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DEPARTMENT OF ENERGY

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

AUDIT REPORT

FEBRUARY 23-26, 1988

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102.7

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 SCOPE AND OBJECTIVE

This DOE-RL and DOE-HQ joint audit on Pacific Northwest Laboratories (PNL) covered selected activities of the Material Characterization Center (MCC) and activities for the Nevada Nuclear Waste Storage Investigations Project (TUFF), carried out at PNL.

The objectives of the audit were:

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

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

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

1.2 BACKGROUND INFORMATION

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.

Max Kreiter is assigned the management responsibility for MCC.

Currently major MCC activities of interest to OGR are in the spent fuel operations and spent fuel characterization groups (Tasks 04 and 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). 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. In addition, LLNL, as sponsor, had provided for additional oversight of TUFF activities of PNL under Special Sponsor requirements of QA Plan (Section 12 of WTC-018, Rev. 1) as for example:

> "Testing begins (at PNL) after LLNL review and approval of all applicable Technical Procedures. Draft procedures for work related to spent fuel testing shall be sent to Henry Shaw, LLNL, and John Dronkers, LLNL."
>
> "Nonconformance Reports, Incident Reports, and Deficiency Reports shall be sent to LLNL for approval of disposition.... Copies of all dispositioned Incident Reports and Corrective Action Reports for work related to Spent Fuel Testing shall be sent to Henry Shaw, LLNL, and John Dronkers, LLNL."

Based on the background information provided for MCC and TUFF activities at PNL, the current audit addressed 18 Quality Assurance Criteria as they relate to MCC and TUFF programs. The audit team was led by T. K. Subramanian of DOE-RL's BWIP Quality Systems Division (currently Quality Engineering Branch of DOE-RL). The three sub-audit teams including the technical advisors, their responsibilities and the observers are shown in Attachment 1 to this audit report.

2.0 OVERALL QA & TECHNICAL PROGRAM ASSESSMENT

2.1 QA PROGRAM

The audit team verified that both MCC and the TUFF activities are governed by sponsor approved QA plans which comply with the PNL MA-60, QA Manual for License-Related Programs. The implementation of the QA program criteria applicable to the current level of audited activities was verified as achieving the intended purposes, with the exception of items addressed in the seven concerns shown in Attachment 6.

2.2 TECHNICAL PERFORMANCE

Technical advisors from DOE-HQ, DOE-RL, Brookhaven National Laboratories and Lawrence Livermore National Laboratories participated in the audit. Their goal was to assess the technical adequacy of the activities including the adequacy of the controls used to assure a technically sound product. In addition, the technical advisors also assessed the technical procedures to determine if they reflect accepted scientific methods.

The reports from the technical advisors included in Attachment 3, provide details of their investigations and the results of their evaluation. Based on the concerns issued and the reports from the technical advisors no significant technical deficiencies were identified in either the MCC or the TUFF program technical implementation.

2.3 OVERALL PERFORMANCE

The audit team's conclusion is that the overall performance, (the implementation of the QA program and technical performance) is achieving the intended purpose. This view is supported by the absence of noncompliances which could lead to reduced product quality, or audit findings, in the audit results shown as Attachment 6 to this report.

3.0 COMMENDABLE PRACTICES

Based on interviews with the MCC and TUFF management and staff, it was obvious that they are cognizant of their responsibilities. Their professionalism and cooperation were commendable. Responses provided to the questions of the audit team, especially the technical advisors, indicated a willingness and commitment on the part of the PNL staff to perform their duties in a manner consistent with good quality practices.

4.0 AUDIT PERFORMANCE

4.1 CHECKLIST PREPARATION

This DOE-RL/DOE-HQ joint audit required checklists covering MCC and TUFF programs with input from their respective sponsors, i.e. DOE-HQ and LLNL auditors. The audit team prepared QA checklists based on PNL-MA-60 and administrative procedures applicable to the MCC and TUFF programs covering criteria 6, 8, 11 and 15. These were transmitted to DOE-HQ and LLNL for

review. Based on their comments, QA checklists for all 18 criteria were prepared and transmitted to auditors and NRC. Checklists covering technical procedures and software control procedures were handled differently. Technical advisors were briefed on their role relative to the audit objectives. They were required to review the technical procedures and generate technical checklist questions for use during the audit. LLNL, the sponsor for TUFF, was chosen to prepare the SCP checklists, with the concurrence of DOE-HQ, based on two factors: 1) LLNL would provide relatively independent support as they are not involved in MCC software control. Software Control Procedures (SCP) were included in the QA Plan for MCC but not for TUFF program; 2) LLNL has had relevant experience in software control issues related to repository programs.

Completed checklists containing the investigations pursued by the entire audit team (including QA, SCP and Technical checklist questions) are in DOE-RL audit files.

4.2 SUB-AUDIT TEAMS

The three sub-audit teams and their responsibilities for auditing MCC and TUFF activities are shown in Attachment 1. Activities common for both MCC and TUFF programs (eg., procurement, document control, records, etc.) were assigned to sub-audit team C. Audit team leader (ATL) assisted the teams and responded to the observers comments.

Before the audit, DOE-RL audit team members had a preliminary discussion with MCC, TUFF and QA staff of PNL to confirm the current project activities and obtained a list of software and M&TE being used for each project. DOE-RL audit team also visited the laboratory site to become familiar with security badge requirements and to know the location of the project offices and records. Based on the information collected, the ATL provided a briefing for the (Sub-Audit Team A) auditors and technical advisors at DOE-HQ on the audit procedure, role of the technical advisors and the information on the software and M&TE used, and current status of test activities. While the M&TE information was transmitted to LLNL, the briefing by the ATL was provided at Richland before the Sub-Audit Team B lead and the technical advisor started the audit. In addition, ATL provided similar briefing to P. E. LaMont, DOE-RL Technical Advisor.

The Technical Advisors, P. E. LaMont, S. Gomberg, C. Pescatore, and D. Van Rooyen for MCC have relevant experience for the technical advisor role. Henry Shaw, Technical Advisor for Sub-Audit Team B has appropriate qualification and experience for assisting Sub-Audit Team B. However, he is identified in the TUFF QA plans as the (LLNL) sponsor contact for receipt of Draft Test Program Plans, Technical Procedures and Reports, Incident Reports, Nonconformance Reports and other documentation relative to Spent Fuel Testing. His assignment as a Technical Advisor was accepted after discussion with DOE's QA Manager for TUFF work and on the basis that he mostly coordinated the documents reviewed at LLNL and was independent from the audited activity. The Technical Advisors' resumes are in the audit files and ATL had reviewed them to ensure that the Technical Advisors have experience relevant to the audited disciplines.

Pre-audit briefing for observers was held on February 22, 1988, to provide the observers with the final audit plan, and to discuss the definitions for audit findings, concerns and observations and the role of the observer. Audit entrance was held on February 23, 1988, to discuss the scope and schedule of the audit with PNL.

Sub-Audit Team A auditors and technical advisors investigated the following MCC activities:

a. Spent Fuel Operations

- Procedural adequacy
- Receiving, handling and storage
- Cutting fuel rods into segments
- Fission Gas Sampling
- Gamma Scanning
- Physical and chemical analysis
- Documentation (Computer Software Control verification was performed by Sub-Audit Team B)

b. Glass Preparation

- Procedural adequacy
- Receiving and control
- Glass batch preparation
- Glass characterization and analysis
- Documentation

The results of these investigations indicated that, in general, the MCC personnel are performing their functions in accordance with required procedures. No findings, were identified. The concerns identified pertained to procedural adequacy and qualification. The observations identified areas in which the program could be strengthened to provide more meaningful and consistent results. The concerns and observations included in Attachment 6 are described in more detail in other sections of this report.

Sub-Audit Team B investigated the one on going Quality Level 1 task: Spent Fuel Oxidation conducted at PNL for the TUFF program. This task consisted of two subtasks, oxidation of spent fuel and UO_2 using thermogravimetric apparatus and oven oxidation test of spent fuel and UO_2.

Based on the limited ongoing test activity (limited number of quality level 1 testing, and use of only two technical procedures by PNL at the time of the audit) the technical advisor examined use of a procedure which will be used in future for fuel dissolution tests at PNL to determine if solution sample identification control and generic test control aspects will be adequate. Please refer to the Technical Advisor, Henry Shaw's report, shown as Attachment 3 to this audit report, for complete details.

In addition, Sub-Audit Team B lead completed the verification of the software control portion of the checklist for MCC.

The concern and observation (8801-04 and 8801-02) identified are shown in Attachment 6 to this audit report.

Sub-Audit Team C examined records and interviewed personnel to verify implementation of criteria common for MCC and TUFF. Audit team leader also assisted in the verification of portions of checklists for both MCC and TUFF programs. The concerns and observations generated are shown in Attachment 6. The verification details are described under the Section 5, "Discussion of Results."

5. DISCUSSION OF RESULTS

5.1 ORGANIZATION

The audit team verified that the implementation of the following program requirements is adequate.

a. QA personnel have sufficient independence and authority to identify quality problems

b. Responsibilities for establishing and implementing the QA program and for development of a plan for assessment of the QA program are delineated.

The audit team interviewed the Director for Quality Achievement, the QA Department Manager, the QC Manager; and reviewed CAR 87-02 issued by the QAD, Monthly Status Reports, QA Directors attandance of Executive Management Team meetings, and the scope of the Management Assessment Plan.

Interviews and document reviews established that the Quality Achievement Director is a member of and attends Battelle Executive Management Team meetings and that management assessment of QA Program effectiveness per is implemented per PAP 202. QA Department Manager and QC Manager review Trend reporting system documents, interface with Line Management, perform periodic audits and surveillances including vendor audits and surveillances to verify effective implementation of QA Program. QA Manager has also issued the CAR 87-02 to Battelle Director which addresses the deficiency that controlled document recipients are not maintaining their QA manuals or technical procedures.

No concerns or observations specifically applicable to this criterion were issued.

5.2 QA PROGRAM

The audit team verified that the implementation of the following program requirements is adequate.

a. A documented QA Program shall be established including technical aspects of the activities affecting quality.

b. The program shall provide for indoctrination and training of personnel performing activities affecting quality.

c. Management shall regularly assess and assure effective implementation of the QA Program.

The audit team interviewed MCC and TUFF Project Managers, M. R. Kreiter and S. Marschman, respectively, Quality Achievement Director, S. Goldsmith; and reviewed task specific (MCC & TUFF) QA Plans, training documentation for twelve MCC & TUFF personnel and status of sponsor review of technical procedures included in the QA plans.

The audit team determined that the TUFF QA Plan WTC-018, Rev. 1, meets the PNL-MA-60 Section 2.1.1.6 requirements, and the QA Plan and the technical procedures were approved by the sponsor LLNL. The MCC QA Plan WTC-002, Rev. 1 meets the PNL-MA-60, Section 2.1.1.6 requirements and was approved with comments by DOE-HQ. However, technical procedures used by MCC were not required to be reviewed by DOE-HQ (no sponsor requirements for technical procedure review and approval are identified in the QA Plan).

No concerns or observations were written based on the above information. However, deficiencies noted in the implementation of the QA program, which are attributed to the need for augmented training are addressed in Concern 8801-02.

5.3 DESIGN CONTROL

The audit team verified the following:

a. Calculations (hand calculations) are supported by the required (PAP 301) approvals and documentation including Independent Technical Review (ITR) in accordance with the procedure PAP 601.

b. Software control procedure requirements required by Software Control Procedures (SCPs) identified in the MCC QA Plan WTC-002, Rev. 1, are complied with.

NOTE: SCPs were not invoked in the TUFF QA Plan and hence the verification was only for MCC software.

5.3.1 The audit team reviewed hand calculations for three of nine statements of work for ongoing or recently completed work. All the calculations in these three packages were considered to be routine, requiring just supervision review and no Independent Technical Review. Further questioning indicated that the Project Manager determined that routine calculations do not require an ITR. This is consistent with the procedure PAP 301 Rev. 1.

For both MCC and TUFF projects, this audit verified compliance to procedure PAP 604, Rev. 1, Independent Technical Review as a requirement for the preparation of two Technical Procedures.

5.3.2 Sub-Audit Team B (John J. Dronkers) assisted Sub-Audit Team A in determining PNL's compliance with its software control procedures. Sub-Audit Team B verified that the implementation of the Software Control Procedures was generally adequate. It was determined that:

a. Determination of applicable software requirements occurs in accordance with stated requirements contained in procedures found under Tab 7: "Software Control Procedures," of PNL-MA-60 Volume II

b. Transfer of software, data, and/or documentation occurs in accordance with the requirements noted in a) above.

c. Software configuration management occurs in accordance with the requirements noted in a) above.

d. Conversion testing, verification, and/or validation of software occurs in accordance with the requirements noted in a) above.

e. Software application occurs in accordance with the requirements noted in a) above.

This verification was based on the review of documentation that pertained to the acquisition, baselining, configuration management, testing, verification, validation, application, and transfer of the ORIGIN 2/VAX code. The verification was also based on extensive interviews with U. Jenquin, code custodian for the ORIGIN 2/VAX code.

However, lack of evidence for the required Independent Technical Review of SRFs pertaining to ORGIN 2/VAX is reported as concern 8801-04. Observation 8801-02, attached to this report, also resulted from software control review effort.

5.4 PROCUREMENT DOCUMENT CONTROL

The audit team reviewed records for materials, items and services procured by PNL in support of the MCC and TUFF projects. The requirements used as the basis for the audit were PNL procedures identified as PAP 401 through PAP 404. The requirements, in summary, are:

a. Procurement documents include applicable requirements, are reviewed and approved by appropriate personnel to ensure that items and services meet specified requirements.

b. Procurement documents include purchase requisitions, store orders, statements of work, and work orders.

The purchase requisitions reviewed were issued to procure laboratory equipment used in performing tests. Purchase requisitions are typically used by these two projects for this purpose, therefore the number of purchase requisitions available for review is very limited. The purchase requisitions

reviewed appeared to satisfy applicable requirements (four of five purchase requisitions reviewed were prepared prior to the current procedure revision).

Based on interviews with PNL employees it was ascertained that no store orders had been issued for quality level 1 or 2 items. Furthermore, at least one employee indicated that they would never use store orders for quality level 1 or 2 items because PNL could not ensure that the items met the quality and technical requirements of the project.

The Statements of Work (SOW) and associated work orders (work packages) were reviewed for each of the projects being audited. Although the QAD Representative is required to review work orders, the work orders are financial control tools that do not typically transmit technical or quality requirements except by reference to applicable SOWs. The SOWs appear to satisfy the intent of the control system. However, two of the SOWs reviewed reflected minor failure to follow procedures 1) task leader approved one SOW instead of the Project Manager; 2) one SOW did not identify the quality level (quality assurance requirements were included in the SOW).

These two minor discrepancies do not present serious concern to the auditor but when considered collectively-with other minor discrepancies (failure to follow procedures)- they become audit concern No. 8801-02 dealing with training inadequacies.

5.5 INSTRUCTIONS, PROCEDURES AND DRAWINGS

The procedure PAP 501, Rev. 3, ICN #1, "Preparation, Review and Approval of Procedures," addresses the requirements under this criterion. Verification of specific portions of this procedure, (e.g., initiation of administrative or technical procedures and staff members responsible to perform activities affecting quality do infact perform in accordance with applicable approved procedures) is addressed in the checklist questions under Criterion 6 Document Control.

During the preparation of the checklist one isolated case was identified where the procedure PAP 501 was in conflict with QA Manual relative a procedure approval authority. PNL was advised of this conflict. During the audit, corrective action (revision to PNL-MA-60) was verified to be in process to correct the conflict; therefore, this discrepancy was not issued as a concern.

No further discrepancies were noted for MCC or TUFF programs under this criterion.

5.6 DOCUMENT CONTROL

5.6.1 The audit team (Sub-Audit Team C) reviewed records that provide evidence that the requirements of this criterion are satisfactory. The requirements used as the basis for the audit were PNL procedures identified as PAP 501, 601, & 602. The requirements, in summary, are:

a. Measures shall be established for the preparation, review, approval and issuance of documents that prescribe activities affecting quality.

b. Changes to document are controlled.

c. Documents shall be available for use in the area where the activity is performed.

During the audit it was ascertained that PNL had issued a CAR (87-02) during December 1987, that addressed three deficient areas: 1) Controlled document recipients not maintaining controlled documents as required; 2) Interim Change Notices (ICN) not being properly handled; and 3) Controlled Document Transmittal/Receipt (CDTR) acknowledgements not being returned to document control. A sample of approximately 21 controlled documents found in work areas were compared with document control's list and only one isolated case was identified where a cancelled document had not been removed from a manual.

The activities associated with the control of documents appears to satisfy the requirements. The responsibilities for controlling documents are divided between document control and the technical procedures coordinator(s) (TPC). MCC test instruction (TI) are controlled by the task leaders who have been designated as the TPC for TIs. Since only one task leader has issued TI's no verification activities were performed during the audit.

5.6.2 Sub-Team B (John J. Dronkers) verified that the implementation of the Document Control requirements is adequate for TUFF. It was determined that :

a. Technical and administrative procedures are prepared, reviewed and approved in accordance with procedures contained in PNL-MA-60, Section 6.1, Rev. (11/10/86).

b. Technical and administrative procedures have their issue controlled as required by the reference already cited in a) above.

c. Technical and administrative procedures are changed as required by the reference already cited in a) above.

d. When superseded, technical and administrative procedures are collected and stored in accordance with requirements contained in the reference already cited by a) above.

This verification was based on the review of the documents, selected at random from the available documents and on interviews with the following people: D. Alamia, A. C. Philips, W. E. Brooks, C. Wilson, R. Einziger, A. Spooner, B. O. Barnes. As a result Sub-Team B reported Observations 8801-03 and 8801-04 which are attached to this report.

5.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

The audit team reviewed records that provide evidence that the requirements of this criterion are satisfactorily implemented. Typically records related to the MCC and TUFF projects were reviewed, however, where no project specific records were available other records presented by PNL were reviewed in a cursory manner. The requirements used as the basis for the audit were PNL procedures identified as PAP 702, 704, 706, 701, QAP 703, 704, 705 and PAP 404. The requirements, in summary, are:

a. Procured items or services comply with procurement documents.

b. Procured items or services are obtained from an approved source.

No source inspections, supplier non-conformances, material overchecks, or vendor audits for either the TUFF or MCC projects had been performed in the last year. Based on the types of items purchased this appears to be appropriate.

The PNL QC group performs receiving inspection and/or review of vendor supplied documents when required by the Purchase Requisition (PR). Only one item (an autoclave) has been physically receipt inspected in the last year for the MCC or TUFF projects. Although there is evidence that the item had been receipt inspected by PNL QC, the PNL receiving documentation was not in conformance with existing procedures. QC immediately corrected this procedural non-compliance by issuing an internal letter accompanied by the required Inspection/Test Instructions forms. A preaward evaluation, limited to verification of an appropriate ASME Certificate of Authorization, was performed by QC. Vendor supplied documentation was reviewed by QC for conformance to procurement documents. However, only one QC Review Plan and Record for MCC/TUFF projects was reviewed and the QC inspector had failed to record the verification of traceability of vendor document to items. This failure to properly document traceability was corrected immediately by the QC Specialist using an internal letter and an additional note on the RPR form. These specifics were not identified as a concern but were considered to be a part of the concern (8801-02) on "Training"

5.8 IDENTIFICATION AND CONTROL OF ITEMS

Identification and control of test materials and samples were audited to verify that Approved Test Materials (ATM) are traceable and representative. The audit team evaluated objective evidence and the technical adequacy of the MCC's Spent Fuel Operations and Glass Preparation Activities as they apply to control and identification.

The following procedural requirements were verified to be adequate and in accordance with PNL Administrative Procedure (PAP) 801, Rev. 3.

a. The necessary procedures have been established for sample characterization.

b. Material Custodians have been designated.

c. Test Material's Inventory Sheets (TMIS) have been maintained.

d. Test Materials have been uniquely identified and are verified prior to characterization.

This verification was based on interviews and the review of Technical Procedures, TMIS and Shipping and Receiving Reports for ATMs 103 through 106 and 10(F1 to F14) glass.

The technical advisors, based on technical judgement, determined that the control of ATM complied with Technical Procedures requirements.

Based on observations and on discussions with PNL's J. Barner and R. Gould, it was determined that several procedural concerns need to be addressed. The means to prevent loss of fuel from segmented rods during handling and the amount of time fuel samples can be exposed to the hot cell atmosphere were identified. These concerns were consolidated in Concern 8801-01.

In addition, several observations were made and are identified in Observation 8801-01:

a. No method to minimize scraping or binding of fuel rods during removal from fuel assemblies.

b. Cross-contamination may occur due to contaminated state of D-Cell.

c. Deficiency Report 87-127 noted that two (2) sets of negatives were reversed. There was no explanation of how corrective action was performed.

QA checklists for TUFF specific activities under Criteria 8, 9 and 11 were not completed during this audit. Given the current level of actual test activity for the TUFF program, the evaluation that the one ongoing Quality Level 1 activity [oxidation tests of spent fuel and UO_2] is being performed satisfactorily was based on the technical advisor investigations and his (H. Shaw) report included as Attachment 3.

5.9 CONTROL OF PROCESSES

The criterion for control of processes was audited to verify that the Approved Test Materials (ATM) are developed and characterized in a controlled and repeatable manner for MCC's Spent Fuel operations and Glass Preparation activities.

The following procedural requirements were verified to be adequate and in accordance with PNL Administrative Procedure PAP 901, Rev. 1:

a. The necessary Technical Procedures have been developed and implemented.

b. Personnel have been appropriately qualified.

c. Materials and equipment used in the processes are adequately controlled.

d. Their performance of the processes have been monitored.

This verification was based on review of the following documentation: Technical Procedures (MCC-TP-1 through 4, 7 through 10), characterization plan for ATM 10, Training records for operators, Test Instruction and Run Plans.

From interviews and reviews of objective evidence, it is evident that MCC personnel are cognizant of their responsibilities and that they are complying with procedural requirements for the control of ATM processes.

The technical advisors, based on technical judgment determined that, in general, the Glass Preparation and Spent Fuel Operations are in compliance with requirements.

Based on these evaluation, the audit team reported two (2) concerns and several observations. One (1) concern identified the need to reference the design reports for the Gamma Scanning System and the Fission Gas Sampling System. This concern was consolidated in Concern 8801-01.

The other concern identified a control problem with testing methods. The Nuclear Waste Handbook and a referenced document, PNL-3990, identify different versions of the same test method (Static Leach Test Method). This could create confusion among the users of the test method. This concern is noted in more detail in Concern 8801-03.

The following observations were combined in Observation 8801-01:

a. High speed cutting of fuel rods could cause a temperature increase which could compromise the representativeness of the sample.

b. The total inventory of Carbon-14 in crud on fuel rods should be analyzed.

c. The results of Carbon-14 analysis could be affected by handling.

d. MCC-TP-7 should be changed to clarify the sign-off by operators during the process.

e. MCC-TP-7 should include the list of SOPs noted in MCC-TP-8.

f. MCC-TP-7 should be changed to clarify steps to be taken if a problem occurs during the process.

5.10 INSPECTION

The requirements for inspection and surveillance are noted in Section 10.1.1 of the PNL QA Plan, PNL-MA-60, Rev.2. Inspections as defined in Criterion 10 are not performed as the MCC and TUFF activities are not considered a construction effort. Inspections performed under QC receipt inspection are addressed under Section 5.7 of this report.

The audit team verified that the MCC QA Plan, WTC-002, Rev. 1 and TUFF QA Plan, WTC-018, Rev. 1, identify personnel who perform independent surveillances of MCC and TUFF activities. Surveillance Plans for the first and second quarters of FY 1988 have been issued. Surveillances are performed by K. Webster (MCC) and by B. O. Barnes (TUFF).

Based on interviews and review of objective evidence, Reports 88-001A, -002A and -003A, the audit team determined this effort to be adequate.

5.11 TEST CONTROL

The criterion for test control was audited to verify that tests and analyses performed on Approved Test Materials (ATM) were conducted in accordance with applicable procedures.

The following procedural requirements were verified to be adequate and in accordance with PNL PAP 1101, Rev. 2, "Test Planning, Performance and Evaluation."

a. The necessary procedures have been established and implemented.

b. Tests were performed in accordance with Technical Procedures and the results properly documented.

This verification was based on interviews and review of Technical Procedures MCC-TP-1 to 4 and 7 to 10; Test Instructions for ATM 103, 104, 105, 106 (Spent Fuel) and Laboratory Record Book 5501 for Glass Preparation.

Based on interviews, observations and review of Test Instructions for Spent Fuel ATMs, the technical advisors determined that several concerns need to be addressed. The following concerns were combined in Concern 8801-01:

a. The Baritron (No. WA83760) used in the Fission Gas Sampling System cannot be calibrated due to contamination.

b. The Technical Procedures for Fission Gas Sampling and Gamma Scanning should reference the design reports which should address system calibration.

Several observations, combined in Observation 8801-01, were identified by the audit team:

a. The method for positively identifying the orientation (top and bottom) of segments of fuel rods were not noted in procedures.

b. Proper orientation of a spent fuel assembly was not identified.

c. The load limit, as noted on the load cent, when pulling fuel rods from an assembly was not addressed.

d. MCC-TP-9, "Fuel Rod Scanning" needs to address "tagging out" procedure when working on electrical components.

e. A purity check on the argon supply to the Fission Gas Sampling System is recommended.

5.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Control of measuring and test equipment (M&TE) was audited to verify that the Approved Test Material was obtained and characterized using calibrated instruments.

The audit team verified that the MCC has implemented a calibration control system as noted in PNL PAP 1201, Rev. 3. M&TE is calibrated through the use of Work Orders to others and would be audited as part of Criterion 7, "Control of Purchased Items and Services."

The use of calibrated equipment was verified through review of LRB 5501 and copies of PNL Calibration Records for thermocouples #203359-3 and Balance #364-06-01-006. This M&TE was used for Glass Preparation.

Based on interviews, observations and review of Test Instructions for Spent Fuel ATMs, the technical advisors determined that several concerns need to be addressed.

The following concerns were combined in Concern 8801-01:

a. The Baritron (No. 83760) used in the Fission Gas Sampling System cannot be calibrated due to contamination.

b. The Technical Procedure for Fission Gas Sampling and Gamma Scanning should reference the design reports which should address system calibration.

5.12.1 CONTROL OF M&TE (PROCUREMENT PORTION)

Calibration services are typically accomplished by either the WHC Standards Laboratory, PNL Craft Services or by the users. In general PNL Craft Services calibrates instruments in-place whereas WHC Standards Laboratory calibrates items that can be physically moved to the laboratory for calibration. PNL has prepared two generic statements of work (SOW) for calibration services: 1) SOW-CSD-85-1, Rev. 0, Sept. 12, 1985, for Calibration by PNL Craft Services; and 2) SOW-WHC-85-1, Rev. 0, August 9, 1985 for Calibration by WHC Standards

Laboratory. The two SOWs incorporate the requirements specified in PNL's PAP and require the calibrator to have procedures which satisfy the requirements identified in the SOWs. Items identified on the M&TE Control Listing for the MCC & TUFF Projects to be calibrated by PNL Craft Services were selected for further review.

One of the two MCC items to be calibrated by PNL Craft Services was checked to determine that the item specific calibration procedure complied with SOW. A digital thermometer was calibrated in accordance with Standards Maintenance Procedure General Purpose 67, Rev. 1 and General Purpose 37, Rev. 6. These procedures appear to meet the SOW requirements. Acceptance tolerances are provided to the calibrator on a computer preprinted calibration form for the individual piece of equipment (General Purpose 37 was revised as a result of an internal PNL surveillance to include provision for establishing tolerances on the preprinted calibration form for each piece of equipment.)

Two of five TUFF items to be calibrated by PNL Craft Services were checked to determine that item specific calibration procedure complied with the SOW. Neither of the items had been entered into the PNL system since the transfer of the TUFF project from WHC. Although this is not a deficiency appropriate PNL personnel were advised that these items had probably been deleted from the WHC recall system and had not been entered into the PNL recall system.

The subject of the effect of maintenance work performed by outside vendors on calibration status was discussed with appropriate PNL QC personnel. They were not readily aware of any areas where this might be applicable to PNL activities. The PNL personnel knowledgeable in the calibration area were aware of the possibility of deficiencies when maintenance is performed on calibrated equipment.

5.13 HANDLING, STORAGE AND SHIPPING

This criterion was audited as part of Criteria 7, 8, 9, and 11. Any Concerns or Observations are noted in discussions of those criteria.

5.14 INSPECTION, TEST AND OPERATING STATUS

This criterion addresses the control of status indicators during the installation and operation of equipment. There was no testing in progress during the audit; therefore, auditing of this criterion was not applicable.

5.15 CONTROL OF NONCONFORMING ITEMS

The audit team verified that the implementation of the following program requirements are adequate.

a. That items not conforming to specified requirements are controlled to prevent inadvertent installation of use.

b. That controls are in place to provide for identification, documentation, evaluation, segregation, and disposition of nonconforming items, and for the notification to affected organizations.

Verification was based upon the review of objective evidence, and interviews of program cognizant QA personnel.

The nonconforming control system was verified for effectiveness only for the Nuclear Waste Materials Characterization project. A small amount of nonconformance reports were generated.

The Nevada Nuclear Waste Storage Investigations Project was not verified because no NCR's were generated.

5.16 CORRECTIVE ACTION

The audit team reviewed the Corrective Action Program documentation maintained by the Quality Assurance Department (QAD) in support of the MCC and TUFF repository work activities. The audit team verified that the implementation of the following program requirements are adequate:

a. Conditions adverse to quality are being documented, evaluated and reported on a periodic basis by the cognizant project personnel.

b. Adverse quality conditions are being reviewed, evaluated and analyzed by the cognizant QAD personnel to identify significant conditions requiring timely corrective actions.

c. Significant adverse quality conditions are being documented, reviewed, processed, statused, verified and closed-out as corrective action requests (CAR) by the cognizant QAD personnel.

The documentation reviewed by the audit team (Semi-annual MCC, TUFF and QAD assessments of Conditions adverse to Quality) and discussions held with cognizant QAD personnel identified that the adverse quality conditions documented and evaluated during the years 1987/88 did not result in the issuance of corrective action requests or escalation of (those which are open) CARs to top management as related to the MCC & TUFF repository project activities.

The audit team reviewed the CAR Log Book, maintained by the QAD secretary, which indicated an overall timeliness in processing CARs, including sponsor notifications, verification of disposition implementation and close-out activities. CARs 86-03, 04 & 05 were reviewed for compliance with the procedure requirements prescribed in QAP-1602 and were found to have been satisfactorily processed and closed-out. In addition, the team also reviewed the technical disposition adequacy, verification of disposition implementation and close-out activities related to deficiency report MCC DR #85-54, with the coordination of the technical advisor (P. E. LaMont) from Sub-Audit Team A. The audit team determined that the activities reviewed relative to DR #85-54 were found to be satisfactory.

5.17 QUALITY ASSURANCE RECORDS

The audit team reviewed records that provide evidence that the requirements are being implemented in a satisfactory manner. The requirements used as the basis for the audit in summary are:

1. Records that furnish documentary evidence of quality shall be specified, prepared, and maintained.

2. Records shall be legible, identifiable, and retrievable.

3. Records shall be protected against damage, deterioration, or loss.

4. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

   The MCC project records have been and are being collected by the Project Records Custodian, transmitted to the PNL Records Center, and maintained by the Records Center.

   TUFF records generated since consolidation were checked for compliance to the PNL procedural requirements. Records generated prior to consolidation were the responsibility of WHC, therefore, were not considered during this audit. During the audit, it was determined that the TUFF project was not in compliance with the PNL procedure requiring transfer of completed records to the records center on a monthly basis. Although there is evidence that this subject had been discussed with the sponsor (LLNL), the QA Plan for the project had not been modified to allow deviation from the existing procedure. In addition, it was identified that the PNL TUFF Project Manager had not been assuring that laboratory records books (LRB) were reviewed monthly. (The Project Manager had not directed that the LRBs be reviewed at different frequency.) These two procedural discrepancies have been identified as concern 8801-7 and 8801-6. These discrepancies were determined by the audit team to be non-hardware affecting.

5.18 AUDITS

The audit team reviewed audit documentation maintained by PNL-QAS&A Section in support of the Materials Characterization Center (MCC) and TUFF Repository work activities. The requirements used as the basis for the audit are summarized as follows:

a. Plans identifying audits to be performed including frequencies and schedule have been developed and followed.

b. Audits performed covered all aspects of the QA Program including a satisfactory rationale for not covering certain areas.

c. Audit preparation, performance and reporting system complied with the internal audit procedure requirements.

d. Audit response, follow-up, records, and audit data analysis (to provide for management) activities are satisfactory.

The documentation reviewed and discussion held with cognizant personnel by the audit team revealed that the MCC project activities have been audited internally on an annual basis. The TUFF repository work activities have not been audited since the consolidation of work activities which took place on June 29, 1987. The PNL Quality Assurance Department audit schedule for fiscal year 1988 (reference: QAS-016-NCF, dated 1/11/88) indicated that an audit of TUFF repository work activities is scheduled to be performed in April 1988. The QAD Manager informed the audit team that the TUFF repository work activities are being surveilled by the cognizant quality engineer and the resulting data is being furnished to the QAS&A Manager for audit consideration (reference: QEM-031-DER, dated 10/1/87 & 1/11/88, respectively).

To verify compliance with the requirements prescribed in Procedure QAP-1801, the audit team selected and reviewed PNL internal audits A-86-08-27-60 and A-87-10. These were the annual internal audits performed by the QAS&A auditors in 1986 and 1987, respectively, on the MCC project activities. The review noted that technical specialists and/or management representatives, who were independent of the activities audited, have been utilized as auditors during the audit performance. The audit documentation included corresponding technical and QA activity checklists, activities assessed with results, deficiencies noted for follow-up action, audit plans and auditor qualifications (where required). The auditor training and qualification files, applicable to the audits reviewed, included information relative to training completed, personal resume, previous certification (if any) and lead auditor qualifications and certification documentation (where required). The audit team noted that the audit preparation and documentation included follow-up actions and evaluations performed of the previously identified deficiencies in the audited area.

The over all review of the PNL internal audit activities pertaining to the frequency, schedule, preparation, performance, reporting, response and follow-up, records and audit data analysis for the MCC project appeared to have satisfied the QA program audit process control systems. However, the audit team is concerned that the PNL's QA audits did not include verification of activities performed by the Quality Engineering and the Quality Control departments. This exception was neither justified and documented, nor sponsor approved. This item was discussed with the QAD management during the course of the audit and has resulted in documenting as an audit concern (reference: QA Concern 8801-05).

6.0 AUDIT CRITIQUE

This joint DOE audit on PNL has been an attempt to integrate audit efforts of the DOE Departments. The concept is considered desirable and has been feasible because PNL performs work for a number of DOE Departments (sponsors) in accordance with one basic PNL QA Manual. Comments received indicate that joint audit effort should be allowed to continue.

Before the DOE-RL Audit, the audit team visited most of the laboratory buildings to be covered during the audit to become familiar with the building locations and access requirements. During the audit PNL staff form both QA and Program provided escort support to the audit team. Yet a number of logistical problems were identified and were solved during this audit. Therefore, future joint audits on PNL will have to reckon with the fact that the PNL Departments are spread out and building access/escort requirements are time consuming and need to be provided for.

The role of technical advisors has been the subject of a lot of discussion. There is agreement on their contributions in determining technical adequacy of the audited activities; the concern seems to be in the perception that on various occasions the technical advisors investigation tends to change the audit into technical peer review. A related concern is that a small group of technical advisors "may not be qualified to pass valid judgments on all aspects of a piece of work. Judgement in these cases should be left to a formal peer review rather than a technical audit."

It is recognized that neither a technical advisor nor a QA audit should replace a peer review requirement. The background information on these issues relative to Audit 8801 is provided below to allow informed decisions to be made for future audits.

Audit team leader briefed the technical advisors to focus on whether the technical procedures/processes used at PNL reflect accepted scientific methods in addition to the traditional assessment of technical adequacy of the program implementation. The reasons for such a briefing were that NRC emphasized in their June 1987 audit of Los Alamos National Laboratories similar assessments. NRC expects DOE to perform similar assessments as they have expressed in various presentations and documents. In addition, the MCC technical procedures were not reviewed by the sponsor as there was no such requirement in the QA Plan WTC-002, Rev. 1.

During the audit the technical advisors' discussion focussed on the design basis for MCC test procedures. MCC staff concurred with the technical advisors on the need for a design report to address their design basis for MCC test procedures and are preparing such a design report. Concern 8801-01 addresses this issue.

The debate on what the technical advisors should and should not address in a given audit may continue as it is bounded by intelligent choices rather than specific right or wrong solutions. As far as technical advisor comments during the audit are concerned, the focus perhaps should be on what is said rather than who said it. Based on such concepts, the audit 8801 supported

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
ATTACHEMNT 1
AUDIT CRITERIA AND TEAM RESPONSIBILITIES

ATTACHMENT 1
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, 4, 5, 8, 9, 10, 11, 12, 13, 14, & 15	X	X	
4, 7, 16, 17, & 18			X

SUB-TEAM RESPONSIBILITIES	MATERIAL CHARACTERIZATION CENTER ACTIVITIES	TUFF PROGRAM ACTIVITIES	PNL GENERIC PROGRAM ACTIVITIES (TRAINING, PROCUREMENT, ETC.)
AUDIT PERSONNEL			
SUB-AUDIT TEAM LEAD	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)
LLNL: LAWRENCE LIVERMORE NATIONAL LABORATORY
BNL: BROOKHAVEN NATIONAL LABORATORY

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

\# Section 5.0 of the audit report addresses details of the QA criterion covered during this audit.

DOE-RL/DOE-HQ JOINT QA AUDIT 8801

ATTACHEMNT 2

AUDIT ATTENDANCE ROASTER

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
PRE AUDIT BRIEFING

February 22, 1988, Room G53

Name	Organization	Phone Number
K. M. Vadlamani	DOE-RL/QSD	376-1381
C. K. Kasch	DOE-RL/QSD	376-5183
G. W. Rosenwald	DOE-RL/TDD	376-5349
Joel C. Haugen	DOE-CH/MID	972-2093
Nancy Ann Voltura	NRC/Division of HLW	492-0437
P. E. LaMont	DOE-RL/HWVP	376-6117
John Mathur	DOE-HQ/DWTM	FTS 233-3772
David Langstaff	DOE-RL/STD	FTS 444-1069
Dave Brown	DOE-HQ/Weston	202-646-6760
William H. Camp	DOE/RL QSD (MACTEC)	376-4674
Harold B. Litz	DOE/RL QSD	376-3805
Steve Gomberg	DOE-HQ	FTS 896-5560

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
AUDIT ENTRANCE MEETING

February 23, 1988

Attendance List

Name	Phone Number	Affiliation
C. K. Kasch	376-5183	DOE-RL/QSD
H. B. Litz	376-3803	DOE/RL/QSD
W. H. Camp	376-4672	DOE-RL/QSD (MACTEC)
S. Goldsmith	376-2970	Battelle Qual. Ach.
H. D. Smith	376-3588	Battelle
B. O. Barnes	376-4842	PNL QAD
K. S. Webster	376-9993	PNL QAD
G. B. Mellinger	375-2152	MCC
J. C. Haugen	972-2093	DOE-CH/M10
Steve Gomberg	FTS 896-5560	DOE-HQ
Dave Brown	(202) 646-6760	Weston QA
Paul Turner	376-3903	MCC
Chuck Wilson	376-5354	PNL
W. D. Richmond	375-2203	PNL
R. C. Pratt	376-0570	PNL QAD
J. S. Mendel	376-0748	MCC
B. L. Neth	376-0512	PNL/MCC
G. M. Holloway	376-3354	PNL/MCC
C. K. Thornhill	376-4653	PNL/MCC
W. E. Brooks	375-3685	PNL/PAD
Deborah L. Alamia	375-2816	PNL/PAD
Deborah K. Hanson	375-6855	PNL/PAD

Name	Phone Number	Affiliation
Cecil E. Hughey	376-1326	PNL/QAD
Charles L. Simpson	375-2892	PNL/PAD
Sue L. Sutter	376-8172	MCC
R. S. Kemper	375-2528	PNL M&CS Center
J. L. Daniel	376-7069	MCC
M. N. Campbell	376-0546	DNLW-PO/WHC
S. C. Marschman	376-3569	PNL/WTC
G. E. Meadows	376-3366	PNL/Chemistry
Cecil H. Kinole	376-5904	PNL
Dennis E. Ryder	376-0075	PNL/QAD
David G. Coles	376-0882	PNL/CSA Section
Robert Einziger	376-3453	PNL/CSA Section
David Langstaff	376-1069	DOE-RL/STD
D. Van Rooyen	FTS 666-4050	BNL
Mike Karol	FTS 444-6152	DOE-RL/STD
K. M. Vadlamani	376-1381	DOE-RL/QSD
Gary Rosenwald	376-5349	DOE-RL/TDD
R. P. Saget	376-7250	DOE-QSD
N. A. Voltura	(8) 429-0437	NRC
C. Pescatore	(8) 666-2731	BNL
T. K. Subramanian	376-3175	DOE-RL/QSD
Max Kreiter	376-9587	PNL
Martin D. Merz	375-2775	PNL/MCC
P. E. LaMont	376-6117	DOE-RL/HWVP

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
AUDIT EXIT MEETING

February 26, 1988

Name	Phone Number	Affiliation
Larry Worden	376-0579	QAD
Dennis Ryder	376-0075	QAD
David G. Coves	376-0882	CSA Sect. Mgr.
Don E. Knowlton	376-3525	WTC Ops. Mgr.
R. S. Kenyon	375-2528	M&CSC Ops. Mgr.
W. E. Brooks	375-3685	P and A. D.
C. L. Simpson	375-2892	PAD
Steve Marschaman	376-3569	PNL/WTC
Harold B. Litz	376-3803	DOE-RL/QSD
K. M. Vadlamani	376-1381	DOE-RL/QSD
C. K. Kasch	376-5183	DOE-RL/QSD
R. P. Saget	376-7250	DOE-RL/QSD
K. S. Webster	376-9993	PNL/QAD
B. O. Barnes	376-4842	PNL/QAD
P. E. LaMont	376-6117	DOE-RL/HWVP
N. A. Voltura	492-0437	NRC
R. C. Pratt	376-0570	PNL/QAD
C. K. Thonhill	376-4653	PNL/MCC
J. E. Mendel	376-0748	MCC
D. L. Alamia	375-2816	PNL/PAD
D. K. Hanson	375-6855	PNL/PAD
M. H. Campbell	376-0546	WHC/DHLW-LO
C. E. Higbey	376-1326	PNL/QAD

Name	Phone Number	Affiliation
D. C. Langstaff	376-1069	DOE-RL/STD
T. K. Subramanian	376-3175	DOE-RL/QSD
Dave Brown	(202) 646-6760	Weston QA
Claudio Pescatore	FTS 666-2731	BNL
Stan Goldsmith	(509) 375-2970	PNL
W. D. Richmond	(509) 375-2203	PNL
Gary Rosenwald	FTS 444-5349	DOE-RL/TDD
Sue Sutter	376-8172	PNL/MCC
Max Kreiter	376-9587	PNL/MCC
John J. Dronkers	8-532-1414	LLNL
Henery F. Shaw	FTS 543-4645	LLNL
William H. Camp	376-4674	DOE-RL/QSD/MACTEC

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
ATTACHMENT 3

TECHNICAL ADVISORS REPORT(S)

1. P. E. LAMONT (2 pages)
2. C. PESCATORE (2 pages)
3. S. GOMBERG (4 pages)
   D. VAN ROOYAN "
4. HENERY SHAW (8 pages)

INFORMAL NOTE

To: T. K. Subramanian, QSD March 7, 1988

From: P. E. LaMont, PMD

Subject: Report to Audit Team Leader - QA Audit 8801

My activities as a technical advisor to the "A Team" on the subject DOE audit of selected activities at PNL supporting OCRWM are summarized below. The A Team reviewed the Materials Characterization Center (MCC) activities. As a technical advisor, I was concerned with the following general criteria:

- o Technical basis of the procedures,
- o Clarity of the procedures,
- o Proper implementation of the procedures.

Preparation

Prior to initiation of the audit on February 23, 1988, I reviewed 1) the MCC QA Plan, 2) Administrative Procedure PAP-901, Control of Processes, and 3) technical procedures for spent fuel and borosilicate glass. A list of comments and questions on spent fuel and borosilicate glass related to the first two criteria listed above were developed as a basis for discussion during the audit (Attachment 1). (Questions concerning spent fuel test procedures for the Tuff-related work were provided to the Tuff Project technical representative, Henry Shaw, for information.)

February 23, 1988

Following an initial kick-off meeting, most of the morning was spent on a tour of the MCC facilities for spent fuel disassembly, gamma scanning, fission gas sampling, fuel rod segmenting, and rod and segment storage in the 324 Bldg. In the afternoon, Dr. C. Pescatore from Brookhaven National Laboratory, the audit team technical representive for HQ-OGR, and I returned to the 324 Bldg. in order to discuss details of the spent fuel operations with C. Thornhill, the PNL-MCC Task Leader for spent fuel. These discussions led to the identification of several concerns and observations submitted jointly by Dr. Pescatore and myself (Attachment 2). Questions related to the design qualification of the Fuel Rod Scanning System and the Fission Gas Sampling System arose during these discussions, but were deferred until the next day so that PNL could arrange to have additional cognizant staff available.

February 24, 1988

In the morning Dr. Pescatore and I resumed our discussions with C. Thornhill, J. Barner, and R. Goles on the Fission Gas Sampling System and Fuel Rod Scanning System. These discussion allayed a number of potential concerns, primarily in the area of calibration methodology used on the Fuel Rod Scanning System. However, the lack of technical manuals or a design report, and the

lack of a procedure for on-line calibration of the principal pressure sensing instrument on the Fission Gas Sampling System are concerns as described in our joint submittal.

February 25, 1988

In the morning I discussed my prepared questions and comments on glass testing procedures with M. Kreiter, G. Mellinger, and L. Daniels of PNL in the 326 Bldg. conference room. These questions and comments were considered to be generally editorial in nature, except as related to the existence of several different documented versions of the MCC-1 and MCC-3 Leach Test Methods. These test methods are included in the Nuclear Waste Materials Handbook, which is a widely distributed controlled document. The fact that the Handbook is not being updated with the latest versions of test methods was considered to be a technical concern.

In the afternoon Dr. Pescatore and I completed our joint submittal. All concerns and observations described on our joint submittal were related to the technical bases and clarity of the spent fuel procedures. I also documented the above-mentioned concern related to the lack of the latest versions of test methods in the Handbook (Attachment 3). All of these concerns and observations were included in the March 3, 1988 letter, 88-QSD-052, from R. P. Saget to PNL. It should be understood that the questions and comments prepared prior to the audit were for discussion purposes only; therefore, there is no unique correspondence between the concerns and observations on one hand and the questions and comments on the other.

(A)

Attachments:

1. Initial Comments and Questions by P. LaMont
2. Concerns and Observations on Spent Fuel Procedures Submitted Jointly by C. Pescatore and P. LaMont
3. Concern on Handbook Procedure Submitted by P. LaMont

(B)

AUDREP.RI

NOTE BY AUDIT TEAM LEADER:

(A) PL. REFER TO ATTACHMENT #6 TO THIS AUDIT REPORT 8801.

(B) DOCUMENTATION RETAINED WITH DOE RL AUDIT 8801 FILE.

R. Subramanian 4.1.88.

Technical Advisor's Summary Report

Technical Advisor: C. Pescatore
Brookhaven National Laboratory

Criterion: 9 "Control of Special Processes"
11 "Test Control"
12 "Control of Measuring and Test Equipment"

As a Technical Advisor to Sub-Team "A", I participated in QA Audit 8801 of the PNL's MCC on 2/23-26/88. A summary of my activities on each day is provided hereafter:

Tuesday, 2/23

The morning was spent partly in an orientation caucus and partly having an initial look at the MCC facilities pertaining to the activities involved in this audit. This included a visit to the hot cells where gamma scanning and fission gas sampling are performed.

In the afternoon, I concentrated on the hot cell activities: rods and sample transfer and identification; gamma scanning and fission gas sampling. I asked several questions to familiarize myself further with these activities and offered comments to the MCC Task Leader (C. Thornhill). Several observations were identified and are reported in the joint report with P. Lamont. Other questions and observations could not be readily answered by C. Thornhill and were deferred to the next day.

Wednesday, 2/24

In the morning, I participated in discussions with J. Barner, cognizant engineer for fission gas sampling, and R. Gould, cognizant engineer for gamma scanning. These discussions allayed my concerns regarding the gamma scanning. However, my concern regarding the calibration of the Baratron gage, used in fission gas sampling, was not addressed and this is noted in an audit concern.

In the afternoon, I participated in the review of the metallographic and ceramographic activities.

Thursday, 2/25

I continued discussions with J. Mendel and D. McCown. After discussions and a tour of the metallography and ceramography laboratories, it appears that the activities are adequately controlled.

I did, however, identify one potential concern and an observation:

(1) Special handling and storage procedures should be implemented to prevent loss of content when a spent fuel rod is cut into segments.

(2) There is a potential for "cross-contamination" of high-burnup and low-burnup fuel during handling. This does not appear to be a serious concern at present because the approved test materials are all of the same approximate burnup.

Friday, 2/26

I attended the Audit Exit Meeting. All of my concerns and observations were included in the Draft Concerns and Observations which was presented to M. Kreiter, MCC Program Manager, at the Exit Meeting.

A more detailed list of my concerns and observations is provided in a joint summary report with P. Lamont. In addition, I investigated all of the preliminary concerns transmitted to D. Brown on 2/19/88 and addressed them as appropriate.

CP:gfs
3/9/88

Claudia Pescatore

Summary Report of Technical Advisors

Technical Advisors: S. Gomberg, HQ-OGR
D. Van Rooyen, Brookhaven National Laboratory

Criteria: 8 "Identification and Control of Items"
9 "Control of Special Processes"
11 "Test Control"
12 "Control of Measuring & Test Equipment"

As technical advisors to Sub-Team "A", we participated in QA Audit 8801 of the PNL's MCC on 2/23-26/88. Our group concentrated on the technical activities performed in MCC's Analytical Laboratory (Buildings 325 and 327). The audit team consisted of H. Litz (DOE/RL) auditor and S. Gomberg (HQ-OGR) and D. Van Rooyen (BNL) as technical advisors.

General

The analytical laboratory performs radiochemical and solid state analysis and special sample preparation of spent fuel.. All procedures to be followed are specifically identified in either Statements of Work (SOW) or Requests for Work (RFW). In general, MCC prepares SOWs in order to provide a generic statement for a particular work need. ROWs are more detailed descriptions of the work need which provide specific guidance and procedures to be followed. The SOW or RFW usually refer to PNL Administrative Procedures or Technical Procedures, or Westinghouse Hanford Corporation Testing Procedures ("HEDL-MG-184"). In some instances, universally-recognized procedures such as ASTM standards or requestor-specific procedures are referenced.

The Analytical Laboratory was audited by reviewing the following Statements of Work (SOW):

B71986 - Ceramography and Metallography of Spent Fuel
B71987 - Transmission Electron Microscopy for Spent Fuel
B71989 - Fuel Material Radiochemical Analysis
B71991 - Analytical Procedure Preparation
M28045 - Ultrasonic Core Drilling of Spent Fuel
M29690 - Cs137 Burnup Calculation
M32978 - Preparation of Special Spent Fuel Samples
M32984 - Microprobe Analysis
M36853 - Estimation of Accuracy of Radiochemical Analysis

SOWs B71986, B71989 and M32978 were selected, based on the technical importance of the work being performed, to be more thoroughly investigated.

The general strategy for review involved:

1. Discussion with senior MCC staff (primarily J. Mendel) to understand the overall aspects of the spent fuel handling, sampling, and testing activities being conducted by the Analytical Laboratory.

2. Review of available records involving the specific activities selected for review. These records included program office requests, SOWs, RFWs, applicable procedures, and nonconformance and deficiency reports.

3. Tour of the facilities where the particular studies under review are conducted.

4. Interview with activity manager to address questions based on items 1 - 3 above.

5. Review of laboratory record book to trace quality of recent studies from original work request through final product, including any identified problems.

Specific

B71986 - Ceramography and Metallography of Spent Fuel

The team toured the facilities in Building 327 and had extensive discussion in this area. Technical procedures were clear and obviously enforced. Personnel qualifications, experience, and training were described and conformed to requirements. Documentation, records, references and traceability appeared consistent with required criteria.

Two cases of reversal of specimens or information were mentioned as the only ones that had occurred. DR 87-121 showed a switch of two metallographic samples, which was discovered before reporting because examination of the structures showed a mismatch. Corrective action was introduced and appeared to be sufficient to avoid similar occurrences - double checking and the exact way in which this would be done was included in the instructions.

DR 87-127 indicated that two (2) sets of photograph negatives had been reversed. While it is expected that the observations of experienced staff would (and did in this case) identify such an error before it advanced further in reports, it would be good to see a recommendation for a correction similar to the one for the sample switch mentioned above. At present, the recommendation seems too weak to be totally effective, in that it requires metallography be informed to double check, without being more specific about who would do so and how. This case is identified in draft Audit Observation 8801-01.

B71989 - Fuel Material Radiochemical Analysis

The analysis for total C14 by the laboratory combustion method was reviewed for detail. It appeared to satisfy the required criteria. Auditors performed the following:

1. Verify that RFWs provided adequate details regarding specific isotopes to be analyzed and specific test methods.

2. Review applicable procedures identified in SOWs and RFWs for clarify and thoroughness.

3. Review records concerning calibration of measuring and test equipment.

4. Review contractor reports to ensure that results are correctly reported and reviewed. Ensure that all items identified in the SOWs and RFWs are included.

5. Review additional records including nonconformance or deficiency reports.

The C14 on the external rod surface is determined in a procedure that provides only carbon-oxygen compounds such as CO_3. In view of the possible use of such data in establishing inventories, it would be advisable to compare the present results with total (external) C14 if suitable methods can be employed. MCC (D. L. Baldwin) indicated that work is underway on loose crud determinations, which may satisfy some of the observations regarding losses and analyses. This condition is noted in Draft Audit Observation 8801-01.

M32978 - Preparation of Special Spent Fuel Samples

Special spent fuel samples are developed in accordance with requesting laboratory specifications. These are used as the basis for developing the RFW and special written instructions. Special samples are cut from selected fuel rods in hot cells, and subsequently provided to other laboratories for their research. They may be used for various purposes, such as the determination of the C14 inventory and potential release as radioactive carbon dioxide when waste package containers are breached. (The conversion to CO_2 is believed to occur in the presence of radiation and oxygen, with increased temperature as an accelerating factor. The initial release involves the C14 that is present on the outside surface of the fuel pin). MCC carries out various tests on the fuel rods to establish what may be called a "pedigree" for each one. Following sample preparation, the rods are stored in accordance with approved technical procedures and archived.

The auditors reviewed the records available from J. Mendel on the preparation of special spent fuel samples requested by the NNWSI project. This set of samples were most recently completed, and therefore, provided a case to determine traceability of records from original request to finished product. It was discovered that parts B and C of the final RFW (RFW M25798-1, dated 7/15/87) were not signed, although the special samples were prepared and delivered to the client. When a concern was raised that samples may have been shipped without proper MCC review of the finished product, J. Mendel provided a memorandum (MCC letter MCC087:0003, dated 10/2/87) which confirmed that the special samples had been prepared and shipped in accordance with client specifications (minor deviations were noted in attachments to the letter).

To further ensure that the specimens were properly prepared, the team asked to interview the manager of the Post Irradiation Test Facility and to review the laboratory record book on this particular sample request. The interview and record examination focused on ensuring sample preparation was clearly identified, work was directed by the manager, specimens were traceable, records transferring samples were complete, a description of each specimen was prepared, and any discrepancies from the client's specifications were identified. All records appeared to satisfy the required criteria.

The following observations were noted by the audit team during review of RFW M32978:

Noted in Draft Audit Observation 8801-06

- It appears that the quality of the final product was not affected by the lack of sign-off on the RFW. The above-referenced letter certifies the quality of the sample. However, it is required that RFWs be signed to document the quality of the sample.

Noted in Draft Audit Observation 8801-01

- During the removal of a rod from the original assembly, there is bound to be scraping or rubbing of the external surface against other parts, and this could be made worse by some misalignment of equipment during pulling. At present there is no quantitative estimate available of the potential loss of crud during this procedure. There is also no indication that it is serious, but such knowledge would improve the confidence placed in sample quality. A procedure with such a goal in mind may be useful.

- During rod removal, there is provision in the operating plan to prevent misidentification. However, if a rod arrives misplaced, there does seem to be a change that the mistake could be perpetuated since no specific requirement to read and record the actual number exists.

- Loose crud on the external rod surface could be dislodged during handling and transporting, so that it would be reassuring to determine quantitatively that the potential for loss by this means is not significant. If it is significant, C14 inventory calculations would be nonconservative.

- Sample cutting is done rapidly, and could result in a short period of localized heating as well as vibration. Both of these could potentially result in some loss of C14: vibration could physically dislodge loose crud, while heating could accelerate oxidation of C14 to carbon dioxide. In this regard, it is noted that work done by NNWSI has not yet reported the quantitative temperature effect on oxidation in the presence of the radiation field, but they do report an early release of substantial C14 (as gas) under conditions of early container breach where hot conditions and radiation prevail. Knowledge of the potential effect on data due to C14 loss is not available, and procedures may benefit from the inclusion of a way to demonstrate that the errors are sufficiently small.

Conclusion

From the interviews of MCC personnel and from observation of activities, it appears that the MCC Analytical Laboratory is complying with their QA Program. Prior to the audit, the technical advisors reviewed the MCC technical procedures which apply to spent fuel characterization. Any questions developed from this review were satisfactorily addressed during the audit or are noted in the Draft Audit Observations.

Steven E Glomberg
March 21, 1988

D. van Rooyen
March 18, 1988.

Report of the Technical Advisor to Subteam B of the DOE-RL/DOE-HQ Joint QA Audit 8801 of PNL Activities in Support to the Tuff Repository.

Technical Advisor - Henry F. Shaw, NNWSI/LLNL

I. Introduction

On February 25 and 26, 1988, I participated in the joint DOE-RL/HQ audit of the Pacific Northwest Laboratories. My role in the audit was as a "technical advisor" to audit subteam B, which was charged with examining activities conducted by PNL for the Nuclear Waste Storage Investigations (NNWSI) Project. During the my entrance briefing with the audit team leader, I was charged with three responsibilities:

(1) to assess whether the technical procedures used in the QAL I NNWSI work at PNL reflected accepted scientific methods;

(2) to determine if those procedures were being followed;

(3) to make an assessment of the ability of the relevant PNL staff to perform the work and produce quality results.

These three tasks are the same as those performed by the technical audit team in a recent NRC audit of the NNWSI mineralogy/petrology program at Los Alamos National Laboratory.

Of the three tasks listed in the previous paragraph, only the second one can be completed in an entirely objective manner. The other two tasks necessarily involve some degree of subjective judgement on the part of the auditors. This caveat should always be kept in mind when the technical aspects of the results of a QA audit are being reviewed. Because of this, I feel it is appropriate to discuss briefly the considerations I used in making my evaluations.

The first task involves a degree of subjectivity, in that more than one technique is often available for making a measurement. In addition, work for the repository program often involves the development of new, state-of-the-art measurement techniques that may not be easily evaluated unless the technical auditor is a true expert in that specific field. In such cases, a single technical advisor or even a small group of advisors may not be qualified to pass valid judgments on all aspect of a piece of work. Judgement in these cases should be left to a formal peer review rather than a technical audit. In short, a technical advisor in a QA audit cannot and should not be viewed as a replacement for peer review. In making my own evaluation, I attempted to determine whether the techniques being used would produce data of sufficient accuracy and precision that they would be suitable for their intended use, and to determine if the laboratory practices, both as given in the written procedures and

II. Procedures

At the time of this audit, there were two QAL I activities being conducted at PNL for the NNWSI Project: "Oxidation tests of spent fuel and UO_2 using a thermogravimetric apparatus", and "Oven oxidation tests of spent fuel and UO_2". These activities correspond to activity numbers D-20-44 and D-20-45, respectively, in the "Scientific Investigation Plan for NNWSI WBS Element 1.2.2.3.1.1: NNWSI Spent Fuel Waste Form Testing" (SIP). There are three technical procedures directly relevant to these activities; additional PNL procedures, which cover various post-test sample characterizations, are referenced by these three. Prior to the audit, a series of questions were drafted on each of the procedures as a starting point for discussions with the PNL technical staff. However, it was learned during the audit that only two of the procedures have actually been used at PNL. The remaining procedure (SFO-1-1) had been used in a previous version when the work being audited was being performed at the Hanford Engineering Development Laboratory of the Westinghouse Hanford Co. (HEDL-WHC). That work was not considered a part of the present audit. The specific questions and resolutions to the questions are given in the following section of this report.

Because of the limited number of QAL I tests that had actually been conducted at PNL at the time of this audit, I took the opportunity to examine the some of the technical procedures that will be used in future fuel dissolution tests at PNL (SIP activity D-20-42). This examination took the form of following the route taken and the procedures followed in handling a solution sample from the point at which it is taken from a specimen in a hot cell (SFL-3-7 Solution sampling), through the splitting operation, to two analytical techniques (HTA-4-5, Alpha spectrometry, and HTA-4-16, U by laser-excited fluorescence), chosen at random from the many analyses that will be performed on these samples. The laboratory records of an ongoing QAL III scoping experiment on spent fuel was used as examples of what will be done in the case of the planned QAL I tests. The purpose of this exercise was to determine how the traceability of samples is to be maintained, to look at the completeness of the records and lab notes from the standpoint of an outsider trying to recalculate a datum, and to evaluate the competence of the cognizant staff as outlined in the introduction to this report.

as recorded in laboratory notebooks, reflected good scientific practice.

The third task ultimately requires a rather personal judgment. In making my evaluation of the ability of the PNL staff to perform work in a quality manner, I tried to determine how well the person performing a measurement or procedure understood the measurement technique, how aware the person was of possible sources of error, and how attentive the person was during the conduct of an anaylsis (as evidenced by the level of detail recorded in laboratory notebooks). Following written procedures does not necessarily guarantee quality results; if they are followed in a rote manner by people lacking an understanding of the measurement being performed, they can actually act in a manner adverse to quality. A slavish adherence to the written procedure, without a constant alertness for unusual events or observations that might lead to a deeper understanding of the processes taking place in a test, is clearly undesirable in a research environment. As a concrete and perhaps absurd example, I believe that if samples being analyzed by a particular procedure normally turn green upon the addition of a particular reagent, but one unusual sample turns purple instead, this should be noted, and the procedure halted for further investigation of the sample, regardless of what the written procedure may say. It is vitally important to avoid the assembly line mentality that can often develop when standard procedures are being followed.

My own goals in this audit, from the standpoint of the technical representative of the NNWSI Project, were to:

(1) determine if there was sufficient documentation in the form of written plans, procedures, and instructions that a group of peers in a similarly equipped laboratory could reproduce the tests;

(2) determine if there was sufficient documentation in the form of written plans, procedures, instructions, and laboratory notebook that a group of peer could take over the experiments in progress with no significant interruption of progress;

(3) determine if a peer could, by looking at the objective record of a test or measurement (laboratory notebooks, procedures, etc.), reconstruct the calculations that went into the production of a piece of data;

(4) assure myself that the tests are being conducted in a manner consistent with the standards of laboratory practice that I would impose if I were supervising the tests personally.

I believe these goals are broadly consistent with the overall aims of the audit.

III. Results and Conclusions

Question	Resolution
Procedure SFO-1-1. Sample preparation for use in oxidation testing using a dry bath heating system. Note: this procedure had not been used at PNL at the time of the audit.	
1. Were the specified data entries made in the laboratory notebook?	NA Procedure not yet used at PNL.
2. What range of $^{137}Cs/^{154}Eu$ activity ratios is deemed acceptable, i.e., indicative of no physical or chemical fractionation of the fuel.	NA Discussions with the PNL staff in charge of the test revealed that no such range had been established. It was suggested to the staff that a criterion should be established and documented.
2. How was the range considered in the previous question established?	NA See above.
4. Are the techniques specified for measuring the ratio considered in question #2 adequate to measure the ratio to the precision necessary to place a meaningful limit on the amount of fractionation induced by sieving the fuel?	NA Discussions with the PNL staff in charge of the test revealed that no analysis of the adequacy of the proposed method had been performed. It was suggested that such an analysis be performed and the adequacy of the techniques reviewed.

Procedure SFO-1-2. Dry bath operation procedure.

5. Is there evidence that each step specified in the procedure has been followed (i.e. a checklist in the lab notebook).	There was no checklist <u>per se</u> in the notebook, however there was a detailed record of the day-to-day operations of the apparatus, including a step-by-step documentation of the start-up and shut-down procedures. There was clearly sufficient documentation in the notebook to show that the procedure had been followed. If unusual events occurred or problems had been encountered, these, too, were documented in detail.
6. Could a scientist familiar with standard laboratory practice unambiguously identify the weight measured for each sample at each interim weighing from an examination of the laboratory notebook?	Yes, easily. The sample weights, zeros, and results of weighings of a standard weight were easily identified. An outsider would be able to reconstruct the weight gain history of any given sample from these notebooks.
7. How are the thermocouples (or the temperature measurement system as a whole) calibrated?	The thermocouples were initially calibrated prior to installation of the apparatus in the hot cell at the Westinghouse Hanford Co. calibration lab, which maintains NBS-traceable standards. In addition, the system as a whole was calibrated prior to its installation.
8. Where is the evidence that the thermocouples and temperature measurement system were initially calibrated?	The initial calibration was conducted at HEDL-WHC. Documentation of the initial calibration is in WHC notebooks, which were not subject to the present audit.

9. Are the thermocouples and measurement system re-calibrated at regular intervals? Where is the evidence for this?	The thermocouples cannot be removed from the system not that it has been installed in the hot cell. They have not been recalibrated since that time because they cannot be removed from the apparatus without destroying them. There does not appear to be a simple way around this problem because of the difficulties of working in a hot cell. The measurement system, exclusive of the thermocouples, is calibrated on an annual basis. The results of these calibrations are documented in laboratory notebooks.

Procedure SFO-2-1. Measurement of fuel oxidation using a TGA system.

10. Have the specified notebook entries been made in the lab notebook?	Yes. The notebooks contained a detailed record of the day-to-day operations of the TGA, including a step-by-step documentation of the start-up and shut-down procedures. There was clearly sufficient documentation in the notebook to show that the procedure had been followed. If unusual events occurred or problems had been encountered, these, too, were documented in detail.
11. How is the microbalance calibrated?	The balances (see question #12) are calibrated through the central calibration lab, using NBS traceable weights.
12. Is calibration performed before and after each TGA run?	No. Calibrations are done on an annual basis. The procedure, however, calls for the sample to be weighed on a second balance both before and after the oxidation run. This provides an independent check of the weight gain recorded by the microbalance associated with the TGA itself.

13. Where is the evidence that the microbalance has been calibrated?	Certificates of calibration issued by the central calibration lab are pasted into the WHC or PNL laboratory notebooks.
14. How is traceability maintained during the gas and solid sample analyses performed on post-test TGA samples?	No solid characterizations had been performed at PNL at the time of the audit. Gas samples are sent to an analytical lab with a work order detailing the analyses to be performed on the sample. The sample is assigned a unique number, which is then referenced in the analytical report returned by the gas lab. This procedure appears to be adequate to maintain traceability of the samples.
15. How is ^{85}Kr determined in the gas samples? Is this technique adequate?	Cover gas samples are analyzed in accordance with PNL technical procedure HTA-4-34, using mass spectrometric techniques. Considering the use to which these data are put, the technique provides more than adequate sensitivity and precision.

In general, I came away from this audit well satisfied that the work is being conducted in a quality manner, by personnel who are both technically competent and eager to find ways to enhance the credibility of the data they produce. The quality of any piece of work ultimately depends on the integrity of the people doing the work. In the case of the PNL staff with whom I spoke, I developed the (admittedly subjective) feeling that they truly cared about the work they were performing.

I was impressed by the level of detail recorded in the laboratory notebooks used in the fuel oxidation work and feel confident that these, together with the written test plans and technical procedures, would provide a peer with sufficient information to either continue an ongoing test, or retrieve the fundamental data and calculations that led to the production of a datum. That is, I believe the controls that are in place are sufficient to establish the traceability of samples and results related to the work currently being performed at PNL for the NNWSI Project.

The exercise in following the trail that solution samples from future fuel dissolution tests will follow was quite instructive and led to the identification of one instance in which I was not confident that an external peer would be able to recalculate a datum from the objective record. The raw data and calculations resulting from each analysis performed on a particular solution sample are recorded on "sample follower cards". These cards, together with any original output from analytical instruments form the record of the analysis. In general, this appears to be an excellent method of maintaining traceability and control of the samples.

In the case of the uranium concentration measurement (procedure HTA-4-16), however, I was unable to reconstruct the calculation performed by the cognizant scientist from looking at the relevant follower card and technical procedure, without additional explanation from the scientist. This led to my making a recommendation for a change in the format of the card that would allow the unambiguous identification of the data and calculations recorded on the card. Note that this procedure has not yet been used at PNL for a QAL I test. The cognizant scientist agreed to make the requisite changes in the card prior to its use in such tests in the future.

Submitted by,

Henry F. Shaw
March 31, 1988

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
ATTACHMENT 4

AUDIT DEFINITIONS:

FINDINGS

CONCERNS

OBSERVATIONS

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 ACTON 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

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
ATTACHMENT 5

LIST OF MANUALS/PROCEDURES USED FOR THIS AUDIT

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
ATTACHMENT 5

LIST OF MANUALS/PROCEDURES USED FOR THIS AUDIT

1. PNL-MA-60, Revision 3, Quality Assurance Manual for License-related Program.
2. WTC-002, Revision 1, Dated 11/18/87, Quality Assurance Plan for the Materials Characterization Center.
3. WTC-018, Revision 1, Dated 7/27/87, Interim QA Plan for LLNL TUFF Repository Waste Package Development Program.
4. SFO-1-1 R/1 Sample Preparation for Spent Fuel using a Dry Bath Heating System.
5. SFO-1-2 R/1 Measurement of Spent Fuel Oxidation using a Dry Bath Heating System.
6. SFO-2-1 R/3 Measurement of Spent Fuel Oxidation using a Thermoqvauwotsic Analysis System.
7. HTA-3-2 R/4 Solids Analysis Transmission/Scanning Transmission Electron Microscopy.
8. QAP101 R/1 Stop work Request.
9. PAP201 R/2-4 Indoctrination and Training.
10. PAP203 R/1-1 Qualification and Certification of Inspection/Test Personnel and NDE Personnel.
11. PAP301 R/1 Hand Calculation Documentation and Review.
12. PAP604 R/1 Independent Technical Review.
13. PAP401 R/2 Preparation Review and Approval of Purchase Requisition.
14. PAP402 R/1 Preparation and Control of Store Orders.
15. PAP404 R/3 Obtaining Services Via Work Orders.
16. PAP 501 R/3 CN #1 Preparation, Review and Approval of Procedures.
17. PAP601 R/3 Document Control.
18. PAP602 R/2 Document Change Control.
19. PAP704 R/2 Source Inspections, Test and Surveillance.
20. PAP705 R/1 Control of Supplier and Hanford Contractor NCR.
21. PAP706 R/1 Reviewing Inspection ICN# 706-R-1-1.
22. QAP701 R/1 Preaward Evaluation/Surveys.

23. QAP703 R/1 Material Overcheck.

24. QAP704 R/2 Suppliers and other Hanford Contractor Audits.

25. QAP705 R/1 Review of Supplier/contractor Submitted Documents.

26. PAP801 R/3 Test Control and Sample Identification and Control.

27. PAP802 R/0 Test Material and Sample Archiving.

28. PAP901 R/1 Control of Processes.

29. PAP902 R/1 Special Processes.

30. PAP1101 R/2 Test Planning Performance and Evaluation.

31. PAP1201 R/3 Calibration Control System.

32. PAP1401 R/1 Inspection Test and Operating Status.

33. PAP1501 R/1 Nonconformance Reports.

34. PAP1502 R/1 Controlling Deviation from QA Requirements and Establishing Procedures.

35. PAP1701 R/2 Research Records Systems.

36. PAP1704 R/1 ICN#1 Laboratory Record Books.

37. RCP 1701 R/2 Storage and Management of Completed Research Records.

38. QAP1701 R/1 QAD Records.

39. QAP1801 R/3 Internal Audits

40. SCP312 R/1 Determination of Software Requirements.

41. SEP313 R/1 Final Internal Development Review of Software and Documentation.

42. SCP314 R/1 Software Configuration Management.

43. SCP315 R/1 Conversion Testing, Verification and/or Validation of Software.

44. SCP316 R/1 Software Application Control.

45. SCP317 R/1 Transfer of Software date and/or Documentation.

46. TCP201 Laboratory Training Evaluation and Assessment Program

47. TCP202 Collection and maintenance of Training Records.

NOTE: Refer to Attachment 3, Technical Advisors Reports for additional procedures used.

DOE-RL/DOE-HQ JOINT QA AUDIT 8801
ATTACHMENT 6

AUDIT RESULTS

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

QUALITY AUDIT CONCERN

DEPARTMENT OF ENERGY – RICHLAND OPERATIONS

2. QAC CONTROL NO. 8801-01

1. TO: Name: M. KREITER — Title: MCC PROJECT MANAGER

3. Location: 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) T K Subramanian

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

1—

2—

3—

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: C. E. HUGHEY, Title: 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)	9. Issue Date	10. Response Due Date
R. 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

1—

2—

3—

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 Brownman

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
1—
2—
3—

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	Title	3. Location
MAX KREITER	MCC PROJECT MANAGER	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 Subramanyam	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

1—

2—

3—

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: C. E. HUGHEY, Title: QAD MANAGER

3. Location: PNL- Richland, WA

4. Reference/Requirements: CRITERION 18, NQA-1 (1986), Basic Requirement 18, "Audits"

PNL-MA-60, Section 18.1 (11/10/86)

5. Audit No. 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): R. Subramanian

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.
8801-06

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. Bernard

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
1—
2—
3—

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 L Bernaman	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 _____

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.

AUDIT NO. 8801

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.

AUDIT NO. 8801

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.