

United States Government

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Carlsbad, New Mexico 882208
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DATE: June 29, 1999

REPLY TO: CAO:QA:SLV 99-0859 UFC 2300.00

SUBJECT: CAO Audit Report A-99-08, Idaho National Engineering and Environment Laboratory (INEEL)

TO: Lori Fritz, Acting Manager, Waste Management Program, ID

The Carlsbad Area Office (CAO) conducted an audit of the INEEL Waste Characterization, Certification, and Transportation activities on May 17-20, 1999. The audit team concluded overall that the INEEL technical and QA programs were marginally adequate in accordance with the CAO QAPD and QAPP. The audit team also concluded that INEEL procedures were being marginally implemented and the evaluated processes were marginally effective. The CAO audit report is attached.

There were 18 CAO corrective Action Reports (CARs) issued as a result of the audit. They have been forwarded to you under separate cover. Three observations and six recommendations were also identified during the audit.

If you have any questions or comments concerning this report, please contact me at (505) 234-7484 or Samuel A. Vega, INEEL Certification Manager, at (505) 234-7423.

Bar Marc A. Italiano
Quality Assurance Manager

Attachment

990621



cc w/attachment:

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U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

AUDIT REPORT

OF THE

IDAHO NATIONAL ENGINEERING & ENVIRONMENTAL LABORATORY


IDAHO FALLS, IDAHO

AUDIT NUMBER A-99-08

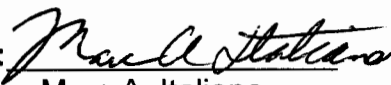
MAY 17-20, 1999

TRU WASTE CHARACTERIZATION, CERTIFICATION, AND
TRANSPORTATION



Prepared By: 
Steven D. Calvert
Audit Team Leader

Date: 6/16/99

Approved for Issue By: 
Marc A. Italiano
CAO QA Manager

Date: 6/16/99

1.0 EXECUTIVE SUMMARY

Carlsbad Area Office (CAO) Audit A-99-08 was conducted to evaluate the adequacy, implementation, and effectiveness of Idaho National Engineering & Environmental Laboratory (INEEL) Transuranic (TRU) Waste Characterization, Transportation, and Certification activities. The audit was conducted at the INEEL facility May 17 through 20, 1999.

During the audit it was found that major changes to the INEEL technical and QA procedures were made in late 1998 and early 1999. Approximately 40% of 347 applicable procedures have been revised since INEEL was certified for WIPP. Required CAO approvals to specified project documents were not obtained prior to effecting these changes. The Transuranic Reports, Inventory, and Processing System (TRIPS) was only recently brought on line; replacing the CAO-approved manual control systems for the WIPP Waste Information System (WWIS).

The audit team concluded that, overall, the INEEL technical and Quality Assurance procedures were marginally adequate relative to the flow down of requirements from the CAO Quality Assurance Program Document (QAPD); Quality Assurance Program Plan (QAPP); Waste Acceptance Criteria (WAC); and TRUPACT-II Authorized Methods for Payload Control (TRAMPAC). The audit team also concluded that, overall, the defined QA Program was being marginally implemented in accordance with the INEEL Quality Assurance Project Plan (QAPjP) and implementing procedures. The INEEL technical areas evaluated by the audit team were determined to be marginally implemented and marginally effective. It was noted that several key areas were unsatisfactorily implemented and ineffective. These areas include transportation, activities performed by ANL-W, headspace gas sampling, acceptable knowledge, and corrective action management.

The audit team identified 30 conditions adverse to quality resulting in the issuance of 18 CAO Corrective Action Reports (CARs) that require corrective actions (i.e., procedure adequacy, failure to follow procedures, coring, headspace gas sampling, corrective action, identification of nonconforming items, transportation, batch data reporting, training and qualification acceptable knowledge, chain-of-custody, and visual examination). Twelve isolated deficiencies requiring only remedial corrective actions were Corrected During the Audit (CDA). Three Observations were identified. Six Recommendations are being offered for management consideration. The CARs, CDAs, Observations, and Recommendations are described in Section 6.0 of this report.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of technical and quality assurance processes related to the INEEL TRU Waste Characterization, Certification, and Transportation activities.

The following elements were evaluated in accordance with the CAO QAPD:

- Organization
- QA Program Implementation
- Personnel Qualification and Training
- Quality Improvement
- Documents and Records
- Work Processes
- Procurement
- Measuring and Test Equipment
- Assessments/Audits
- Sample Control
- Data Documentation, Control, and Validation
- Software Control
- QA Grading

The following CAO characterization technical elements were evaluated in accordance with the CAO QAPP:

- Sampling Design
- Sample Handling
- Headspace Gas Testing
- Testing – Nondestructive Assay (NDA), Real-Time Radiography (RTR)
- Visual Examination
- Hydrogen and Methane Analysis
- Volatile Organic Compound Analysis
- Metals Analysis
- Data Validation
- WIPP Waste Information System (WWIS)

The following transportation technical elements were evaluated in accordance with the CAO TRAMPAC:

- Inspection of Packaging
- Visual Inspection
- TRUPACT-II Preparation and Loading
- TRUPACT-II Leak Check
- Shipping Preparation
- Package Maintenance
- Documentation and Records
- Payload and Drum Certification
- Transportation Tracking and Communications (TRANSCOM)

Evaluation of INEEL TRU Waste Characterization Program (TWCP) documents was based on current revisions of the following documents:

INEEL Site Project Office Quality Assurance Project Plan (QAPjP) for the Transuranic Waste Characterization Program, PLN-190, including the subtier Facility Implementation Plans

INEEL TRU Waste Characterization, Transportation, and Certification Quality Program Plan (QPP), PLN-182

Program Plan for Certification of INEL Contact-Handled Stored Transuranic Waste, INEL-96/0345

RWMC Compliance Plan for TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), WM-PD-88-012

Related INEEL and ANL-W technical and quality assurance implementing procedures

3.0 AUDIT TEAM AND OBSERVERS

AUDITORS/TECHNICAL SPECIALISTS

Steve Calvert	Audit Team Leader, CTAC
Amy Arceo	Auditor, CTAC
Steve Davis	Auditor, CTAC
Mario Chavez	Auditor, CTAC
Jack Walsh	Auditor, CTAC
Jeff May	Auditor, CTAC
Chet Wright	Auditor, CTAC
Pete Rodriguez	Auditor, CTAC
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Mark Doherty	Technical Specialist, CTAC
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Trey Greenwood	Technical Specialist, CTAC
Dick Blauvelt	Technical Specialist, CTAC
Ava Holland	Technical Specialist, CTAC
Tom Ward	Technical Specialist, WID

OBSERVERS/INSPECTORS

Sam Vega	CAO Certification Manager
Beth Bennington	CAO Management Representative
Mark Coffman	NMED Representative
James Oliver	Inspector, EPA
Mike Eagle	Inspector, EPA
Don Hammer	Inspector, ICF (EPA)
Howard Finkel	Inspector, ICF (EPA)
Ray Wood	Inspector, Trinity Engineering (EPA)
William Volke	Inspector, TechLaw (EPA)
Gary Walvatne	Inspector, TechLaw (EPA)
Robert Thielke	Inspector, TechLaw (EPA)
Ben Walker	Observer, EEG
Bill Weston	Observer, WID
Alan Merritt	Observer, State of Idaho

4.0 AUDIT PARTICIPANTS

INEEL individuals involved in the audit process are identified in Attachment 1. A preaudit meeting was held in the INEEL Radioactive Waste Management Complex (RWMC) Building Conference Room on May 17, 1999. Daily meetings were held with INEEL management and staff to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held in the RWMC Building Conference Room on May 20, 1999.

5.0 SUMMARY OF AUDIT RESULTS

Attachment 2 provides a list of specific procedures audited.

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that, overall, the INEEL technical and Quality Assurance procedures were marginally adequate relative to the flow down of requirements from the CAO Quality Assurance Program Document (QAPD); Quality Assurance Program Plan (QAPP); Waste Acceptance Criteria (WAC); and TRUPACT-II Authorized Methods for Payload Control (TRAMPAC). The audit team concluded that, overall, the defined QA Program was being marginally implemented in accordance with the INEEL Quality Assurance Project Plan (QAPjP) and implementing procedures. The INEEL technical areas evaluated by the audit team were determined to be marginally implemented and marginally effective.

The audit team concluded that the adequacy of the LMITCO QA Program was satisfactory in capturing the requirements of the CAO QAPD, Revision 2; the QAPP, Revision 0 and Interim Change 11/96; the WAC, Revision 5 and Change Notice 1; and the TRAMPAC, Revision 16. The audit team concluded that the QA program was being marginally implemented. The LMITCO technical processes evaluated by the audit team were determined to be marginally implemented and marginally effective. It was noted that several key areas were unsatisfactorily implemented and ineffective. These areas include transportation, activities performed by ANL-W, headspace gas sampling, acceptable knowledge, and corrective action management.

The audit team concluded that the Argonne National Laboratory-West (ANL-W) QA Program was unsatisfactory in meeting the requirements of the CAO QAPD, Revision 2; the QAPP, Revision 0 and Interim Change 11/96; the WAC, Revision 5 and Change Notice 1 and the audit team concluded that the QA program was being unsatisfactorily implemented. The INEEL technical processes evaluated by the audit team were determined to be unsatisfactorily implemented and ineffective.

5.2 QA Program Audit Activities

Details of audit activities, including specific objective evidence reviewed, are contained within the audit checklists. The checklists are maintained as QA records. CARs 99-055, 99-056, 99-057, 99-059, 99-063, and 99-067 were issued against the QA Program. See Section 6.0 for a description of the CARs.

CAR 99-068 was written against the ANL-W procedures for solid sampling. This is considered to be an issue dealing with procedure adequacy and a significant condition adverse to quality.

5.3 Technical Activities

Evaluations of applicable INEEL technical activities are summarized below.

5.3.1 Nondestructive Assay (NDA)

The SWEPP Gamma-Ray Spectrometer/Passive-Active Neutron (SGRS/PAN) NDA system was evaluated during the audit. Sludges are assayed using the active mode of the PAN instrument for TRU activity ranges $>100\text{nCi/g}$ and mass loadings of $<16\text{g}$ weapons grade (WG) Pu. Graphite wastes are assayed in the passive PAN mode for loadings in the range of 5 -160g WG Pu. INEEL's total measurement uncertainty methodology was previously approved by an expert panel. Based on that approval and the documents examined before and during the audit, the assay procedures at INEEL were determined to be adequate, satisfactorily implemented, and effective.

5.3.2 Data Validation; Level 2, Project Level Data Review and Reporting

The data validation process was evaluated at the Site Project Office (SPO). The TRU waste project Site Data Validation Officer (SDVO) is responsible for the level 2 data validation. The evaluation included examination of the data packages to assure that validation reviews are occurring. The data validation procedures were determined by the audit team to be adequate, satisfactorily implemented, and the process was determined to be effective (CDAs 2, 3, and 4; Observation 1).

5.3.3 Data Reporting

During the evaluation of visual examination activities, it was noted that several batch reports had not been forwarded within the 28-day time limit (CAR 99-058). During the evaluation of solid sampling activities, several deficiencies in the procedure and its implementation were noted (CAR 99-065). The ANL-W data reporting procedures were determined to be inadequate and unsatisfactorily implemented. The audit team concluded that the data reporting process was ineffective.

5.3.4 Real-Time Radiography

Operation of the Real-Time Radioscopic (RTR) system was evaluated by observation of container scans and a review of video recordings and RTR documentation. RTR activities performed at INEEL incorporate all CAO requirements as specified in Methods Manual Procedure 310.1 and section 10 of the QAPP. The radioscopic equipment upgrades completed last year by INEEL have greatly enhanced the system. The INEEL RTR procedures were found to be adequate and satisfactorily implemented. RTR activities performed in accordance with these procedures were determined to be effective.

5.3.5 Visual Examination

Visual examination activities at ANL-W were evaluated to the requirements of Methods Manual Procedure 310.2, QAPP Sections 5 and 10, and INEEL internal implementing procedures. These activities include calculation of the miscertification rate, selection of containers to open, and the actual examination of the containers. The visual examination process was observed and videotaped recordings and documentation were reviewed. The audit team identified a condition adverse to quality dealing with the role, responsibilities, and performance of visual examination by the Visual Examination Expert (CAR 99-064). The audit team determined the procedures to be inadequate. The team concluded that the visual examination process was unsatisfactorily implemented and ineffective.

5.3.6 Hydrogen and Methane Analysis and Gas Volatile Organic Compounds (VOCs)

Laboratory analysis and data review activities were evaluated to ensure effective performance. The processes were observed and applicable documentation reviewed to support the evaluation. The evaluation was based on Methods Manual Procedures 520.1 (H₂ and CH₄) and 430.1 (gas VOCs) and QAPP Sections 11 and 12. INEEL's internal Analytical Chemistry Methods Manual is used for the hydrogen and methane analysis process. The quantitative determinations of hydrogen and methane in gas samples are made by gas chromatography with thermal conductivity detection using nitrogen as a carrier gas. Procedure ACMM-9930 is used for analysis of gas VOCs. The VOCs in headspace gas samples are determined by using the gas chromatography/mass spectrometry method. INEEL procedures for these processes were determined to be adequate, satisfactorily implemented, and the processes were determined to be effective for hydrogen, methane, and gas VOCs analyses (CDAs 8 and 9; Observation 2; Recommendation 3).

5.3.7 Solid Sampling

The solid sampling process (coring) was evaluated at ANL-W. The audit team determined the procedure for coring to be inadequate (CAR 99-068). Conditions adverse to quality were identified relating to equipment cleaning and design and operational checks (CAR 99-066). The audit team concluded that the process was unsatisfactorily implemented and ineffective.

5.3.8 Volatile and Semi-Volatile Organic Compound Analysis

The procedures and processes for determination of volatile and semi-volatile organic constituents and polychlorinated biphenyls (PCBs) in TRU waste characterization samples were evaluated and found to be satisfactory. Method performance data were also reviewed and determined to be complete (i.e., the precision and accuracy data indicate acceptable laboratory performance on the method performance samples). Method detection limit determinations were determined to be within QAPP limits. The analytical results were determined to be technically sound. A condition adverse to quality was identified relating to missing information in data reports (CAR 99-062). The audit team concluded that the procedures for the determination of volatile and semi-volatile constituents and PCBs in TRU waste characterization samples are adequate, satisfactorily implemented, and the processes are effective (Recommendation 1).

5.3.9 Total Metals Analysis

Metals analysis activities were evaluated in accordance with the requirements of QAPP Section 15, the Methods Manual, and INEEL internal implementing procedures.

Evaluated activities included the preparation of samples, control of quality control standards, determination of percent solids, microwave digestion of solid samples, analysis of mercury using cold vapor atomic adsorption and fluorescence spectrophotometry, analysis of arsenic and selenium using graphite furnace atomic absorption spectrometry, and analysis of trace metals by inductively coupled plasma atomic spectrometry. The Total Metals Analysis procedures evaluated by the audit team were determined to be adequate and implemented and the processes are effective.

5.3.10 Sample Handling and Chain-of-Custody

The process for sample handling was evaluated at the Analytical Chemistry Laboratory (ACL) and Environmental Chemistry Laboratory (ECL). The evaluation established that handling of samples in these facilities was performed in accordance with the procedures. The samples are stored correctly after receipt and are tracked as they move through the analysis processes. It was concluded that the sample handling procedures are adequate and satisfactorily implemented and the process is effective. The chain-of-custody process at ACL and ECL was examined for samples coming from RWMC to the various laboratory facilities. The overall chain-of-custody program and procedures were determined to be adequate and satisfactorily implemented and the process is effective.

The process for sample handling and chain-of-custody was evaluated at ANL-W. The audit team determined that the processes for sample handling and chain-of-custody at ANL-W do not meet program requirements (CAR 99-069). The audit team determined the procedures for these processes are inadequate. The audit team concluded that the processes were unsatisfactorily implemented and were ineffective.

5.3.11 Sampling Design

The activities being implemented to comply with specific container selection, sampling, examination, and data analysis requirements for transuranic waste were reviewed. INEEL procedures that address these activities were determined to be adequate and satisfactorily implemented and the process is effective (CDAs 5 and 6).

5.3.12 Headspace Gas Sampling

The procedures used for the sampling of volatile constituents in headspace gas were evaluated and determined to be adequate. The activities are being performed at the Stored Waste Examination Pilot Plant (SWEPP). The audit determined the manual process for sampling using SUMMA Canisters to be satisfactorily implemented and effective.

The execution of the procedures was witnessed during the audit for the Fourier Transform Infrared System (FTIRS). Conditions adverse to quality were identified

relating to minimum detection limits (MDLs), leak rate testing, manifold temperature maintenance, and filter sealing prior to sampling (CAR 99-060). The team determined the procedures to be adequate. The audit team concluded that the process was unsatisfactorily implemented and ineffective.

5.3.13 INEEL Transportation

The audit team evaluated the INEEL TRUPACT-II visual inspection, payload and drum certification, packaging, and the transportation tracking and communications (TRANSCOM) processes. This evaluation was based upon the review of the documentation of the first shipment KN990401. A loading demonstration was not performed for the audit team nor was there a real-time loading operation in process. The audit team reviewed the documentation pertaining to shipment KN990401 and determined that the operations were implemented in an unsatisfactory manner relative to the approved procedures. The audit team concluded that the processes and controls were unacceptable for the shipping operations pertaining to shipment KN990401. Safety Analysis Report for Packaging (SARP) required inspections were not being documented, allowing the shipment to be made with an open nonconformance report (NCR), numerous errors and omissions occurring in the documentation of the loading activities (CARs 99-050, 99-051, and 99-052). The audit team determined that the nonconforming item had been resolved, but had not been documented. The audit team concluded that the transportation procedures were adequate. Implementation of procedure requirements was unsatisfactory and ineffective (Recommendation 2).

5.3.14 Software

Implementation of the requirements for the development, procurement, maintenance and use of computer software used for processing, controlling, measuring, and statusing radioactive waste materials was evaluated. The evaluation included a review of the development and control of software baselines. The documentation reviewed for RWMC systems included the Passive Active Neutron (PAN) System, SWEPP Assay (sub) System (SAS), the SWEPP Gamma-Ray Spectrometer System (SGRS), VAXGAP subsystem, the Drum Vent System (DVS), the Fourier Transform Infrared Spectrometer (sub) System (FTIRS), Residual Gas Analyzer (RGA), and the Nondestructive Assay Methodology (NDAM). The PAN and SGRS systems share a single Software Verification and Validation Plan (SVVP) which was also evaluated. Software procedures are adequate, satisfactorily implemented and effective (CDAs 11 and 12; Recommendations 4, 5, and 6).

5.3.15 Transuranic Reports, Inventory, and Processing System (TRIPS)

The implementation of the TRIPS was evaluated at the RWMC. The process applies to implementation of the TRIPS Data Change Request (TDCR) relating to production

reference tables. The TDCR procedure is adequate, satisfactorily implemented and effective.

NOTE: This audit only covered the TRIPS Data Change Request. The rest of the developed portion of TRIPS was evaluated during CAO Surveillance S-99-10, performed May 3-4, 1999. Three Corrective Action Reports resulted from S-99-10. TRIPS was determined to be marginally implemented and the technical areas effective at that time.

Because major portions of TRIPS are not completed and implemented, its implementation and effectiveness are indeterminate.

5.3.16 WIPP Waste Information System (WWIS)

The WWIS was evaluated to the requirements of the INEEL procedure. The evaluation included a demonstration of data input and system capabilities. It was proven during the demonstration that data could be satisfactorily transmitted to the WIPP Site. The audit team determined that the procedure was adequate, satisfactorily implemented, and the process is effective.

5.3.17 Acceptable Knowledge

Acceptable knowledge (AK) activities were evaluated to determine compliance with the requirements of the QAPP, QAPjP, and internal implementing procedures. During the evaluation, several instances of failure to follow procedure requirements were discovered (CAR 99-061). The audit team concluded that the AK procedures are adequate. The audit team also determined the process to be marginally implemented and ineffective.

6.0 CARs, OBSERVATIONS, & RECOMMENDATIONS

6.1 Corrective Action Reports

6.1.2 CARs Initiated as a Result of CAO Audit A-99-08:

The following 18 CARs, initiated as a result of Audit A-99-08, have been transmitted to INEEL under separate cover. A brief description of each CAR is provided below.

6.1.2.1 CAO CAR 99-050

During the review of the completed copies of TPR-1723, it was determined that steps 4.2.3.4 and 4.4.3.4 were not signed off as completed for TRUPACT-IIs A and C for shipment KN990401. Therefore, it could not be verified that INEEL inspected and determined that water was not present in the inner containment vessel (ICV) of

TRUPACT-II's A and C as required by the above listed documents.

6.1.2.2 CAO CAR 99-051

INEEL nonconformance report (NCR) RWMC-WIPP-86 was prepared to document "that portions of the required inspections were not documented as required" for shipment KN990401 (specifically the outer containment vessel (OCV) Seal Test Port Insert Plug and O-ring seal and the ICV lower and upper spacers). This NCR was dispositioned on 4/23/99 to remove the ICV from TRUPACT 129 and perform the required inspections and remove the payload from TRUPACT 134 and perform the required inspections. Verification that inspections were performed was not documented on the NCR. These TRUPACTs were part of shipment KN990401. The shipment was made prior to closure of NCR RWMC-WIPP-86.

6.1.2.3 CAO CAR 99-052

The audit team determined that numerous errors and omissions occurred during the completion of the six different copies of procedure TPR-1723 for shipment KN990401. RWMC opened a new TPR-1723 for each day that loading operations were performed and two revisions of TPR 1723 (Revs. 10 & 11) were initiated during the loading period. This resulted in six TPR-1723 copies that were inconsistent, incorrect, and missing information.

6.1.2.4 CAO CAR 99-055

INEEL has not established a formal process for notifying and obtaining approval from the DOE field office and the NTP team leader prior to making changes that affect performance criteria or data quality (reference CAR 99-058). Several instances of failure to follow procedure requirements were identified during the audit (reference CARs 99-050, 99-051, 99-057, 99-059, 99-062, 99-063, and 99-067).

6.1.2.5 CAO CAR 99-056

Stored Waste Examination Pilot Plant (SWEPP) Operators performing on-line analyses [Fourier Transform Infrared Spectroscopy (FTIRS) and residual gas analyzer (RGA)] do not meet the minimum training and qualifications requirements of the QAPP and the QAPjP. The Initial Qualification Prerequisites for "SWEPP Operator," as specified in the Training Implementation Matrix, PLN-127, Rev. 2, lists that the "SWEPP Operator," be a "SWEPP Basic Facility Operator". The Initial Qualification Prerequisites for the "SWEPP Basic Facility Operator" requires only a "high school graduate or equivalent." Neither matrix specified the experience requirement.

6.1.2.6 CAO CAR 99-057

The following instances are examples of failure to complete corrective action in a timely manner and failure to assess the impact of nonconforming items on completed work:

- SPO QA Surveillance Report QAPS-98-03 identified three (3) deficiencies concerning AK activities with a request for a written corrective action response no later than 12/18/98. The written corrective action response was not received until 4/21/99.
- SPO QA Surveillance Report QAPS-98-04 identified five (5) deficiencies concerning NCR activities with a request for a written corrective action response no later than 12/11/98. The written corrective action response was not received until 4/23/99.
- The RWMC Facility QA Officer has not issued a semi-annual QA Report to the SPO QA Officer since February 1998.
- Several errors and inconsistencies were identified in VOC (Method 9261) quantitation by the Level 1 Surveillance performed on Data Report ACL96007V (97-SPO-01). To date, 19 NCRs have been issued for individual VOC data reports that detail QC sample failures due to the requantitation. The NCRs assess the impact of the failures on the reported sample data, but no corrective action to correct previous work or improve processes were identified in the disposition.

6.1.2.7 CAO CAR 99-058

Several batch reports were not forwarded within the 28-day time limit. ANL-W had added a statement to the Facility Implementation Plan allowing up to 45 days to forward data reports to the Site Project Office (a procedure change was issued during the audit to address this after being identified as a condition adverse to quality). The Environmental Chemistry Laboratory (ECL) issued Procedure Change Notice (PCN), ECL-PCN-20, that provides for an allowance to extend the data reporting period from 28 days to 56 days, as needed. The PCN was used for both the testing and analytical batch data reports that were reviewed during the audit.

6.1.2.8 CAO CAR 99-059

Examples of nonconformances that were internally recognized but were not formally identified under the applicable corrective action process include:

- Two drums were identified as having non-resolvable anomalies on a Visual Examination SQA Drum Data Checklist.

- Inspection activities for water in the TRUPACT inner containment vessel (ICV) were not performed.
- Validated data was not available to revise the Description of the SWEPP Certified Waste Sampling Plan.
- Several cases of analytical data exceeding the 28-day reporting requirement.

6.1.2.9 CAO CAR 99-060

Vents are not sealed prior to collecting headspace gas samples. Leak check criteria embedded in the FTIR software [4.5 um Hg/second (4.5 millitorr/sec)] does not meet the leak check requirements for testing the FTIR manifold. Portions of the headspace gas sampling manifold were not maintained at a temperature of $\geq 110^{\circ}\text{C}$ during the sampling process. MDLs are not constantly updated using the results of the on-line control sample, as required by Methods Manual 430.7. MDLs for hydrogen were not redetermined prior to sample analysis, subsequent to major work on the residual gas analyzer (RGA). A new multiplier and clean source block were installed in the RGA. RGA was out of service for about one month and returned to service on 5/17/99.

6.1.2.10 CAO CAR 99-061

During the evaluation of the acceptable knowledge process several instances of failure to follow procedure requirements were discovered. The AK process is not performed in a consistent manner. Conditions adverse to quality were discovered in the areas of control of AK Documents and records, consistency in AK summary documents, and procedure compliance.

6.1.2.11 CAO CAR 99-062

Review of two data packages (ACL 99001M & 99002M) did not have method printouts included. MS/MSD recoveries for data package ACL 99002N were out-of-limits for all compounds except Methanol, due to interference. The associated samples were not "Z" flagged, as required.

6.1.2.12 CAO CAR 99-063

ANL-W had not received CAO approval for grading procedure AWP 4.2. The procedure is not based on CAO QAPD requirements. The procedure has been determined to be inadequate as written.

6.1.2.13 CAO CAR 99-064

Data is reported to the Site Project Office (SPO) as individual waste container reports, not as batch reports. The individual container reports do not meet the batch report requirements for review, verification, and validation. Reports do not contain all the information required by the QAPP, Section 8.6. The visual examination expert's (VEE's) decision-making criteria are not present in the procedure. The VEE is not always present at the glovebox during the examination and, therefore, cannot direct the scope of the exam based on the actual conditions found in the container. The current VEE is not qualified as a visual examination operator and is not qualified to work in the examination glovebox.

6.1.2.14 CAO CAR 99-065

Core sampling is not reported on a batch basis. The individual container reports do not meet the batch report requirements for review, verification, and validation. Reports do not contain all the information required by the QAPP, Section 8.6. ANL-W container reports do not contain independent technical supervisor reviews, per QAPP, Section 3.1.1. The independent technical reviewer is actually completing part of the data package. The weight of the sludge in the drum is recorded during the review. The facility QA officer review does not verify that quality control (QC) checks were properly performed and that the Quality Assurance Objectives (QAOs) have been met. Data reports do not include applicable minimum information, as required by the QAPP. Data reports have not been forwarded to the SPO within 28 days; this has taken as long as 11 months.

6.1.2.15 CAO CAR 99-066

Sampling tools and equipment are not cleaned and stored between samples, as required. It is not possible to demonstrate that there is no cross-contamination between samples. The performance of the weekly operational checks is not documented, therefore, there is no objective evidence that the checks have been performed. ANL-W calculates core recovery based on the depth of the waste cored, not on the entire depth of the waste. This provides a percent recovery that is greater than the actual recovery. The coring equipment design and operation is not in compliance with the QAPP. ANL-W has modified the equipment and procedure without written approval by CAO.

6.1.2.16 CAO CAR 99-067

Objective evidence was not produced to substantiate recurrent or annual TRU Waste Project program training that includes CAO QAPD, QAPP, INEEL QAPjP, or TWP implementing procedures. Evidence of training conducted prior to use of a new or revised TDWP procedure could not be produced.

6.1.2.17 CAO CAR 99-068

The ANL-W SOPs for solid sampling do not adequately capture CAO QA and technical program Requirements. Areas of inadequacies include and may not be limited to chain-of-custody, core sampling, and data packages/batch reporting (matrices have been attached to the CAR).

6.1.2.18 CAO CAR 99-069

Chain-of-custody at ANL-W is not being performed according to specified requirements. Samples are not maintained in effective custody. Sample release and acceptance is not recorded to provide an unbroken chain from collection to disposition.

6.2 Deficiencies Corrected During the Audit (CDA)

1. A receipt acknowledgement for a batch data report from ANL-W could not be located. A receipt acknowledgement for the batch data report was located and put in the appropriate file.
2. A Site Quality Assurance Officer (SQA) Drum Data Review Checklist was missing the weight information. Missing RTR records were located and weights were entered in the appropriate SQA Drum Data Review Checklist.
3. Data reports received via TRIPS were not being entered in the Validation Ledger Database. Data reports received via the TRIPS were entered into the Validation Ledger Database.
4. The Core Sampling Quality Assurance Analysis Report did not identify the drum population for the analysis performed. The Core Sampling Quality Assurance Analysis Report was revised to identify the drum population for the analysis performed.
5. SPO Core Sample Plans were not being formally transmitted to ANL-W. SPO Core Sample Plans were formally transmitted to ANL-W.
6. The drum substitution forms for visual examination were not signed. The forms were signed.
7. No certification traceable to a known standard was on file for a thermometer at ACL. A certification traceable to NIST was located and put in the file.

8. Procedure MCP-2017 referenced the use of operational variances. The procedure was revised to delete the use of operational variances.
9. Several procedures at the ECL were missing some information from the QAPP and Methods Manual. The activities were being performed as required by the upper tier documents. The procedures were revised to include the missing information.
10. Self assessment checklists for RWMC were missing some information. A process Deficiency Report (4959) was issued by RWMC to address this issue.
11. Hand calculations for a computer program (NDAM 2.0) had not been completed. The hand calculations were completed and found to be acceptable.
12. The software inventory only listed the system components, not the software packages. The inventory list was updated to include the software package information.

6.3 Observations

The following three Observations were identified during the audit:

1. The SPO should add an item to the SDVO checklist to verify that the SQA review has been completed.
2. The ECL should verify and record the instrument configuration and operating conditions and include information on sample volume, column type, temperatures, and flow rates.
3. ANL-W should maintain records of overview activities performed by SPO.

6.4 Recommendations

The following six Recommendations are presented for INEEL management consideration:

1. Instrument run logs for the Inductively Coupled Plasma (ICP) unit should be included in the data packages. ICP data is extensive and complex and cannot be reviewed efficiently without the run logs.
2. INEEL currently segregates parts by TRUPACT II part number with the WID purchase order number referenced. It is recommended that procedure MCP-1783 be changed to match the TRUPACT II Operating and Maintenance Instructions.

3. It is recommended that INEEL request an equivalency for the practice of releasing SUMMA canisters prior to data validation.
4. INEEL should consider using procedure MCP-550 *Software Management* for all software packages.
5. Currently changes to software can be implemented prior to the completion of reviews and approvals. Reviews and approvals for software changes should be completed prior to use.
6. INEEL should consider using a common procedure for software development and software configuration management.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: INEEL Procedures Audited

PERSONNEL CONTACTED DURING THE AUDIT

PERSONNEL CONTACTED				
NAME	TITLE/ORG	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Aki, Francis	Secretary, ANL-W		X	
Allred, James	Calibration Supervisor, LMITCO		X	
Anderson, Molly	SDVO, LMITCO	X	X	X
Arbon, Rod	Site Project Manager, LMITCO	X	X	X
Bagley, Julia	Certification Specialist, LMITCO		X	
Beausoleil, Geoffrey	Facility Director, DOE-ID		X	
Benedict, Robert	Director, ANL-W		X	
Beutler, Paul	QA Engineer, LMITCO			X
Bishoff, Jim	Operations, LMITCO	X	X	X
Blackwood, Larry	Consulting Scientist	X	X	
Bronson, Tim	Sr. Scientist, LMITCO		X	
Bradford, Rhett	PQAR Reviewer, ANL-W		X	
Bryngelson, Dwayne	Project Engineer, ANL-W	X	X	X
Chappell, Julie	Document Control, ANL-W		X	
Christiansen, Dale	TRIPS Engineer, LMITCO		X	
Clements, T.L. Jr.	Manager, TRU Waste Program, LMITCO	X	X	X
Coburn, Klayne	Group Leader, ANL-W		X	
Colburn, Julie	Technician, ANL-W		X	
Contreras, Paul	Facility Engineer, DOE-		X	X

PERSONNEL CONTACTED				
NAME	TITLE/ORG	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
	ID/RWMC OPS			
Cook, Scott	TRIPS Engineer, LMITCO	X		
Crowder, Catherine	Technical Lead, LMITCO	X	X	X
Custer, Gerald	SWEPP Foreman, LMITCO			X
David, Loren	Calibration Coordinator, LMITCO		X	
David, Ron	Technical Lead, LMITCO		X	
Davis, Darrin	Sr. Operator, LMITCO		X	
Davis, Kurt	RTR System Engineer, LMITCO	X	X	X
Davis, Larry	RADCON Technician		X	
DeCoria, G.	Analytical Custodian, LMITCO		X	
Dumas, Elvin	FQAO, LMITCO	X	X	X
Dwight, Carla C.	TDWP Manager, ANL-W		X	
Evans, Robert	Lab Technician, LMITCO		X	X
Fackrell, Paula	Procedure Writer, ANL-W		X	
Flores, Arturo	Document Control, LMITCO		X	X
Ford, Bryant	3100 Project Manager, LMITCO	X	X	X
Forgeon, Larry	Chief Technician, LMITCO		X	
Fritz, Lori	DOE-ID	X		
Gies, Carol	Chemist, LMITCO		X	

PERSONNEL CONTACTED				
NAME	TITLE/ORG	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Gilman, Janice	Document Control, LMITCO		X	X
Griffin, John	Calibration Technician, LMITCO		X	
Hailey, Sheila	AK Expert/SDVO, LMITCO	X	X	X
Hand, Rodney	Manager, Analytical Labs., LMITCO			X
Harker, Yale	Consulting Scientist, N&RPhys/LMITCO	X	X	
Hartley, Diane	TWMIS Data Admin, Waste Management		X	X
Hayes, Glen	Site QA Officer, LMITCO	X	X	X
Hawley, Connie	QA Engineer, LMITCO			X
Heath, Shawn D.	SWEPP/OPS, LMITCO		X	
Henscheid, Joseph	Lab Supervisor, LMITCO		X	X
Henslee, Paul	Associate Director, LMITCO		X	X
Herring, Catherine	Software Engineer, LMITCO		X	
Hollenbeck, Dennis	TRIPS Engineer, LMITCO	X		X
Hudman, Rod	Chemical Technician, LMITCO		X	
Jeter, Jeff	Technical Lead Organics, LMITCO			
Kendrick, Randy	Training Coordinator, LMITCO	X	X	X
LaFreniere, Mike	DOE-ID	X		X

PERSONNEL CONTACTED				
NAME	TITLE/ORG	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Lang, Jeff	Technical Lead, LMITCO		X	
Lent, Dave	Training Coordinator, LMITCO	X		X
Lewis, Larry	Systems Engineer, LMITCO	X	X	X
Lundholm, Duane	Tech Spec., ACL		X	
Lundquist, Kevin	Certification Specialist, LMITCO		X	X
Magnan, J. M.	Systems Engineer, ANL-W		X	
Mason, Christal	Technician, ANL-W		X	
Menkhaus, Dan	Systems Engineer, LMITCO	X	X	X
Mickelsen, Ted	Equipment Operator, LMITCO		X	
Miller, Ernie	Technician, ANL-W		X	
Miller, Terrence	Software Engineer, LMITCO	X	X	
Moody, Harry	Manager, Metrology Lab, LMITCO		X	
Neal, Cindy	Sr. Scientist, LMITCO		X	
Park, Lori	Secretary, LMITCO		X	
Peterson, Barbara	TRIPS Project Manager, LMITCO		X	
Poenitz, Christa	Business Support Supervisor, LMITCO			X
Pound, Don	Transportation Certification Officer,	X	X	X

PERSONNEL CONTACTED				
NAME	TITLE/ORG	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
	LMITCO			
Preston, Tim	Staff Quality Engineer, LMITCO	X	X	X
Reidle, Martha	Training Administrator		X	
Riggs, Matt	SDVO, LMITCO	X	X	X
Rogers, N.	Facility Manager, LMITCO			X
Sabel, Frances A.	PR Office Specialist, LMITCO		X	X
Sailer, Shelly	ALD QA Officer, LMITCO	X	X	X
Sayer, Randy	RADCON Technician, LMITCO	X		
Swartzenberger, D.	Sr. Engineer, LMITCO		X	
Schwendiman, Wyn	TRIPS System Administrator, LMITCO	X	X	
Seamens, James	Principal Scientist, LMITCO		X	
Shannon, Colleen	Scientist, LMITCO		X	
Sharp, Michelle	Site Document Control, LMITCO	X	X	X
Sherick, Mark	Advisory Engineer, LMITCO			X
Spencer, Dave	TRIPS Engineer, LMITCO	X		X
Stanley, Cliff	Engineer Lead, LMITCO	X		
Tawfik, Isis	Document Control, LMITCO		X	
Taylor, Spence	Technical Specialist, LMITCO		X	

PERSONNEL CONTACTED				
NAME	TITLE/ORG	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Tedford, Gina K.	Waste Certification Official LMITCO	X	X	X
Teller, Steve	TRIPS QA, LMITCO		X	
Thomas, Mariam	Sr. Scientist, LMITCO		X	
Twedell, Gary	Engineer, LMITCO		X	
Wasylow, Jim	Maintenance Engineer Supervisor, LMITCO/RWMC	X		X
Webb, Kelly	Technician, LMITCO		X	
Webster, Judy	Document Control, LMITCO		X	
Wells, Jerry	DOE-ID	X	X	X
Wenczel, Victor	Procurement Quality Engineer, LMITCO	X	X	
Whitehead, Marie	Certification Specialist, LMITCO		X	

INEEL PROCEDURES AUDITED IN A-99-08

NUMBER	PROCEDURE NUMBER	TITLE
1.	ACLP 1.01	Preparation of QC Reagents and Standards
2.	ACLP 2.05	Control Distribution and Use of Spectrochemical Standards
3.	ACLP 4.10	Determination of Method Detection Limits for Gas Analysis
4.	ACLP 4.20	Sample and QA Nomenclature Conventions for TWCP
5.	ACLP 4.25	Sample Receiving, Custody, and Storage
6.	ACLP 4.30	Standards Preparation, Documentation and Storage
7.	ACLP 4.40	Summa Canister Cleaning
8.	ACLP 4.45	Gas Transfer Manifold Systems
9.	ACLP 4.50	Equipment Maintenance
10.	ACMM-2350	Determination of Arsenic & Selenium in Samples
11.	ACMM-2900	Determination of Trace Metals in Samples
12.	ACMM-7801	Determination of Mercury by Atomic Absorption
13.	ACMM-7802	Determination of Mercury by Fluorescence Spectrophotometry
14.	ACMM-8909	Microwave Assisted Digestion of Homogeneous Solids and Soil/Gravel
15.	ACMM-8969	Determination of Percent Solids
16.	ACMM-9081	Determination of PCBs in Rad Organic Sludges by GC/ECD
17.	ACMM-9260	VOCs by GC/MS: Capillary Colume Technique
18.	ACMM-9261	Determination of Total VOCs in Homogeneous Solids and Soil/Gravel By GC/MS
19.	ACMM-9271	Determination of Semi-VOCs in TRU Waste Samples
20.	ACMM-9441	Determination of Nonhalogenated VOCs by GC/FID
21.	ACMM-9501	Sample Prep of TRU Samples for Organic Analysis
22.	ACMM-9910	Analysis of Gas Samples for Alcohols and Ketones by GC/FID
23.	ACMM-9920	Analysis of Gas Samples for Hydrogen/Methane by GC/TCD
24.	ACMM-9930	Analysis of Gas Samples for VOCs by GC/MS
25.	AWP-2.5	Measuring and Test Equipment
26.	AWP-2.8	Chain of Custody
27.	AWP-4.2	QA Grading
28.	AWP-4.3	Document Management System
29.	AWP-4.4	Document Control
30.	AWP-4.7	Nonconformance Control
31.	AWP-4.11	Vital and QA Records
32.	AWP-4.14	Procurement Document Preparation
33.	AWP-5.4	Independent Assessment
34.	HFEF-OI-1251	Records Management
35.	HFEF-OI-6862	Sample Packaging and Shipping
36.	HFEF-OI-6890	Waste Characterization
37.	HFEF-OI-6892	Waste Characterization Data Packages
38.	HFEF-OI-6910	Core Drilling Operations
39.	HFEF-OI-6921	Sludge Sample Preparation
40.	MCP-100	Developing Procedures
41.	MCP-147	Vendor Assessment Program
42.	MCP-196	Assessor/Lead Assessor Qualification
43.	MCP-538	Control of Nonconforming Items
44.	MCP-540	Graded Approach & Quality Level Assignment
45.	MCP-550	Software Management
46.	MCP-552	Conduct of Independent Assessments
47.	MCP-561	QPP/QAPjP Development
48.	MCP-590	Procurement Quality Requirements
49.	MCP-591	Evaluated Supplier Program

INEEL PROCEDURES AUDITED IN A-99-08

NUMBER	PROCEDURE NUMBER	TITLE
50.	MCP-592	Acquisition of Goods and Services
51.	MCP-598	Process Deficiency Resolution
52.	MCP-1773	RWMC Reporting/Surveillance Requirements
53.	MCP-1775	RWMC Self Assessment
54.	MCP-1783	TRUPACT II Container Maintenance Program
55.	MCP-1793	TRU Waste Program Records Management and Retention
56.	MCP-1802	RWMC Facilities Requisition Control
57.	MCP-1803	Configuration Control of RWMC Hardware/Software
58.	MCP-1805	Document Preparation, Review, Control, and Release
59.	MCP-1809	Records Management
60.	MCP-1815	RWMC/SWEPP Level I Data Validation
61.	MCP-2001	Control of Analytical Methods and Procedures
62.	MCP-2002	Analytical Chemistry Chain of Custody
63.	MCP-2004	Sample Management in Analytical Chemistry Lab
64.	MCP-2005	Analytical Lab Dept QC Program
65.	MCP-2006	Analytical Lab Dept Training and Qualification Program
66.	MCP-2007	Analytical Records Management
67.	MCP-2008	Analytical Data Recording, Review and Reporting
68.	MCP-2011	Analytical Logbooks
69.	MCP-2017	Analytical Nonconformance and Variance Reporting
70.	MCP-2018	Analytical Corrective Actions & Deficiency Tracking
71.	MCP-2391	Calibration Program
72.	MCP-2392	Independent Performance Assessment
73.	MCP-2492	Standards and Calibration Lab Operations
74.	MCP-2502	Standards and Calibration Lab Calibration Intervals
75.	MCP-2516	Key Project Personnel
76.	MCP-2517	Data Flow and Reporting
77.	MCP-2518	Duties of INEL Site Personnel
78.	MCP-2519	Project Files
79.	MCP-2520	QA Records Management
80.	MCP-2521	Site Project Data Base
81.	MCP-2522	Preparation & Control of Management Control Procedures
82.	MCP-2523	Indoctrination & Training of INEL SPO Personnel
83.	MCP-2524	Sample and Control Charts
84.	MCP-2525	Drum Core Sample Plan
85.	MCP-2526	Control of QAPPs and FIPs
86.	MCP-2527	DQO Reconciliation at SPO Level
87.	MCP-2528	Computer Software Control
88.	MCP-2529	Drum Data Review by Site QA Officer
89.	MCP-2530	SQAO Drum Data Review Checklists
90.	MCP-2531	Nonconformance Reporting
91.	MCP-2532	Independent Assessment
92.	MCP-2533	Reports to Management
93.	MCP-2534	Level I Surveillances
94.	MCP-2535	Level II Data Processing by the SDVO
95.	MCP-2536	Evaluation by SDVO
96.	MCP-2537	Activities Conducted by the SDVO
97.	MCP-2538	Data Reduction and Waste Stream Summarization by the SDVO
98.	MCP-2539	Report Preparation

INEEL PROCEDURES AUDITED IN A-99-08

NUMBER	PROCEDURE NUMBER	TITLE
99.	MCP-2542	Preparation of Waste Profile Forms
100.	MCP-2544	WWIS Data Transfer
101.	MCP-2546	Visual Examination Process
102.	MCP-2990	Radioassay Total Uncertainty Process Using Modified Statistical Sample Approach
103.	MCP-2991	Radioassay Total Uncertainty Process Using Statistical Sampling Approach
104.	MCP-2992	QA Program Surveillances
105.	MCP-2993	TWCP Action Tracking and Trend Analysis
106.	QTP-002	RTR System
107.	QTP-004	Qualification Test Procedure (PAN)
108.	QTP-011	Qualification Test Procedure (SGRS)
109.	PLN-127	Training Implementation Matrix for RWMC
110.	TDWP-AP-01	Documents and Records Management
111.	TDWP-AP-02	TWCP PQAR Data Package Review
112.	TDWP-AP-03	TWCP Project Manager Packages
113.	TDWP-AP-04	TWCP Quality Improvement Trending and Tracking
114.	TDWP-AP-05	TWP Training Plan
115.	TPM-3.3.4	HFEF Waste Characterization Area Initial and Continuing Training
116.	TPR-1522	RTR System
117.	TPR-1523	Assay System
118.	TPR-1534	Gamma Ray Spectrometer System Description
119.	TPR-1572	Operating the RTR System
120.	TPR-1573	PAN Drum Assay System
121.	TPR-1581	Transuranic Package Transporter-II Operations
122.	TPR-1584	Drum Venting Operations
123.	TPR-1585	Tracking of Waste Using Barcodes
124.	TPR-1588	Gamma Ray Spectrometer System
125.	TPR-1610	Determination of Method Detection Limits for Hydrogen Using RGA
126.	TPR-1611	Determination of Method Detection Limits for VOCs and Methane Using FTIRS
127.	TPR-1612	On-Line Determination of hydrogen in HGAS Using GASLAB 300
128.	TPR-1613	On-Line Determination of VOCs and Methane in HGAS Using FTIRS
129.	TPR-1614	Method Performance Evaluation for Methods 430.7 and 510.1
130.	TPR-1719	Calibration of Gamma Assay/System
131.	TPR-1722	Drum Vent Operations
132.	TPR-1723	TRUPACT Operations
133.	TPR-1724	Waste Retrieval Operations
134.	TPR-1725	TRU Waste Payload Handling
135.	TPR-1726	TRU Waste Examination for SWEPP
136.	TPR-1728	Manual Gas Sampling
137.	TPR-1735	Container Inspection and Final Disposition
138.	WM-PD-88-012	RWMC TRAMPAC
139.	MCP-2988	Confirmation, Resolution, and Re-evaluation of Acceptable Knowledge Information
140.	MCP-2989	Collection, Review, and Management of Acceptable Knowledge Documentation
141.	PLN-182	INEEL TRU Waste Characterization, Transportation and Certification Quality Program Plan
142.	PLN-185	RWMC Implementation Plan for TRU Waste Characterization Program