that a particular step has been completed as required, but does not indicate the corrective action if a mistake was made. In general, procedures involving safety or significant programmatic issues should specify the appropriate procedural steps if the operation can not be or is not completed as intended. This could be generic, such as; 1) stop; 2) notify Task Leader; 3) develop a recovery plan. (This type of action may already be specified in the SOPs, in which case the SOP should be referenced.)

It is not clear from the procedure that a method has been implemented for positively identifying the original orientation (top and bottom) of the segments in the fuel rod. This problem needs considerations.

The procedure specifies that the load cell must be tested and the readout verified prior to use, but didn't provide steps to accomplish this or what the appropriate load limit should be during the actual pulling of a fuel rod. The load limit should be based on prevention of damage to the fuel rod being pulled.

It isn't clear from the procedure how proper orientation of the assembly can be positively maintained after removal of the assembly head. The procedure should be revised, if necessary, to assure that orientation of the assembly can be maintained, for example, by the addition of an index mark on one side of the spacer grids.

MCC-TP-9, FUEL ROD SCANNING PROCEDURE

This procedure was reviewed by the Building Manager, Safety, and RM. It is suggested that the other procedures also be reviewed by these organizations prior to use.

Section 4.8.4: The instruction is unclear. It is suggested that power to the motors be shut off and tagged out anytime someone is working on the power supply, leads, or motors. This should be done at the circuit panel rather than relying on the IBM computer.

MCC-TP-10, FISSION GAS SAMPLING

This procedure does not require purity check on the argon supply. It is recommended that the procedure require a positive check on the argon purity, e.g. analyses, or that the argon be filtered through a molecular sieve to avoid potential system contaminations.

- In general the terms used in procedures should be consistent throughout the procedure and among procedures. For example, in one sentence an item may be called a probe but the next reference may call it a device.

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS

AUDIT OBSERVATION

AUDIT NO. 8801
Observation 8801-02

PNL-MA-60, SCP 317, Paragraph 5.2.3:

This requirement states that: "The custodian shall assure that the approved RFT, [instrument used to obtain a computer code from outside PNL]...[is] sent in accordance with PAP-101,.. The reference AP is applicable to communications with and commitments made to sponsors. For acquisition from suppliers it refers the user to procedures contained in other sections of the PNL-MA-60 manual. The acquisition of ORIGIN2/VAX code was accomplished by sending the approved RFT with a cover letter to the ORNL.

The audit team observed that for code acquisition the reference to PAP-101 seems out of place.

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS

AUDIT OBSERVATION

AUDIT NO. 8801

Observation 8801-03

PNL-MA-60, Section 6.1, PAP 601, Rev. 3, Section 4.1.2, and 4.2.1

"The Technical Procedure Coordinator (TPC) assigned by the line or Project Manager...shall maintain the distribution list for Quality Level I TP's and TI's." (Section 4.1.2)

"...and the TPC shall prepare master lists of the documents which they distribute. These lists shall be either Table of Contents...or Controlled Document Lists (CDL's typically used for TP's and TI's)."

The observation pertains to TI's (Technical Instructions). Interviews with C. Wilson, R. Einzinger and B. O. Barnes seemed to indicate that no TI's had been issued yet. It was further explained that a TI is used to augment a TP (Technical Procedure) with details not usually found in TP's. However; review of laboratory notebooks revealed that something akin to supplementary guidance was used by a task leader who called it Technical Instructions. These letters however, served to augment a Technical Plan and were in the format of an official memorandum from one task leader to another.

The audit team recommends that the concept of Test Instructions be examined and explained to those who have to work with it. The recommendation is particulary made with respect to any augmentation, clarification, or increased level of detail of procedures or test plans for Quality Level I work.

The audit team specifically suggests that procedures SFO 2-1 and SFO 1-2 explicitly require that any memos intended to initiate a specific oxidation run be included in the laboratory notebook or otherwise be retained as a part of the test documentation.

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS

AUDIT OBSERVATION

AUDIT NO. 8801
Observation 8801-04

PNL-MA-60, SECTION 6.1, PAP 601, REV. 3, SECTION 4.1.2

"The Technical Procedure Coordinator (TPC)...shall maintain a distribution list for Quality Level I TP's and TI's."

In the case reviewed the distribution list was physically maintained by Document Control Section of the Records Center. The TPC did retain the authority to add or delete names from the list, but the TPC did not have a distribution list available to him.

Several interpretations may be attached to the phrase "maintain a distribution list." The manner in which distribution lists are maintained and controlled now appears to be working well. The audit team therefore recommends that the Line or Project Manager assign the Document Control Section of the Records Center as TPC.

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS

AUDIT OBSERVATION

AUDIT NO. 8801
Observation 8801-05

PAP-602, Rev. 2, Paragraph 4.1.10

States that the QADPC shall assign an effective date for ICNs. The ICN form has a block for "date issued" but no indication of when the ICN is to be effective. Based on interviews: 1) Quality Assurance personnel state that the "date issued" is the effective date, 2) individuals in two different departments who issue the documents state that the "date issued" is the date the ICNs must leave their offices to the controlled document holders. Recommend that this difference in interpretation be resolved by adding an effectivity date to the ICN form.

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS

AUDIT OBSERVATION

AUDIT NO. 8801
Observation 8801-06

MCC did not sign Part C of a Request of Work # M25798-1 (dated 7/15/87) even though work was completed and delivered to Argonne National Laboratory. The work involved preparation of special spent fuel samples. A memorandum was found which acknowledged the work was completed, therefore, it is not believed that this affected the quality of the product. However, work needs to be approved in a timely manner and the appropriate Request for Work needs to be signed as soon as possible prior to shipment of spent fuel samples.