DOE F 1325.8

United States Government **Department of Energy**

memorandum

Carlsbad Area Office
Carlsbad, New Mexico 88221

DATE: June 9, 1997

REPLY TO ATTN OF: CAO:NTP:RAS:97-1166 UFC 2300

SUBJECT: CAO Audit Report A-97-02

TO: Joel Case, ID

The Carlsbad Area Office (CAO) conducted an audit of your Quality Assurance (QA) Program for TRU Waste characterization, transportation and certification activities in Idaho Falls, Idaho, on April 21-25, 1997. The audit team determined the INEEL QA Program was effectively implemented. The team was not able to make a procedural adequacy determination.

As a result of the audit, ten (10) Corrective Action Reports (CARs) were issued, and five (5) Observations and eleven (11) Recommendations were identified. Observations 1, 2, 3, and 5 require a written response. The CARs were transmitted to INEEL under a separate letter.

If you have any questions or comments concerning this report, please contact Robert A. Stroud, NTP Certification Manager, at (505) 234-7483.

Don Watkins
Manager
National TRU Program

RECEIVED JUN 1997

Attachment

cc w/attachment:
D. Brown, CAO
K. Hunter, CAO
R. Stroud, CAO
J. Wells, ID
D. Winters, DNFSB
B. Walker, EEG
M. Eagle, EPA
J. Oliver, EPA
T. Clements, INEEL-LMITCO
G. Hayes, INEEL-LMITCO
S. Zappe, NMED
M. Horseman, CTAC

970604

U.S DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

AUDIT REPORT

OF THE

IDAHO NATIONAL ENGINEERING AND ENVIRONMENTAL LABORATORY (INEEL)

IDAHO FALLS, IDAHO

AUDIT NUMBER A-97-02

APRIL 21-25, 1997

TRU WASTE CHARACTERIZATION, CERTIFICATION, AND TRANSPORTATION PROGRAM

Prepared by: R Dennis Brown **Date:** 6/5/97

R. Dennis Brown
Audit Team Leader

Approved By: Robert A. Stroud **Date:** 6/6/97

Robert A. Stroud
CAO NTP Certification Manager

1.0 EXECUTIVE SUMMARY

Carlsbad Area Office (CAO) Audit A-97-02 was conducted to evaluate the adequacy, implementation, and effectiveness of Idaho Engineering and Environmental National Laboratory (INEEL) characterization, transportation, and certification activities. In addition, the audit scope included the verification of the completion and effective implementation of corrective actions for conditions adverse to quality previously identified by CAO.

The audit was conducted at the INEEL April 21 through April 25, 1997. The audit team concluded that the QA Program was being effectively implemented in accordance with INEEL implementing procedures. The team was not able to make an adequacy determination. For the technical areas evaluated, the INEEL program was determined to be effective except for the Real Time Radiography (RTR) and Nondestructive Assay (NDA) systems, which were indeterminate. The audit team also concluded that the corrective actions for previous CAO Corrective Action Reports (CARs) continue to be effective.

The audit team identified ten (10) CARs that require corrective action in the areas of training, procedure implementation, document review and control, QA records, data review, and software control. Twenty-seven deficiencies requiring only remedial corrective actions were corrected during the audit (CDAs). Five (5) observations and eleven recommendations are being offered for management action and consideration. Observations 1, 2, 3, and 5 require a written response. The audit team noted six exemplary practices being used by INEEL. The CARs, CDAs, observations, recommendations, and exemplary practices are described in Section 6.0 of this report. INEEL program adequacy will be addressed prior to the next audit scheduled for later in the year.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of the technical and quality assurance activities as related to the INEEL Transuranic Waste characterization, transportation, and certification programs.

The following CAO QAPD elements were evaluated:

Organization/QA Program Implementation
Personnel Qualification and Training
Quality Improvement
Documents & Records
Work Processes

Procurement
Inspection and Testing
Measuring and Test Equipment
Assessments
Sample Control
Software Requirements

The following CAO Characterization (QAPP) technical elements were evaluated:

Acceptable Knowledge
Sampling Process Design
Sampling - Headspace Gas, Solids
Testing - Nondestructive Assay (NDA),
Testing - Real Time Radiography (RTR)
Visual Examination
Analysis - Headspace Gas, Solids
Data Validation, Usability, and Reporting
Performance Demonstration Program (PDP)

The following CAO Transportation technical elements were evaluated:

Inspection of Packaging
Preparation and Loading
Shipping
Packaging Maintenance
Documentation and Records

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

CAO Quality Assurance Program Document, CAO-94-1012

Transuranic Waste Characterization Quality Assurance Program Plan, CAO-94-1010

Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-069

Safety Analysis Report for TRUPACT-II Shipping Package, Appendix 1.3.7, TRAMPAC and the TRUPACT-II Certificate of Compliance, NRC 71-9281

The programmatic and technical checklists were developed from the active revision of the following documents:

INEEL Site Project Office Quality Assurance Project Plan (QAPjP) for the Transuranic Characterization Program, INEL-94/0085, including the subtier facility QAPjPs

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

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

Related INEEL and Argonne National Laboratories-West (ANL-W) technical and quality assurance implementing procedures

CAO Corrective Action Reports and observations from Audit A-95-02

3.0 AUDIT TEAM AND OBSERVERS

AUDITORS/TECHNICAL SPECIALISTS

R. Dennis Brown	CAO QA Manager, Audit Team Leader
Robert A. Stroud	CAO Certification Manager, Technical Specialist
Hugh Lentz	Auditor, Audit Coordinator/CTAC, Sub-Team Leader
Beth Bennington	Auditor/CAO, Sub-Team Leader
Bruce Langsteiner	Auditor/CTAC, Sub-Team Leader
Ava Holland	Auditor/CTAC, Sub-Team Leader
Sam Vega	Auditor/CAO
Pete Rodriquez	Auditor/CTAC
Steve Davis	Auditor/CTAC
Fred Dunhour	Auditor/CTAC
Mike Brown	Technical Specialist/CAO
Cindy Zvonar	Technical Specialist/CAO
Sid Ailes	Auditor/Technical Specialist/CTAC
Clint Kelley	Technical Specialist/WID
Dave Baran	Technical Specialist/CTAC
Laurie Sparks	Technical Specialist/WID
Mark Doherty	Technical Specialist/CTAC

OBSERVERS

Mike Eagle, EPA/ORIA
John Goode, A.T. Kearney
Angela Jones, A.T. Kearney
Steve Zappe, NMED
Tom Tatkin, NMED
Ben Walker, EEG
Rensay Owen, State of Idaho
Allen Merrit, State of Idaho
Sandy Wander, LANL
Chris Lewis, Hanford
Brandon Williamson, RFETS
Daniel Goade, RFETS

4.0 AUDIT PARTICIPANTS

Individuals involved in the audit are listed in Section 3.0 and Attachment 1. A preaudit meeting was held at the INEEL office in RWMC on April 21, 1997. A daily meeting was held with INEEL management and staff to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the Technical Support Building (TSB) in Idaho Falls, Idaho on April 25, 1997.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that the QA program was being effectively implemented in accordance with INEEL procedures within the scope of this audit. The team was not able to make a determination of procedural adequacy. For the technical areas evaluated, the INEEL program was effective except for the Real Time Radiography and Nondestructive Assay systems, which were determined to be indeterminate. The audit team also verified that the corrective actions for previous CAO Corrective Action Reports continue to be effective.

5.2 QA Program Audit Activities

A summary table of audit results is provided as Attachment 2. The details of the audit activities, along with the specific objective evidence reviewed, are contained within the audit checklists. The checklists are maintained as QA Records.

5.3 Technical Activities

5.3.1 Performance Demonstration Program (PDP)

Activities performed by INEEL in support of the Performance Demonstration Program were evaluated at the ECL, RWMC, and AWL-W laboratories. The NDA samples were stored in a safe, in a locked, controlled access room. All activities were being performed satisfactorily and analyses were being performed in accordance with demonstrated methods.

5.3.2 Acceptable Knowledge

Adequacy and implementation of the procedure used for the collection, review, and management of acceptable knowledge (AK) documentation for INEEL-stored TRU waste [from Rocky Flats Environmental Technology Site (RFETS)] were evaluated. This procedure was a draft included in INEL-96/0280, *Acceptable Knowledge Document for INEL Stored Transuranic Waste - Rocky Flats Plant Waste*, 10/96, as Appendix B. INEL-96/0280 contains a basic summary with references to source documents and excerpts for the 22 waste groups in the INEEL inventory. The draft procedure was being implemented with one exception (see Observation number 4). INEL-96/0280 contains some statements regarding the presence or absence of hazard/toxicity characteristics, but does not qualify them to reflect the information required in the source documents. A new revision of the procedure, which was not significantly different than the draft in Appendix B of INEL-96/0280, was reviewed during the audit. Two of the 22 "waste group files" were reviewed in detail and found to be acceptable. The AK for the RFETS plant waste was properly compiled into auditable files.

See CARs 97-047 and 97-048; observation number 4; and exemplary practice number 5 for a further discussion of this area.

5.3.3 Gas and Solids Sampling/Visual Examination

The technical specialist observed the core drilling operation in the Waste Characterization Area (WCA). The core drilling machine operates within the Waste Characterization Chamber (WCC), where the entire drilling process is recorded on video and audio tape. The observation of the visual examination was accomplished by viewing these tapes, as ANL-W was not performing core drilling at the time of the audit.

Core drilling was being used to sample a drum of sludge. A random position for the coring is determined by the Site Project Office (SPO), which is included in the sampling

plan, is then forwarded to the ANL-W. The core is then drilled and packaged for sampling. This process was determined to be effective.

Visual examination of waste drums included head space gas sampling of the drum and each individual bag of waste within the drum. Visual examination is used as verification of the waste code and physical form. This process was determined to be effective.

See CAR 97-046 and CDA numbers 18 and 20 for a further discussion of this area.

5.3.4 Real Time Radiography

The Real Time Radiography examination system was evaluated using existing procedures and documents. This system is undergoing hardware upgrades; consequently, the system is not currently in operation. The upgrades should not affect system performance. Procedures will have to be revised to address the upgraded hardware and software. Due to the upgrades, this area is considered to be indeterminate.

5.3.5 Nondestructive Assay

The PAN/SGRS assay system and the alpha spectrometry systems were evaluated using existing procedures and documents. The procedures address the QAPP requirements in a logical, well-defined manner. The alpha spectrometry system was evaluated and determined to be effective. The PAN/SGRS is currently being upgraded in both hardware and software plus the continuing project of calculating the total uncertainty for the assay. The upgrades are on schedule and should not affect the system's ability to assay waste. The total uncertainty calculation is an excellent approach to a difficult problem.

Procedures will have to be revised to address the upgraded hardware and software. Since the PAN/SGRS is currently being upgraded, this area is considered to be indeterminate.

5.3.6 Headspace Gas Analysis Activities for H_2, CH_4, and VOC

The Environmental Chemistry Laboratory (ECL) has issued a complete set of new procedures for controlling headspace gas analysis operations; however, no analyses had been performed using the new procedures at the time of the audit. Objective evidence is available to demonstrate that the ECL had an effective program for analysis of headspace gas to the prior set of procedures, including: complete and satisfactory operating and maintenance logs; complete and satisfactory analytical data packages; successful participation in the Headspace Gas PDP; adequate sample receipt and

chain-of-custody procedures; satisfactory physical and environmental consideration in the laboratory layout; complete and satisfactory control of analytical reagents that have shelf-lives; and the appropriate preparation procedures for standards.

See CDA number 19, 22, and 23; and exemplary practice number 3 for a further discussion of this area.

5.3.7 Solids Analysis for VOC, SVOC, and Metals

At the Analytical Chemistry Laboratory (ACL) the procedures and methods manual, including sample control and management, were evaluated. Implementation of some of the totals analyses procedures was observed (to the extent possible in a working laboratory) during the audit. The processes observed were correctly implemented and effective.

Completed data packages were also reviewed. The data have been subjected to the required reviews and the data packages contained the required checklists and signatures. The data showed that the solids analyses were properly completed (as demonstrated by the QC results). The data in the packages were determined to be reasonable. The audit team concluded that the Solids analysis activities were effectively implemented.

See CDA number 24 for a further discussion of this area.

5.3.8 Transportation

TRUPACT-II use and maintenance was evaluated to verify INEEL compliance with applicable requirements. The audit team observed TRUPACT-II operations at ANL-W and RWMC. In addition, items identified during CAO Surveillance S-96-001 were reviewed. Results of this assessment were positive, except for minor concerns. These concerns are: inconsistent completion of crane inspections at the RWMC TRUPACT-II loading facility; unissued ANL-W draft procedures for waste shipping; and inconsistent completion of RWMC checklists for TRUPACT-II physical conditions. These conditions are described as CDA number 25, 26 and observation number 5. The INEEL procedures and operations were determined to be effective. The audit team determined that the INEEL has effective controls in place and has effectively implemented the required programs for the use of the TRUPACT-II.

5.3.9 Software

The effective implementation of software quality assurance program requirements for control of software used for analysis, measurement, and data acquisition and reduction

activities was evaluated. The evaluation included a review of the software classification and evaluation process; a review of the process for the development and control of software baselines, and the technical review process of completed software documentation. At the time of the audit, complete life-cycle documentation was available for four RWMC programs (SGRS, PAN, TWMIS, and PRCIS). The requirements traceability matrix, provided as an appendix to each document, provided positive and effective controls to ensure that test results were fully traceable to functional and performance requirements.

During the audit, the testing process for the new version of the Passive-Assay Neutron system software was observed. The testing procedure was well written, providing detailed step-by-step test instructions and specific acceptance criteria for each functional and performance requirement that was verified.

The audit team concluded that the code documentation reviewed was complete and provided sufficient descriptions of the software development, change control, and test activities for much of the RWMC software. However the life-cycle documentation available for the Drum Vent System and the Data Management System was limited to requirement specifications and qualification testing. The draft revision of RWMC MCP 18-03 *Configuration Control of Hardware/Software* will address the evaluation of vendor software for the acceptability of the documentation needed to support software design, implementation, and operation. However, until the procedure is approved for use and implemented, the effectiveness of the software program is considered to be indeterminate.

See CARs 97-046; CDA numbers 11, 12, 13, and 14; and Recommendation 4 and 5 for a further discussion of this area.

6.0 CORRECTIVE ACTIONS/OBSERVATIONS & RECOMMENDATIONS

The audit team identified 37 deficiencies during the audit, requiring the issuance of ten (10) Corrective Action Reports; 27 deficiencies were corrected prior to the postaudit meeting.

6.1 Corrective Action Reports

A brief description of each Corrective Action Report is detailed below.

CAO CAR 97-039

Objective evidence was not presented to the audit team to verify that Management training for Hot Fuel Examination Facility personnel had been completed.

CAO CAR 97-040

Several manual sets of Management Control Procedures (MCPs) and Technical Procedures (TPRs) at the RWMC contained deleted or superseded procedures along with the current procedure version.

CAO CAR 97-041

RWMC Detailed Operating Procedures were issued without incorporating all the changes and comments agreed to on the applicable Document Revision Requests (DRRs).

CAO CAR 97-042

RWMC QA records: were not given a designator of "lifetime" or "nonpermanent"; were not validated by the originating organization; and were not properly approved or validated.

CAO CAR 97-043

Receiving inspection was not performed on one (1) ANL-W Purchase Order.

CAO CAR 97-044

MCP-1803, Rev. 1, *Configuration Control of RWMC Hardware/Software* does not fully address the specified QAPD requirements for qualification or documentation of existing RWMC software.

CAO CAR 97-045

The software used at ACL for the mercury analysis was modified without documenting what was done and why.

CAO CAR 97-046

Four (4) drum data packages had temperature data outside the acceptable range.

CAO CAR 97-047

The procedure for assembling and evaluating acceptable knowledge does not contain all the information required by the QAPjP.

CAO CAR 97-048

The Statement of Work for the subcontractor for AK work did not include requirements for qualification and training of personnel.

6.2 Deficiencies Corrected During the Audit (CDA)

Those deficiencies that are considered isolated in nature and only require remedial action may be corrected and verified during the audit. The following 26 deficiencies were corrected and verified:

1. ECL training and qualification records were not initially provided to the audit team to document that personnel received indoctrination of requirements pertaining to the: TWCP; QAPjP; QAPP; and SOPs for the control of records, documents, NCRs, and CARs. The audit team verified that training had been previously completed and documented.

2. A HFEF Training Specialist signature was not on a remedial training plan. The audit team verified that the HFEF Training Specialist signed the Remedial Training Plan during the audit.

3. Procedure MCP-2531, discussed the establishment of a Material Review Group (MRG), but did not address the purpose of the group. The procedure was not clear on the role of individuals within the group. The audit team verified that a

   DAR was generated to describe the MRG participant roles pertaining to and Nonconformance Report (NCR) disposition activities.

4. Procedure MCP-2531, required the Site Quality Assurance Officer (SQAO) to verify corrective actions. This is not consistent with the QAPjP and MCP-538, which require the SQAO to oversee and monitor the corrective actions. The audit team verified that a DAR to MCP-2531 was issued to change the procedure to read "The SQAO will oversee the NCR process and coordinate with facilities...." This revision makes the INEEL procedures consistent with the QAPjP and MCP-538.

5. Four (4) NCRs, still open after a year, were found to be dispositioned differently than identified in the NCR log. The log was not up-to-date and approval was not given by the SPO for the change in disposition. The audit team verified that copies of the four (4) NCRs were requested from facilities and placed in the file and that the NCR index was updated.

6. Although not a QAPD or QAPjP requirement, procedure MCP-538, required that a list of individuals qualified to assist in the NCR process be maintained. This list did not exist. INEEL determined that this list provided no additional process control. The audit team verified that a DAR was issued to delete the INEEL internal requirement.

7. At SPO, the Record of Variance forms are electronically prepared. Two (2) of six (6) forms reviewed were missing signatures. The audit team verified that the two (2) forms were signed. In addition, all remaining variances were reviewed for missing signatures and none were found. This was verified by the audit team.

8. Although not a QAPD or QAPjP requirement, the site Document Control Officer was not maintaining the required log of inventories, including the receipt dates for records sent to dual storage. INEEL determined that this log provided no additional process control. The audit team verified that a DAR was issued to remove the INEEL internal requirement for maintaining the log.

9. An evaluation of audit activities is required annually for each facility. There was no documented justification for not evaluating or auditing all facilities during FY96. ECL was not audited during 1996, but this had no impact on the characterization program based on the satisfactory results from previous assessments. The audit team verified that DAR TWCP-20 was issued, requiring the preparation of a documented justification for the audit schedule.

10. The INEEL QPP requires "periodic" management assessments contrary to the CAO QAPD which requires "annual" management assessments. The audit team verified that a DAR was issued to change the QPP to require annual management assessments.

11. The draft design document for SGRS version 2 modified one (1) of six (6) functional requirements in the software calculation methods document (INEL-96/0484). The calculation methods document states "Fit photo peaks specified by the user". The draft design document states the user is to "Fit photo peaks specified by the Registered Library". The audit team verified the issuance of DAR E0-R1-3122 that requires a revision to the calculation methods document to state that functional requirements are to be consistent with the draft design document.

12. ANL-W Operational Baseline Software back-up copies of Paragon software have not been prepared for the latest version (Paragon 544). The audit team verified

that the inventory was completed, the backup tape prepared, and the backup procedure followed.

13. Test results of ACL software had not been reviewed for completeness for one (1) of four (4) verifications performed of personal computer software macros. The audit team verified that the test results were reviewed and signed off.

14. Procedure MCP-2009 for the ACL organization did not provide for the evaluation or approval of changes to ACL software. The audit team verified that DAR ALD-010 was issued to incorporate QAPD requirements for software change control, evaluation, and approval into procedure MCP-2009.

15. Two (2) completed data packages were sent to the ANL-W Document Center without being identified as "controlled". Further sampling identified no other cases. The audit team verified that the two (2) packages were identified as controlled.

16. Corrective actions for one (1) of five (5) SPO Level I surveillances reviewed were not verified. The audit team verified that the corrective action had been completed and that the proper documentation was placed in the file.

17. The Site Data Validation Officer (SDVO) was using desktop manual for data management activities as specified in MCP-2537, Rev. 1, Paragraph 4.2. The audit team verified that DAR TWCP-22 was issued to no longer allow use of desktop manuals.

18. One (1) gas sample Chain-of-Custody (CoC) form from a sample of 30 CoCs did not contain the sampler's signature. The audit team verified that the original CoC form was signed and a copy was faxed to ANL-W.

19. Section 8.1 of Method Manual Procedure 210.1 provides the guidance that canisters used for VOCs be clean and free of contaminants prior to use. The audit team requested objective evidence to ensure that the cleanliness requirements were being met. The audit team verified that the cleanliness is ensured through the measurement of an equipment blank.

20. ANL-W Procedure HFEF-OI-6921 was not clear regarding entry of the CoC number from the sample CoC log. The audit team verified that the request for procedure change, number 6978, was issued to clarify the procedure.

21. In one (1) of six (6) laboratory areas reviewed, one superseded ECL procedure was still available for use in the lab. The audit team verified that the procedure was discarded.

22. In one (1) case an ECL procedure maintenance requirement to check the humidifier was not documented. The audit team verified that there was no impact from missing the one (1) check. The logbook was corrected.

23. An ECL logbook entry was not complete. The supervisor review did not indicate the pages that were evaluated. The audit team verified that the supervisor properly corrected the entry.

24. One (1) of two (2) ACL Data Package Reviewer Checklists was not signed. The audit team verified that the checklist was signed during the audit.

25. Two (2) of four (4) RWMC checklists for determining the TRUPACT unimpaired physical condition were not completed consistently. The audit team verified that the supervisor annotated the existing records to indicate where the data was recorded.

26. The inconsistent performance of daily and monthly crane inspections on the 8T crane in the TRUPACT loading facility (WMF618) was identified. Because there is no clear guidance for criteria that is listed on the inspection form. Equipment operators have interpreted them differently. The audit team verified that training was performed during the audit to inform all responsible personnel of the meaning of each checklist item.

27. ACL Procedures ACLP-0.02 and ACLP-0.27 had not been reviewed at the required two year interval. These procedures were entered into the review cycle during the conduct of the audit.

6.3 Observations

The following five (5) observations are presented to INEEL management for consideration. Observations 1, 2, 3 and 5 require a written response, describing actions taken or to be taken.

1. Several sections of the INEEL QPP and QAPjP need to be revised to clarify the independence of the QA function. Based on interviews, the audit team concluded that the QA staff does have sufficient independence.

2. Nonconformances (NCRs) are not being controlled in accordance with the requirements of the QAPjP: 15 of 31 did not meet the SPO variance review time table of 4 days; level "C" NCRs are not being trended; and 18 of 80 NCRs had not been reviewed for completeness and adequacy of implementation. These conditions had been previously identified during the SPO assessment conducted in November 1996 and are being tracked to completion.

3. During a review of the SPO assessment files, various documents were missing which indicated a lack of formality as required by the audit process. The audit team observed that the assessment scope for three (3) of four (4) files reviewed was limited and similar to that of a surveillance. These assessments should be in accordance with a surveillance procedure and MCP-2532 should be conducted for the formal audit process.

4. The AK document contains statements not corroborated by the source documents. These statements should be edited to reflect information that is consistent with the source documents.

5. Draft management and operating procedures at ANL-W covering the shipping of radioactive and mixed materials have been under development for three (3) to four (4) years and have not been issued.

6.4 Recommendations

The following eleven recommendations are presented for INEEL management consideration:

1. It is recommended that a matrix be included in training files to list the required training, education, and experience.

2. Numerous NCRs have been documented and dispositioned on activities or items that do not have any impact on the overall quality program (for example, Methanol Content, Late Date Packages and Timing of Bagging Samples). It is recommended that this area be evaluated for effectiveness.

3. The ANL-W Purchase Requisition (ANL-451) in use is not the form that is cited in the procedure. All required purchase information was included on both forms. Both forms are being used and should be included within the procedure.

4. Nearly all of the software procedures were revised in the two (2) months prior to the audit and most of the INEEL software used for WIPP is pre-existing or vendor software. INEEL should carefully review the adequacy of the new

procedures to implement the QAPD requirements using a matrix that clearly indicates when site-level procedures will be used.

5. The user documentation for spreadsheet macros consists of simple input instructions and internal "code" documentation. The level of detailed requirements for user documentation is too prescriptive for spreadsheets. The audit team recommends clarifying how documentation will be prepared for spreadsheets.

6. Blank record forms for a prior revision of procedure HFEF-OI-6892 were available for use on the operating floor. The audit team did not find any of the obsolete forms in use. Old forms should be discarded.

7. It is recommended that INEEL document the process for handling and tracking Level II drum data review comments that require returning the data package back to the originator.

8. It is recommended that sidebars be used consistently throughout the source excerpts contained in acceptable knowledge documentation.

9. The data sheets on the weekly glove box checks and glove replacements had not been made during the period of 3/30-4/20/97. Forms also had numerous errors. It is recommended that this situation be evaluated and corrected. Note: This is an operational or safety issue and is not related to WIPP data.

10. ANL-W Procedure HFEF-OI-6812 does not provide space for the supervisor to record numbers for the payload weight determination in Appendix G. It is recommended that the procedure be revised.

11. Although there is no requirement for the classification of QA Records within the Records Tracking Database, the database should reflect records as either "Lifetime" or "Nonpermanent".

6.5 Exemplary Practices

1. The load cell on the crane used to load and unload TRUPACTs at the RWMC TRUPACT Loading Facility is very "user friendly". This cell would be very useful at WIPP and other sites with low clearances.

2. There is no requirement that review checklists should be considered to be treated as controlled documents. The ECL QAO maintains the standardized

checklists on file as controlled, specifies revision numbers when the form is changed, and provides checklists to the reviewers.

3. ECL Sample Receiving uses a standardized form to transfer canister information from the sample to the database.

4. The ECL quarterly management reports include clear pictorials in the form of charts & graphs depicting the number of NCRs, etc.

5. The Acceptable Knowledge records have been compiled into an auditable "file" with useful tools such as sidebars with reference to the text. The files are well organized and complete.

6. To facilitate the maintenance of the "official" controlled procedures, the ANL-W Procedures Group has developed and maintained facility specific maps to identify the location of each "official" facility procedure.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

PERSONNEL CONTACTED DURING THE AUDIT

PERSONNEL CONTACTED DURING AUDIT				
NAME	ORG/TITLE	PRE-AUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Adams, Bruce	ANL-W HFEF/Systems Engineer		X	
Anselmo, Rick	ALD/Sample Custodian		X	
Arbon, Rod	LMITCO/SPO Manager	X		X
Beausoleil, Geoffrey L.	DOE-ID/RWMC/WROC	X		
Bennett, Roger	TRUPACT OPS/Equipment Operator		X	
Beutler, P. S.	LMITCO/RWMC QE	X		
Black, Dave	ACL/Unix Admin		X	
Blackwood, Larry	RWMC/SWEPP/Statistician		X	
Branter, M. K.	LMITCO/Radcon Supervisor	X		
Bronson, Tim	ALD/Sr. Scientist		X	
Bryngelson, Dwayne	ANL-W/Project Engineer		X	
Case, Joel	DOE-ID/Waste Management Programs Manager	X		
Clarkson, Colleen	ALD/VOC Instrument Operator		X	
Clements, Tom Jr.	LMITCO/INEEL/TRU Waste Program Manager	X	X	X
Coburn, Klayne	ANL-W HFEF/Group Leader		X	X
Croft, Dan	TRUPACT-OPS/OPS Specialist		X	
Crowder, Catherine A.	ECL/Staff Scientist	X	X	
Darrington, Don	ANL-W/Project Engineer		X	
David, Ronald M.	LMITCO/RWMC/Document Control		X	X
DeHaan, Mark	LMITCO/TRU Waste Data Manager	X		X

PERSONNEL CONTACTED DURING AUDIT				
NAME	ORG/TITLE	PRE-AUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Deming, Larry	1440 S & CL/Principal Engineer		X	
Derdoorm, Mark	RWMC/SWEPP/Training Specialist		X	
Dumas, Elvin	LMITCO/RWMC/IQAO	X	X	X
Dwight, Carla C.	ANL-W/ID Waste Program Manager		X	X
Eagle, Mike	EPA/Inspector	X		
East, Larry	RWMC/Software Engineer		X	
Evans, Bob	ECL/Principal Engineer		X	
Fisher, Doyle	ANL-W/Quality Advisor		X	
Florez, Arturo	RWMC/Document Control		X	
Franklin, Emil	ANL-W HFEF/Systems Engineer		X	
Friedrich, Gloria	ALD/Admin. Support		X	
Fritz, Lori	DOE-ID/Deputy			X
Goade, Daniel L.	ROCKY FLATS/Observer	X		X
Goode, John	ATK/EPA Inspector	X		
Grey, Dan	RWMC/Maintenance Engineer		X	
Goodwin, Dean	ACL/Analyst		X	
Fife, Cindy	SPO/SQAO		X	
Hailey, Sheila	RWMC/SDVO		X	
Hand, Rod	ACL/Lab Manager		X	
Hannum, Bill	ANL/Director VESH/QA Oversight		X	X
Harker, Yale	RWMC/SWEPP/Physicist		X	
Hartley, Diane	RWMC/Configuration Control Manager		X	

PERSONNEL CONTACTED DURING AUDIT				
NAME	ORG/TITLE	PRE-AUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Hathaway, Terry L.	LMITCO/CRC/QA Lead Assessor		X	
Hayes, Glen	LMITCO/Site QA Manager	X	X	X
Henscheid, Joe	ACL/Analytical OPS Supervisor		X	
Hinckley, Lee	ALD/Principal Lab Tech		X	
Jacobson, Jake	ALD/Statistician		X	
James, Julie	ALD/Organic Tech Leader		X	
Jensen, Bruce	ANL-W HFEF/Systems Engineer		X	
Johnson, V. Jim	ACD/EC/PRM Tech Specialist		X	
Jones, Ron L.	Operations Division/CSMIC Manager		X	
Jones, Angela K.	AIK/EPA Inspector	X		
Jordan, Roberta	ALD/Supervisor		X	
Kerr, Jim	ANL-W/Crew Chief			
Killinski, Pete	ANL-W OPS/Training Rep		X	
Korenke, R. E.	LMITCO/RWMC Settlement Agreement	X		X
Kramme, J. Craig	LMITCO/RWMC Fac.	X		
Krekel, David	RPS DIV Supply Manager		X	
Lang, Jeff	ALD/Tech Leader		X	
Lewis, Christopher J.	RUST FED SERV - HANFORD/Observer	X		X
Lundholme, Diane	ALD/Chemist		X	
MacBath, Bill	ANL/ES&H Compliance Officer		X	
Magnan, Jim M.	HFEF/QA Rep		X	

PERSONNEL CONTACTED DURING AUDIT				
NAME	ORG/TITLE	PRE-AUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Marushia, Pat	ALD/Sample Custodian		X	
McIsaac, Chuck	RWMC/Independent Test Observer		X	
McKinney, Steve	ECL/Technical		X	
Meachum, Theresa	RWMC/SWEPP/Statistician		X	
Menkhaus, Dan	LMITCO/TRU Waste Program Engineer	X		
Merritt, Alan E.	STATE OF ID - OVERSIGHT/Observer			X
Moore, Donna L.	HFEF/Procedures Manager		X	
Nilsson, Steve	1440 S & CL/Engineer Tech		X	
Parker, D. W.	LMITCO/TRU Program Engineer	X		X
Parks, Robert L.	ANL-W/HFEF Manager		X	
Peters, Kevin	WASTREN/TRU Program Support	X		
Pound, Donald G.	RWMC/TCO	X	X	X
Preston, Tim	LMITCO/SPO QA	X	X	X
Randall, Clair, C.	LMTCO/CRC/Assessment Coordinator		X	
Reidle, Marty	COLEMAN/Training	X	X	X
Riggs, Margi	LMITCO/RWMC Training Record Lead			X
Roberts, Mark	ALD/Sample Prep Specialist		X	
Sabel, Fran	ECL/PR Admin Associate		X	
Sailer, Shelly J.	LMITCO/ALD/QAO	X	X	X
Sharp, Michelle	LMITCO/SDCO		X	X
Shepherd, Don L.	Operations Division/Chief Technician		X	

PERSONNEL CONTACTED DURING AUDIT				
NAME	ORG/TITLE	PRE-AUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Stanley, Cliff	LMITCO/RWMC/SWEPP Facility Engineer	X	X	
Tatkin, Tom	NMED/AIP/Observer	X		X
Tedford, Gina K.	LMITCO/SWEPP/WCO	X	X	X
Teton, Julie	TRUPACT OPS/Certification Specialist		X	
Torres, Kiki	LMITCO/RWMC OPS Supervisor	X		X
Tranter, Troy	ICPP-ACL/Radio Chemistry Analyst		X	
Twedell, Gary	RWMC/SWEPP/OPS Physicist		X	
Van Ausdeln, Leo	RWMC/Independent Calc Verification		X	
Wade, Jim	DOE-ID/RWMC Facility Engineer	X		X
Walker, Ben	EEG/Observer	X		X
Wander, Sandy	LANL/Observer	X		X
Warrant, Wade	ALD/VOC GCIMS Analyst		X	
Wells, Jerry L.	DOE-ID/TRU Waste Program Manager	X		X
Wells. Rita	RWMC/Software Engineer		X	
Wilde, Terry L.	1440 S & CL/CARE System Operator		X	
Williamson, Brandon I.	DOE-RFFO/Observer	X		
Winterbottom, Barry	TRUPACT OPS/OPS Specialist		X	
Winter, Marvin	ANL-W/TRUPACT Operations		X	
Zappe, Steve	NMED/HRMB/Observer	X		X

CAO Audit A-97-02 Detail Summary

Requirements Documents		No. of Proc.	No. of Pages	Concern Disposition				QA Evaluation		Technical
				CARs	CDAs	Obs	Rec	Adequate	Implemented	Effectiveness
QPP										
5.1.1	Organization	4	9			1			S	N/A
5.1.2	Qualification/Training	5	32	97-039	1, 2		1		S	N/A
5.1.3	Quality Improvement	6	33		3, 4, 5, 6, 7	2	2		S	N/A
5.1.4	Documents	8	33	97-040 97-041	27				S	N/A
5.1.5	Records	10	57	97-042	8	5	11		S	N/A
5.2.1	Work Processes	4	20			5			S	N/A
5.2.3	Procurement	5	28	97-043			3		S	N/A
5.2.4	Inspection/Testing	4	26						S	N/A
5.3.0	Assessments	9	32		9, 10	3			S	N/A
5.4.0	Sample Control	3	15						S	N/A
5.6.0	Software Control	8	60	97-044 97-045	11, 12, 13, 14		4, 5		I	I
QAPjP										
2.0	Program Demonstration Plan	3	18						S	N/A
3.0	Data Validation	16	49	97-046	15, 16, 17		6, 7		M	E
4.0	Acceptable Knowledge	1	4	97-047 97-048		4	8		S	E
5.0	Sampling Design	1	2						S	E
6.0	Drum/Sample Handling	2	18		18				S	E
7.0	Headspace Gas Sampling	6	30		19				S	E
8.0	Solids Sampling	2	19		20		9		S	E
9.0	Non Destructive Assay	2	13						I	I
10.0	Real Time Radiography	1	3						I	I
11.0	H_2/CH_4 Analysis	3	14		21, 22, 23				S	E
12.0	Gas VOC Analysis	2	20						S	E
13.0	Total VOC Analysis	5	24						S	E
14.0	Total Semi VOC Analysis	1	4		24				S	E
15.0	Total Metal Analysis	4	18						S	E
Site TRAMPAC										
Payload Control (Pkg, Ldg, Shpg)		5	30		25, 26	5	10		S	E
Totals		**120**	**611**	**10**	**27**	**5**	**11**	**Indeterminate**	**Satisfactory**	**Effective**

Definitions:

E = Effective
S = Satisfactory
I = Indeterminate
M = Marginal
N/A = Not Applicable
CAR = Corrective Action Report
CDA = Corrected During Audit
Obs = Observation
Rec = Recommendation