

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

AUDIT REPORT  
OF  
PNL SYSTEMS INTEGRATION PROGRAM  
ACTIVATED METALS ANALYSIS TASK

RICHLAND, WA

AUDIT HQ-93-04

APRIL 13-15, 1993

Prepared by: Marlin L. Horseman  
Marlin L. Horseman  
Audit Team Leader  
Headquarters Quality Assurance Division

Date: May 5, 1993

Approved by: Donald G. Horton  
Donald G. Horton  
Director  
Office of Quality Assurance

Date: 5/27/93

## **1.0 EXECUTIVE SUMMARY**

As a result of Quality Assurance Audit HQ-93-04, the audit team determined that PNL is satisfactorily implementing an effective QA program in accordance with the PNL QA Plan for the Activated Metals Analysis Program and the associated implementing procedures for QA program Elements: 1.0, Organization; 2.0, Quality Assurance Program; 4.0, Procurement Document Control; 7.0, Control of Purchased Items and Services; 8.0, Identification and Control of Samples; 11.0, Test Control; 12.0, Control of Measuring and Test Equipment; 15.0, Nonconforming Materials, Parts, or Components, 16.0, Corrective Action; 18.0, Audits; and 19.0, Software Control.

In addition, the audit team concluded that Elements 5.0, Plans, Procedures, and Drawings; and 17.0, QA Records, were being ineffectively implemented. Element 6.0, Document Control was determined to be indeterminate. In summary, of the fourteen Elements audited, eleven were determined to be effective, two were determined to be ineffective, and one was identified as indeterminate.

The audit team identified eight deficiencies during the course of the audit. Six of these deficiencies requiring only remedial action, were corrected during the course of the audit. Two Corrective Action Requests (CARs) were written to document those deficiencies that could not be corrected during the audit or that required more than remedial action to correct. CAR HQ-93-022 concerned the lack of procedural controls and CAR HQ-93-023 concerned the timely transmittal of completed QA Records to the Records Holding Area. Additionally, five recommendations were offered for PNL management consideration.

The audit team found the PNL Program, Project, Administrative, and Laboratory staff very helpful and cooperative in making the audit a success. Team members wish to express their appreciation.

## **2.0 SCOPE**

The audit evaluated PNL QA Program adequacy, compliance, and effectiveness as described in PNL QA Plan WTC-061, Revision 1 and as implemented on the Activated Metals Analysis Task.

### **QA PROGRAM ELEMENTS/REQUIREMENTS**

This was the first Headquarters audit of PNL and therefore follow-up on previous audits and deficiencies was not applicable.

The QA program elements/requirements evaluated during the audit are in accordance with the published audit plan and are as follows:

- 1.0 - Organization
- 2.0 - Quality Assurance Program
- 4.0 - Procurement Document Control
- 5.0 - Instructions, Procedures, Plans, and Drawings
- 6.0 - Document Control
- 8.0 - Identification and Control of Samples
- 11.0 - Test Control
- 12.0 - Control of Measuring and Test Equipment
- 15.0 - Nonconforming Materials, Parts, or Components
- 16.0 - Corrective Action
- 17.0 - Quality Assurance Records
- 18.0 - Audits
- 19.0 - Computer Software

In addition to those Elements covered in the audit plan, Element 7.0, *Control of Purchased Items and Services* was reviewed.

The following QA program elements/requirements were not specifically reviewed during the audit since PNL has no major activity for which these elements apply:

- 3.0 Design Control
- 9.0 Control of Special Processes
- 10.0 Inspection Control
- 13.0 Handling, Storage, and Shipping
- 14.0 Inspection, Test, and Operating Status
- 20.0 Scientific Investigation

Requirements were drawn from the DOE/RW-0214, *Quality Assurance Requirements Document* (QARD); PNL Quality Assurance Plan, WTC-061, Revision 1, and applicable PNL administrative, quality, and technical procedures.

### TECHNICAL AREAS

The audit team and the assigned Technical Specialist reviewed technical analysis and activities relative to sample preparation, testing, and data analysis (radiochemical and elemental).

### 3.0 AUDIT TEAM AND OBSERVERS

The following is a list of observers and audit team members (and their assigned areas of responsibility):

<u>Name</u>	<u>Organization</u>	<u>QA Program Element/Requirement</u>
Marlin Horseman, ATL	CER/HQAD	1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 16.0, 17.0, 18.0
Tom Swift, Auditor	CER/HQAD	5.0, 8.0, 11.0, 12.0, 15.0, 17.0, 19.0
Richard D. Dresser, Technical Specialist	Weston/HQAD	5.0, 8.0, 11.0, 12.0, 19.0
Carl Weber, Observer	DOE/HQAD	

### 4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at PNL offices in Richland, Washington on April 13, 1993. The audit team met daily to discuss audit activities. Daily debriefings were held with the PNL Program Manager, the Quality Engineering Manager, and their staff. The postaudit meeting was held at PNL offices in Richland on April 15, 1993.

Personnel contacted during the audit are listed in Attachment 1. The list also indicates personnel who attended the preaudit and postaudit meetings.

### 5.0 SUMMARY OF AUDIT RESULTS

#### 5.1 Program Effectiveness

The audit team concluded that, in general, implementation of the PNL QA Program was effective.

Eleven QA Program Elements were determined to be effectively implemented: 1.0, 2.0, 4.0, 7.0, 8.0, 11.0, 12.0, 15.0, 16.0, 18.0, and 19.0.

Two QA Program Elements were determined to be ineffectively implemented: 5.0 and 17.0. Element 5.0 was considered to be ineffective, due to procedural inadequacies and a lack of procedure implementation and procedure availability. Element 17.0 was considered to be ineffective due to a lack of timely transmittal of records to the Records Holding Area.

Eventhough implementation of certain document control provisions ~~were~~ <sup>was</sup> evaluated (See Element 5.0 details), Element 6.0 was considered to be indeterminate, due to the lack of PNL Document Control personnel availability.

**5.2 Stop Work or Immediate Corrective Actions or Additional Actions**

No Stop Work Orders nor any immediate corrective actions were necessary during the audit.

**5.3 QA Program Audit Activities**

Details of the QA program audit activities, are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

**5.4 Technical Activities**

Technical aspects of sample preparation, processing and data analyses were reviewed and found to be adequate for the task. In general, technical activities are being effectively performed.

**5.5 Summary of Deficiencies**

The audit team identified eight deficiencies during the audit. Six of these deficiencies were corrected prior to the postaudit meeting.

A synopsis of identified deficiencies documented as Corrective Action Requests (CARs) and those corrected during the audit are detailed below. Information copies of the CARs are included in Attachment 4.

**5.5.1 Corrective Action Requests (CARs)**

As a result of the audit, the following CARs were issued:

**CAR HQ-93-22**

PNL procedural deficiencies were identified, including procedural implementation, content, and availability.

**CAR HQ-93-23**

PNL QA Plan (WTC-061, Revision 1) included a QA record definition not in accordance with the QARD. Using this definition PNL was not submitting QA records to the Records Holding Area in a timely manner.

### **5.5.2 Deficiencies Corrected During the Audit**

Deficiencies which are considered isolated in nature and only require remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. One individual had not completed training requirements (although quality-affecting activities had not been performed). The individual completed all training during the course of the audit.
2. The verification of a M.S. degree, required by the Senior Scientist position description, had not been performed. Based upon the sample, this was an isolated case. The verification was made, found to be acceptable, and documented immediately.
3. Paragraph 3.2 of PNL-ALO-474 (Measurement of Alpha and Beta Activity by Liquid Scintillation Spectrometry) states, "Log sample positions on a sample log form."

Sample log forms were not available. It was noted by the Analytical Chemistry Laboratory (ACL) staff that a Shielded Lab Bench Sheet was being used instead of the sample log form. A memo to file was issued, documenting the deviation from the technical procedure.

4. Paragraph 5.3 of PAP-70-1201 (Calibration Control System) requires the use of Category 2 M&TE to "maintain calibration documentation that identifies standards used, accuracy of the standards, and traceability of the standards."

During the audit, the auditors noted that two intermediate stock standards records were incomplete. The record did not indicate the expiration date. The ACL staff noted that the expiration date is generally 6 months from preparation. The ACL staff provided a completed intermediate stock standard record which indicated the expiration date.

5. Section 19.6 of the QARD specifies that "where commercial auxiliary computer software is used, all available documentation from the supplier shall be obtained."

During the audit, the ACL staff obtained a copy of the Verification Manual from the supplier for the software used to reduce data obtained during radiochemical analyses.

6. Required changes to QA Plan WTC-061, Revision 1 had been identified but had not yet been incorporated and the changes had not been evaluated for impact on activities in progress. PNL completed the evaluation during the audit and determined there was no adverse impact on activities in progress.

## **6.0 RECOMMENDATIONS**

The following recommendations are offered by the audit team. They do not reflect deficiencies and are intended to provide PNL management with possible opportunities for improving QA program implementation.

1. Although not required, the audit team recommends that records of calibration and sample runlogs and maintenance activities be maintained by all groups in a Laboratory Records Book (LRB) or other equivalent documents.
2. Identified changes to Revision 1 of the RIDs have not been incorporated. While revision 1 is currently in effect, the audit team recommends that revision 2 be processed to reflect the latest information.
3. The audit team recommends the proposed changes identified in Section 5.2.2 (6), be processed in a timely manner and revision 2 of the WTC-061 be submitted to OCRWM for approval.
4. The audit team noted that the ACL routinely verified instrument performance, using Performance Evaluation (PE) samples. The verification, as outlined in NQA-1, can consist of hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature. The audit team recommends that the ACL develop a generic technical procedure to verify the instrument software, which can be performed simultaneously with the instrument performance verification using PE samples. This would enable ACL to receive credit for performing both verifications. In addition, the audit team recommends that the ACL review to ensure that verification documentation is obtained for all commercial auxiliary software, used for quality affecting data analysis.

5. The audit team reviewed the document control process and identified several apparent weaknesses. One issued procedure was identified as being effective on January 4, 1993. This procedure was finally approved on February 8, 1993 and was actually distributed to users on April 13, 1993. This three month lapse in issuance indicates that PNL should review this portion of their Program. Since the procedure had not been used to perform quality affecting work, this is not considered to be a deficiency.

## **7.0 LIST OF ATTACHMENTS**

Attachment 1: Personnel Contacted During the Audit

Attachment 2: Audit Details

Attachment 3: List of Objective Evidence Reviewed During the Audit

Attachment 4: Information Copies of CARs



Personnel Contacted During The Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
D. Baldwin	PNL/ACL	Senior Research Scientist		X	
Ingrid Burgeson	PNL/ACL	Senior Technical Specialist		X	
Richard Dresser	Weston/HQAD	Technical Specialist	X		X
Taffy L. Ehler	PNL	Quality Engineer	X	X	X
Sandra K. Fadeff	PNL	Project Manager (ACL)	X	X	X
Darrin Faulk	PNL/ACL	Senior Technician		X	
Mark Gibson	PQA	Lead Auditor		X	
Nancy Girvin	QA	Surveillance Group Leader		X	
Larry Greenwood	PNL/ACL	Technical Group Leader		X	
Kenneth Harrison	QA	Technical Group Leader		X	
Richard F. Hazelton	PNL/NS&M	Senior Development Engineer		X	
Marlin Horseman	CER/HQAD	ATL	X		X
Max Kreiter	PNL	SIP Manager	X	X	
Kristine Kuhl-Klinger	PNL	ACL QA/QC Project Manager	X	X	X
Patsy M. Lindsay	PNL/ACL	Administrative Secretary		X	
Gene Luczynski	Safeguards & Security	Personnel Group Supervisor		X	
J.E. McGarrah	PNL	QA Manager (OCRWM)	X	X	X
Barbara Minton	PNL	Quality Engineer	X	X	X
Rose Nipper	ACL	Administrative Assistant		X	
B.D. Reid	PNL	Project Manager	X	X	X
Ron Schrotke	PNL	Quality Engineer		X	
Rick T. Steele	PNL/ACL	Technical Group Leader	X		
Thomas R. Swift	CER/HQAD	Auditor	X		X
Vivienne Thompson	QA	Quality Engineer		X	
Shannon W. Thompson	PNL/ACL	Senior Technical Specialist		X	
Mike Urie	PNL/ACL	Inorganic Group Leader		X	
Matthew Vannini	QA	Surveillance Engineer		X	
Carl E. Weber	DOE/HQAD	Audit Observer	X		X
Larry M. Worden	QA	F&PQE Group Leader		X	
Nancy Wynhoff	PNL/ACL	Senior Technical Specialist		X	

Audit Details

The following is a summary of the QA program activities covered during the audit. A list of objective evidence reviewed, by document identification and title, is given in Attachment 3.

1.0 ORGANIZATION

The evaluation of this Element was based on personal interviews and a review of the PNL organization supporting the Activated Metals Analysis (AMA) Task.

The Audit Team reviewed the WTC-061, Rev. 1 chart for currency. Several of the individuals identified no longer work on the AMA Task. While the present organization is adequate, a recommendation was made to update the chart, possibly eliminating names during the required update of WTC-061. See Recommendation in Section 6.0 (3.) of this audit report. See also Deficiencies Corrected During the Audit Section 5.5.2 (6.) of this audit report.

Several monthly program status reports were reviewed, including reports from the task managers and from the assigned quality engineer. These reports were addressed to the Program Manager and identified quality issues. Also reviewed were the reports from the Program Manager, used as input to the Monthly PNL Report to OCRWM. The Program Manager reports reviewed included quality issues.

The Program Manager and other staff members appeared knowledgeable of the status of the AMA Task activities and had the necessary organizational responsibility and authority to adequately handle quality issues.

Conclusion

The Audit Team concluded that for the Activated Metals Analysis Task, Element 1 was effectively implemented.

2.0 QUALITY ASSURANCE PROGRAM

Seven Analytical Laboratory personnel position description (PDs) were reviewed to ensure compliance with WTC-061 requirements to specify specific educational and experience requirements for the position. All seven PDs contained the necessary requirements. Objective evidence of background verifications was reviewed for the seven individuals. Records were well organized and complete. Verification records included telecons, with the name of the individuals contacted, and transcripts from universities with affixed seals. All education and experience information was adequate with one exception. The PD for one Senior Research Scientist required a M.S. degree in Analytical Chemistry. This had not been verified. The Personnel Security organization verified this during the audit and presented acceptable results to the audit team. See Deficiencies Corrected During the Audit in Section 5.5.2 (2.) of this audit report.

Audit Details

The audit team reviewed matrices of required training and verified completion of reading and training assignments. Three individuals had not completed the specified training, but upon further investigation it was determined that one of the individuals was no longer assigned to the activity, another had not yet been assigned, and the third completed assignments during the audit. None of the individuals had performed any quality affecting activities. In addition the training records for specific individuals that had not received training (identified during the PNL surveillance 93-011-MHV) were reviewed and the required training had been completed. See Deficiencies Corrected During the Audit in Section 5.5.2 (1.).

**Conclusion**

The Audit Team concluded that for the Activated Metals Analysis Task, Element 2 was effectively implemented.

**4.0 PROCUREMENT DOCUMENT CONTROL**

Based on interviews with QA procurement and laboratory personnel, it was determined that two procurements had been made on the AMA Task. One procurement was for a <sup>99m</sup>Tc standard from Kadlec Hospital in Richland and the other was for load cell calibration services from Westinghouse, Hanford.

The procurement of the <sup>99m</sup>Tc standard was identified and properly processed as a non-quality affecting procurement. Purchase Request #193728A indicated that the standards were identified as impact level III and therefore did not require any QA involvement. For the Westinghouse calibration services, procurement documents had been prepared and all procurement controls were found to be adequate.

**Conclusion**

The audit team determined that for the Activated Metals Analysis Task, Element 4 was effectively implemented.

**5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS****Preparation and Use of PNL Instructions and Procedures**

The development and requirements of technical procedures and plans were discussed with PNL analytical and QA personnel. The audit team reviewed the Test Instruction Plan developed for the Activated Metals Analysis Task. In addition, a memo describing a planned deviation to the Test Instruction Plan was reviewed. During the audit, discussions with the Analytical Chemistry Laboratory (ACL) staff indicated that they were knowledgeable of the technical procedures and the requirements of those procedures.

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### Audit Details

During the audit, the auditors requested of those individual ACL staff members preparing samples and/or standards, and performing the analysis of the samples to demonstrate the availability of the technical procedures at the work station. With two exceptions, the technical procedures were readily available to the analyst. In addition, the auditors reviewed individual technical procedures referenced in the Test Instruction Plan for compliance to the QA Plan. All technical procedures, except one, were found to adequately comply with the requirements for content. Additionally, one technical procedure that was available and being used was found to be lacking the proper approval signatures. See CAR HQ-93-22 for further details.

The audit team reviewed the preparation and testing of Non-Fuel Bearing Components (NFBC) in the Activated Metals Analysis Task. The Analytical Request Form (ARF) specified the appropriate Test Instruction and Procedures required for the Activated Metals Analysis Task. Also, it was determined that PNL QA Procedure PAP-70-1101 described the proper methods for planning, preparing, performing and evaluating the tests. The functions audited within the ACL included the Shielded Analytical Laboratory (SAL), Inductively Coupled Plasma (ICP) Optical Emission Spectroscopy, and the Radiochemical Analysis.

The ACL group was audited to ensure that the correct instructions, procedures, and technical manuals, were available at the workstation and adequately identified testing requirements. In most ACL areas, effective implementation was observed.

The Gamma Energy Analysis (GEA) data initially were not available for the audit team to review since PNL stated they wanted to approve the data prior to presenting it to the team. Later, the data were made available for review.

There also existed some confusion over which procedure, referenced in the GEA test procedure, was applicable. Later in the audit, PNL issued a memo clarifying the appropriate procedure.

### Conclusion

Based on the condition noted in CAR-HQ-93-22, the audit team concluded, that for the Activated Metals Analysis Task, QA Program Element 5 was ineffectively implemented.

**Audit Details****6.0 DOCUMENT CONTROL**

Due to the unavailability of Document Control personnel to meet with the audit team, this Program Element could not be fully evaluated. However, portions of document control activities were reviewed (See Section 5.0 of Attachment 2). The audit team did note several apparent weaknesses in the document control process. See Recommendation in Section 6.0 (5).

**Conclusion**

Due to the audit team's inability to fully evaluate all document control activities, Element 6 implementation was designated as indeterminate.

**7.0 PURCHASED ITEMS AND SERVICES**

The audit team identified one PNL quality affecting procurement for the Activated Metals Analysis Task. This procurement was for Westinghouse load cell calibration services. A comprehensive audit of Westinghouse, Hanford had been performed and corrective actions documented.

**Conclusion**

The audit team determined that for the Activated Metals Analysis Task, Element 7 was effectively implemented.

**8.0 IDENTIFICATION AND CONTROL OF ITEMS**

The audit team reviewed data and interviewed personnel responsible for receiving the OCRWM supplied Non-Fuel Bearing Components (NFBC) and those responsible for the cutting, preparing and identifying the basic twenty-eight samples to be analyzed. Data was reviewed indicating the proper transfer of the client identification numbers to the PNL identification system (ALO #93-02454 through 93-02481 inclusive.) Duplicate samples were also prepared and identified by a "D" suffix.

The records were very well organized and the personnel enthusiastically explained the procedures they used for this project. There was a cutting problem and the use of a dremel tool had to be replaced by a circular saw. A duplicate sample problem is discussed in the section on Element 15 of this audit report.

Limited shelf life item controls were reviewed and with one exception for an ICP intermediate standard the controls were being properly implemented. See Deficiencies Corrected During the Audit in Section 5.5.2 (4.) of this audit report.

**Conclusion**

Audit Details11.0 TEST CONTROL

Controls for the analysis of samples were reviewed by the auditors. In addition, the audit team discussed the procedures used to analyze the samples and document the results of the analyses with the ACL analysts. The auditors also requested the ACL analysts to demonstrate the availability of the analytical procedures as well as the test instrument manuals. See Deficiencies Corrected During the Audit in Section 5.5.2 (3.) of this audit report.

The audit team found that proper documentation for the preparation of standards were adequately maintained. All standards were traceable to a nationally recognized source (NIST). With one exception, the standards were properly labeled with expiration dates. See Deficiencies Corrected during the audit in Section 5.5.2 (4.) of this audit report.

Conclusion

With the correction of a minor deficiency during the audit, the audit team concluded that for the Activated Metals Analysis Task, Element 11 was effectively implemented.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

During the audit, the audit team reviewed the calibration procedures for the measurement and test equipment. It was noted by the ACL staff that only analytical balances were identified as Category 1 equipment: equipment requiring calibration by the Process Quality Department. The calibration frequency and current status of the balances were examined and the records were found to be current. All other test equipment were identified as Category 2: calibrated by the using organization. See Recommendation in Section 6.0 (1.) of this audit report.

For Category 2 equipment, the audit team reviewed the technical procedures to evaluate the calibration requirements. With one exception as noted in Program Element 5, the technical procedures documented the calibration procedures required for the Category 2 equipment. The calibration records were reviewed by the audit team and were found to be adequate and properly maintained. See CAR HQ-93-22 for further details.

Conclusion

The audit team concluded that for the Activated Metals Analysis Task, Element 12 was effectively implemented.

**Audit Details****15.0 CONTROL OF NONCONFORMING ITEMS AND DEFICIENCY REPORTS**

The Deficiency Report (DR) procedure (PAP-70-1502) applies to PNL procedural or client requirements deficiencies or when the quality of the activity is indeterminate.

The audit team was informed at the start of the audit that no DRs for sample deficiencies had been initiated on the Activated Metals Analysis Task. During the audit, however, PNL was performing a review of test data and determined that one duplicate Rod Cluster Control Assembly sample was not valid. This was caused by a cutting operation problem in the hot cell and the presence of other items which resulted in an incorrect duplicate sample being prepared. DR 93-015 was properly prepared, evaluated, approved and corrective action completed. The data reports will note this sampling problem and reference the DR.

**Conclusion**

The audit team concluded that for the Activated Metals Analysis Task, Element 15 was effectively implemented for DR-93-015.

**16.0 CORRECTIVE ACTION**

Since no formal Corrective Action Requests had been processed on this Task, the audit team evaluated the corrective action process through the review of audit, surveillance, and trend reports and discussions with verification personnel. Two surveillances on the Activated Metals Analysis Task had been performed along with one internal and one external audit. One surveillance (92-110-MHV 12/9/92) identified two procedures that had not been approved and four personnel not receiving training to the ACL Quality Plan (MCS-0033). These open items and the associated corrective actions were being tracked. The audit team verified that one item remained open. Likewise deficiencies identified during surveillance 93-011 MHV dated 3/2/93 were being tracked to completion. Internal audit A93-01 deficiencies had been identified and verification of corrective actions were in process.

The audit team reviewed PNL trend report dated 10/14/92. The PNL QA trend report process is currently being "re-engineered" to include inputs from audits, surveillances, nonconformances, and corrective actions on a PNL-wide basis. The intent is to use the trend data as a tool to effect corrective action.

**Conclusion**

The audit team concluded that for the Activated Metals Analysis Task, Element 16 was effectively implemented.

Audit Details17.0 QUALITY ASSURANCE RECORDS

## Analytical Chemistry Laboratory Records

The audit team reviewed compliance to PNL record procedures, the PNL QA Plan WTC-061 revision 1, and implementing procedure PAP-70-1701, through record review and discussions with the ACL Project Manager, Records Custodian and QA staff.

A Records Inventory and Disposition Schedule (RIDS) for the ACL had been developed. However, Revision 2 draft (3-3-93) needs to be approved by Records Management (See Recommendation in Section 6.0 (2.) of this audit report). The collection of records was still in process and no transfer had yet been made to the DOE Records Holding Area or to the Client. An ACL document list was generated by the Project Manager December 4, 1992, and the ACL local files were reviewed and contained various procedures and some completed test data.

The interim storage files were one hour fire-rated and a sample of documents was reviewed for authentication, traceability, and legibility with no problems noted.

## Project Records

The audit team reviewed records accumulated by the Project Manager. The Project Manager receives Project Records from the various organizations. Upon completion of the Task, these records are transferred to the Program Manager and later to the DOE Records Holding Area. Records in the Project Manager area were placed in metal filing cabinets (without a fire-rating assessment). Currently this practice is permitted by the PNL QA Plan WTC-061 Revision 1. See CAR HQ-93-023 for a description of this deficiency.

The Project RIDs dated 6-5-92 was reviewed. It identified project records, classifications, and index numbers. All records were classified as permanent records.

## Conclusion

Based on the condition identified in CAR-HQ-93-23, the audit team concluded that for the Activated Metals Analysis Task Element 17 was ineffectively implemented.



Audit Details18.0 AUDITS

The audit team verified through interviews and objective evidence that audits and surveillances are being performed on the Activated Metals Analysis Task.

Surveillances 92-110-MHV dated 12-9-92 and 93-011-MHV dated 3/2/93 were reviewed. In addition, internal audit 93-01 and an external audit of Westinghouse were evaluated. All verifications were performed in accordance with detailed checklists. Verification reports had been issued, corrective actions had been requested, and open items were being tracked. The audit team leaders had been qualified in accordance with PNL procedures.

Conclusion

The audit team concluded that for the Activated Metals Analysis Task, Element 18 was effectively implemented.

19.0 SOFTWARE CONTROL

The audit team reviewed the use of software for spectroscopy instrumentation applications and a Monte Carlo Software Computer Code for Neutron and Photon Transport (MCNP) in accordance with PNL procedure MA-70. The instrumentation software was supplied by Canberra Nuclear while the MCNP software was obtained from Westinghouse, Hanford.

Instrumentation Software.

A Canberra Nuclear Software VAX Spectroscopy Application Package was purchased for performing spectroscopy tests. PNL also purchased the associated service agreement, software upgrades, and error reports. A Canberra Verification and Validation Manual is on file at PNL. Additional validation is conducted by PNL while performing their calibrations and daily source checks. See Deficiencies Corrected During the Audit in Section 5.5.2 (5) of this audit report. See also the Recommendation in Section 6.0 (4.) of this audit report.

Computer Software (PNL-MA-70)

An Application Report documented the Software Control Procedures used to define the MCNP software and referenced verification documentation prepared by Westinghouse and described the validation testing performed by PNL. No modifications of the Code were done by PNL and no software discrepancies were noted.

Conclusion

The audit team concluded that for the Activated Metals Analysis Task QA Program Element 19 was effectively implemented.

List of Objective Evidence Reviewed During the Audit

Quality Assurance Program/Plan Documents

PNL-MA-70, 3-13-92

Quality Assurance Manual

QA Plan No. WTC-061, Rev. 1

Systems Integration Program

ACL QA Plan, MCS-033, Rev. 0

Analytical Chemistry Laboratory

RIDs, D7E12/D7E15/D7E17, Rev. 2 Draft

Records Inventory and Disposition  
Schedule/File Index

PNL Memo, 12-4-92, Sandy Fadeff

Records for the NFBC Project

PNL Administrative/Quality Procedures (PAP) (QAP)

PAP-70-201, Rev.2, ICN R2-1

Indoctrination and Training

PAP-70-203, Rev. 2

Qualification and Certification of  
Inspection and Test Personnel

PAP-70-401, Rev. 1, ICN R1-4

Purchase Requisition

PAP-70-801, Rev. 1

Identification and Control of Test Materials

PAP-70-803, Rev. 1, ICN R1-1

Item Identification and Control

PAP-70-1101, Rev. 0, ICN R0-4

Test Planning, Performance and Evaluation

PAP-70-1201, Rev. 2, ICN R2-2

Calibration Control System

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#### List of Objective Evidence Reviewed During the Audit

PAP-70-1501, Rev. 1, ICN R1-3  
Deficiency Reports

QAP-70-1601, Rev. 1, ICN R1-3  
Quality Trend Analysis of Reported Data

PAP-70-1602, Rev. 1  
Corrective Action

PAP-70-1701, Rev. 3  
Records System

QAP-70-1801, Rev. 2  
Internal Audits

#### Position Descriptions

Hazardous Materials Operating Technician I, dated September 30, 1991  
Quality Assurance/Quality Control Project Manager, dated October 8, 1991  
Radio chemist, dated May 7, 1992  
SAL Research Scientist/Technical Group Leader, dated February 3, 1992  
Senior Research Scientist, dated May 6, 1992  
Senior Research Scientist, dated January 6, 1993  
Senior Technical Specialist, dated April 17, 1989  
Senior Technical Specialist, dated November 7, 1989  
Senior Technical Specialist I, dated January 24, 1991  
Senior Technician I, dated April 4, 1990  
Senior Technician I, dated June 20, 1991  
Senior Technician Specialist I, dated March 16, 1992  
Senior Technician II, dated June 18, 1990  
Senior Technician II, dated June 13, 1990  
Senior Technician II, dated April 16, 1991  
Staff Scientist, dated April 17, 1989  
Technical Specialist II, dated June 18, 1990

#### Verification of Education and Experience Files

Rick Steele  
MW Urie  
L. Greenwood  
D. Baldwin

F Vaughn Hoopes  
John Rau  
Shannon W. Thompson

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#### List of Objective Evidence Reviewed During the Audit

##### Test Instructions

TI-NFBC-1	Non-Fuel Bearing Components Project Test Instruction for Subsampling, Sample Preparation, Inorganic, and Radiochemical Analysis (1/4/93)
Memo to File	Planned Deviation to Test Instructions TI-NFBC-1 (4/6/93)

##### Technical Requirements Document

Project # 10994, 12-7-92, Analytical Request Form, T 968-1

##### Technical Documents

PNL-ALO-111	Leach/Dissolution of Neutron Activated Metal Specimens for Radiochemical Analysis (9/9/92)
PNL-ALO-211	Determination of Elements by Inductively Coupled Argon Plasma Emission Spectrometry (ICP/AES) (4/26/91) [ICN-PNL-ALO-211.1(8/19/91)]
PNL-ALO-412	Measurement of Carbon-14 in Metals (11/12/92)
PNL-ALO-449	Zero and Gain Checks and Control Charts - Track Detector (2/3/89)
PNL-ALO-450	Gamma Energy Analysis - Track Detector (GEA) (4/30/90)
PNL-ALO-457	Technetium-99 Analysis of Irradiated Metals (Draft)
PNL-ALO-464	Procedure for Gamma Counting and Data Reduction in the Low-Level Counting Room, 329 Building (9/26/90) [ICN-PNL-ALO-464.2 (5/7/92)]
PNL-ALO-472	Determination of <sup>93m</sup> Nb and <sup>94</sup> Nb (8/15/91)
PNL-ALO-474	Measurement of Alpha and Beta Activity by Liquid Scintillation Spectrometry (LSC) (7/9/92) [ICN-PNL-ALO-474.1(11/4/92)]
PNL-ALO-494	Counting Procedure for Low Energy Photon Spectroscopy (LEPS) (12/1/92)
PNL-ALO-495	Nickel Separation from Radioactive Solutions Using Chromatography (Draft)
PNL-ALO-499	Gamma Energy Analysis Control (Replaces 70-30.9)

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#### List of Objective Evidence Reviewed During the Audit

##### Sample Records

Sample receipt log - received 12/17/92; PNL # 93-02454-93-02481

Shielded Analytical Lab Bench Sheet - PNL sample no. corresponded with sample receipt log; data reviewed and corrected.

##### Training Records

Letters M. Kreliter to Task leaders (11/5/92 and 11/6/92) requiring that training be completed.

Training Matrix dated 1/27/93 for Laboratory Personnel.

##### Program Status Reports

Project Quality Engineer reports to SIP Program Manager dated:

11/03/93	2/10/93
12/01/93	3/15/93
01/18/93	

Trend Report dated 10/14/92

##### Purchase Order Files

Kadlec Hospital, <sup>99m</sup>Tc Standards Purchase Request # 193728A  
Westinghouse, Hanford, Calibration of Load Cells

##### Audit and Surveillance Files

Surveillance, 92-110-MHV, 12/9/92

Surveillance, 93-011-MHV, 3/2/93

Audit, OV-271-MAG, 12/4/92

Audit, A-93-01, 11/2-6/92, issued 12/14/92

##### Standards

ICP-325-405 Standards Log, Room 944A/JJW (entries from October 1, 1991 to present).

Standards obtained from NIST, Johnson Matthey, Inorganic Ventures

Leco Calibration Sample, Lot 186-51-2, Part No. 501-505

LSC Standards, Amersham International pic, Product CFY.64 Batch 64

LSC Standards Preparation Data, BNW52815 Lab Record Book

GEA Standards, Amersham International pic, Product QCY.48, Solution No. RO/145/155 M  
24598

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### List of Objective Evidence Reviewed During the Audit

GEA Performance Samples, EPA-EMSL, Las Vegas

#### Instrument Manuals

GEA, Canberra Nuclear Instrument Manual, 07-0196, Volume I, II  
Total Carbon, Model 5011 CO<sub>2</sub> Coulometer (Rev. 1985)  
LECO Furnace, Model 521/522/523 (Rev. 5/66)  
LSC, Packard Instrument Co., TriCarb Liquid Scintillation Analyzer, Model 2500TR (1992)  
ICP/AES, Bausch & Lomb ARL, AA 30612-02 (Feb. 1993)  
LEPS, Canberra Nuclear, Genie Systems, 07-0312/07-0196, Vol. I, II

#### Calibration Documentation

GEA, <sup>14</sup>Co Lab Logbook, BNW 52776  
Carbon-14, Laboratory Bench Sheets  
ICP-AES, Run Log  
LEPS, Detector Control Log BA-133#54124-83-1

#### Sample Analysis Results

Carbon-14    analysis data sheet [sample # 93-02454-1, #93-02454-2]- sample ID, sample size, observation/comments, instrument no. [WC 01713, W 702401], balance no. [360-06-01-016], run date, signed by analyst and reviewer  
ICP -        computer print-out of analysis data sheet - sample no., sample ID, results, date of analysis; data reviewed and checked by QA  
GEA -        computer print-out of analysis data sheet  
LEPS-        sample run log for sample 93-02459D (C-6); analyzed 4/14/93, 8:49:46, low background, Ni peak identified

#### Calibration of M& TE Records

Shielded Analytical Lab - analytical balance - Tag No. 360-01-016  
ICP Preparation Lab - analytical balance - Tag No. L812287; pipet serial no. LO5928  
Ni Preparation Lab - analytical balance - Tag No. 510-06-01-015; balance/pipet log book BNW 54371

#### Memos

PNL Memo, 4-14-93, LR Greenwood  
Status of GEA Procedures

PNL Memo, 12-31-92, Shannon Thompson

## ATTACHMENT 3

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### List of Objective Evidence Reviewed During the Audit

Gamma detector Calibration for SST GEA

#### Software Documentation

PNL Memo, 2-8-93, T L Miles, Application Report on  
PNL-MA-70 Software Control Procedures (SCP's)  
for MCNP 4.2, HP Version 1.0

Canberra Nuclear, 12, 1989, Spectroscopy Applications  
Algorithms and Software Verification and Validation Manual

GEA,	Canberra Nuclear Instrument Manual, 07-0196, Volume I, II, Version 2.8
LSC,	Packard Instrument Co., TriCarb Liquid Scintillation Analyzer, Model 2500TR (1992)
ICP/AES,	Bausch & Lomb ARL, AA 30612-02 (Feb. 1993)
LEPS,	Canberra Nuclear, Genie Systems, 07-0312/07-0196, Vol. I, II, Version 2.8
	Canberra Nuclear, Verification Manual for Version 2.8

#### Other Documents Reviewed

Project 10994 ACL Records File

Project Manager Records File

LRB, 53810 Project 10994, Sample Preparation Tasks

#### Deviation Reports

DR-93-002, 1-25-93 (AMA Task)  
DR-93-015, 4-15-93 (AMA Task)

**ATTACHMENT 4**

**INFORMATION COPIES OF CARS**

**OF**

**CORRECTIVE ACTION REQUESTS**



OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

CAR NO. HO-93-022  
DATE: 5/15/93  
PAGE: 1 OF 2  
QA

CORRECTIVE ACTION REQUEST

<sup>1</sup> Controlling Document WTC 061 Rev. 1/PAP-70-1101 Rev. 0, ICN-R04, 3/26/93		<sup>2</sup> Related Report No. HQ-93-04
<sup>3</sup> Responsible Organization PNL	<sup>4</sup> Discussed With S.K. Fadell/J. McGarran	
<sup>5</sup> Requirement:  PAP-70-1101  4.3.1 - The Project Manager shall assure that the required Technical Procedures are certified, and that the procedures define the methods of gathering information. Technical Procedures are prepared and approved...  4.3.2 - procedure shall remain at work location throughout the performance of the test. Test instructions shall be complete to the extent that another qualified individual may, at a later date, reproduce the test results.		

Continued on Page 2

<sup>6</sup> Adverse Condition:

- two technical procedures were not at the work station (i.e. PNL-ALO-449, PNL-ALO-474).
- one instance was noted of a test being conducted/performed using a procedure that had been approved but had not yet gone through the document control process. (PNL-ALO-495).
- one technical procedure did not adequately address analysis methods to the extent that another qualified individual may produce the test results (e.g., no calibration information, incorrect reference to obsolete procedure, no equipment or materials identified) (PNL-ALO-450 and the supporting test instruction).

<sup>8</sup> Does a significant condition adverse to quality exist? Yes <u>X</u> No <u>  </u> If Yes, Circle One: A B <u>C</u>	<sup>10</sup> Does a stop work condition exist? Yes <u>  </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	<sup>11</sup> Response Due Date: 5/31/93
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<sup>12</sup> Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

<sup>13</sup> Recommended Actions:  
  
See attached continuation sheet.

<sup>7</sup> Initiator <u>Thomas R Swift</u> Thomas Swift Date <u>5/4/93</u>	<sup>14</sup> Issuance Approved by: QADD Date
<sup>15</sup> Response Accepted QAR Date	<sup>16</sup> Response Accepted QADD Date
<sup>17</sup> Amended Response Accepted QAR Date	<sup>18</sup> Amended Response Accepted QADD Date
<sup>19</sup> Corrective Actions Verified QAR Date	<sup>20</sup> Closure Approved by: QADD Date

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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**CORRECTIVE ACTION REQUEST (Continuation Page)**

<sup>2</sup> Requirement: (continued)

QA Plan WTC 061 Rev. 1

B.9.0 - In addition to the requirements of PAP-70-1101, test plans and procedures shall identify potential sources of uncertainty and errors. Additionally they shall identify and establish steps to control parameters....

PAP-70-1101

4.4.1 - notify the Project Manager when the tests can not be conducted as specified in the Test Plan, Technical Procedures, Test Instructions....

- document the test results, or acquisition data generated, in the manner specified in the Test Plan and/or Technical Procedure/Test Instructions.

<sup>13</sup> Recommended Actions:

- 1) Ensure procedures are at the work location, verify validity of previously performed tests, train personnel to PAP-70-1101 requirements.
- 2) Expedite issuance of procedure, write deviation report or equivalent (PAP-70-1101), evaluate previously performed tests, and train personnel of requirements.
- 3) Revise Technical Procedure and/or test instruction to include all requirements.

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

<sup>1</sup> CAR NO. HQ-93-023  
DATE: 4/15/93  
PAGE: 1 OF 1  
QA

CORRECTIVE ACTION REQUEST

<sup>1</sup> Controlling Document: DOE/RW-0214 and WTC-061, Rev. 1		<sup>2</sup> Related Report No. Audit HQ-93-04	
<sup>3</sup> Responsible Organization PNL		<sup>4</sup> Discussed With J. McGarran	
<sup>5</sup> Requirement:  Section 17.1, QA Records states:  "Documents that are to become QA Records are considered QA Records upon completion and authentication by all required signatures. A complete QA Record is a document that will receive no more entries and whose revision would be subject to a change control process."			
<sup>6</sup> Adverse Condition:  Contrary to the above:  WTC-061, Rev. 1, Para. 6.2.0 states "Program records shall be transferred to the DOE Records Holding Area within 90 days after completion. Activity records shall be transferred to the program office or DOE Records Holding Area within 90 days after activity completion." This does not meet the requirements of DOE/RW-0214, since the requirement for transmittal from individual files should be predicated upon when the record is complete rather than completion of the activity. Records have been maintained in individual files for greater than 90 days after record completion.			
<sup>9</sup> Does a significant condition adverse to quality exist? Yes <u>X</u> No <u>  </u> If Yes, Circle One: A B <u>C</u>		<sup>10</sup> Does a stop work condition exist? Yes <u>  </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	
<sup>11</sup> Response Due Date:  5/31/93			
<sup>12</sup> Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
<sup>13</sup> Recommended Actions:  Revise WTC-061 and implementing procedures to require submittal of records to the Records Holding Area upon completion of the record rather than upon completion of the task, activity, or program completion. Submit records in accordance with the revised WTC-061.			
<sup>7</sup> Initiator <u>Marlin Horseman</u> Marlin Horseman Date 5/4/93		<sup>14</sup> Issuance Approved by: QADD Date	
<sup>15</sup> Response Accepted QAR Date		<sup>16</sup> Response Accepted QADD Date	
<sup>17</sup> Amended Response Accepted QAR Date		<sup>18</sup> Amended Response Accepted QADD Date	
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