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United States Government **Department of Energy**

memorandum

Carlsbad Area Office
Carlsbad, New Mexico 88221

DATE: June 25, 1997

REPLY TO ATTN OF: CAO:NTP:RAS 97-1182 UFC 2300

SUBJECT: CAO Audit Report A-97-01

TO: Bruce LeBrun, LAAO

The Carlsbad Area Office (CAO) conducted an audit of your Quality Assurance (QA) Program for TRU waste characterization and certification activities in Los Alamos, New Mexico, on May 12-16, 1997. The audit team determined that the implementation of the LANL QA Program was marginal. The team was not able to make a procedural adequacy determination.

As a result of the audit, 10 Corrective Action Reports (CARs) were issued and 9 Observations and 14 Recommendations were identified. Observations 2, 4, 5, 7, 8 and 9 require a written response. The CARs were transmitted to LANL under a separate letter.

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

Don Watkins
Manager
National TRU Program

Attachment

cc w/attachment:
D. Brown, CAO
K. Hunter, CAO
R. Stroud, CAO
R. Paedon, CTAC
D. Winters, DNFSB
B. Walker, EEG
M. Eagle, EPA
J. Oliver, EPA
M. Gavett, LANL
P. Rogers, LANL
✓S. Zappe, NMED
C. Wentz, NMEM&NR
CAO QA File

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U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

AUDIT REPORT

OF THE

LOS ALAMOS NATIONAL LABORATORY
(LANL)

LOS ALAMOS, NEW MEXICO

AUDIT NUMBER A-97-01

MAY 12 - 16, 1997

TRU WASTE CHARACTERIZATION AND
CERTIFICATION PROGRAM

Prepared by: R. Dennis Brown **Date:** 6/20/97

R. Dennis Brown
Audit Team Leader

Approved By: Robert A. Stroud **Date:** 6/25/97

Robert A. Stroud
CAO NTP Certification Manager

1.0 EXECUTIVE SUMMARY

Carlsbad Area Office (CAO) Audit A-97-01 was conducted to evaluate the adequacy, implementation, and effectiveness of Los Alamos National Laboratory (LANL) characterization and certification activities. In addition, the audit scope included the verification of the completion and effective implementation of corrective actions for previous conditions adverse to quality identified by CAO.

The audit was conducted at the LANL facilities in Los Alamos, New Mexico on May 12 through May 16, 1997. The audit team concluded that the QA program was being marginally implemented in accordance with LANL implementing procedures. The team was not able to make an adequacy determination. For the technical areas evaluated, the LANL program was determined to be effective. The audit team also concluded that the corrective action for one previous CAO Corrective Action Report (CAR-96-082) in the area of records management was effective, and that the corrective action for one other CAR (96-081), in the area of procedure adequacy, was not fully effective.

The audit team identified ten CARs that require corrective action in the areas of training, procedure implementation, document review, data review, acceptable knowledge (AK), procurement, management assessment, and software control. Thirteen deficiencies requiring only remedial corrective actions were corrected during the audit (CDAs). Nine observations and fourteen recommendations are provided for management action and consideration. The audit team noted three exemplary practices by LANL. The CARs, CDAs, observations, recommendations, and exemplary practices are described in Section 6.0 of this report. LANL QA program adequacy will be addressed by the verification of the corrective action for previously issued CAR-96-081, prior to the next audit scheduled for later in the year.

2.0 SCOPE

The audit scope included the evaluation of the adequacy, implementation, and effectiveness of the technical and quality assurance activities as related to the LANL transuranic (TRU) waste characterization program, and a determination of the progress and status of the LANL certification program.

The following CAO QAPD elements were evaluated:

- Organization/QA Program Implementation
- Personnel Qualification and Training
- Quality Improvement
- Documents and Records
- Work Processes
- Procurement
- Inspection and Testing

Measuring and Test Equipment
Assessments
Sample Control
Data Documentation, Control, and Validation
Software Requirements

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

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

The following CAO Certification (WAC) technical elements were evaluated:

Waste Stream Profile Data Status
WIPP Waste Information System Data Status

The adequacy evaluations of LANL TRU Waste Characterization Program (TWCP) documents were 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

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

LANL Transuranic Waste Quality Assurance Project Plan, TWCP-PLAN-0.2.3-001, R.1

LANL Transuranic Waste Certification Plan, Revision 0, PLAN-CSTDO-004, R.0
Related LANL technical and quality assurance implementing procures

CAO Corrective Action Reports (CARs) from Surveillance S-96-48

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
Robert Paedon	Auditor, Audit Coordinator/CTAC, Sub-Team Leader
Rich Hicks	Auditor/CAO, Sub-Team Leader
Jeff May	Auditor/CTAC, Sub-Team Leader
John Ptacek	Auditor/CTAC, Sub-Team Leader
Sam Vega	Auditor/CAO
John Pelletier	Auditor/Technical Specialist/CTAC
Bill Weston	Technical Specialist/WID
Jim Bresson	Technical Specialist/CTAC
R. Vann Bynum	Technical Specialist/SAIC

EPA INSPECTION TEAM

Mike Eagle, EPA
James Oliver, EPA
Kyle Rogers, EPA
Howard Finkel, ICF Inc.
John Goode, A.T. Kearney
Paula Hugo, A. T. Kearney
Patrick Kelley, S. Cohen & Associates
Julie Shanahan, A. T. Kearney

OBSERVERS

David Ralston, DNFSB
Dermot Winters, DNFSB
Steve Zappe, NMED
David Baggett, NMED
Tom Tatkin, NMED
James Channell, EEG
Ben Walker, EEG

CAO MANAGEMENT REPRESENTATIVE

Don Watkins, CAO

4.0 AUDIT PARTICIPATION

Individuals involved in the audit are listed in Section 3.0 and Attachment 1. A preaudit meeting was held at the LANL TA48 Building 29 conference room on May 12, 1997. A daily debriefing was held with LANL management and staff to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the LANL conference room on May 16, 1997.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that the QA program was being marginally implemented in accordance with LANL 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 LANL program was effective. The audit team also verified the corrective actions for two previous CAO CARs. The audit team concluded that the corrective action for one previous CAO CAR (96-082), in the area of records management was effective, and that the corrective action for the other CAR (96-081), in the area of procedure adequacy, was not fully 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)

LANL participation in Cycle 9 of the Performance Demonstration Program (PDP) for Headspace Gas Analysis was evaluated. Performance of these activities, including sample chain-of-custody, analysis, data records packages, and final results were satisfactory and in accordance with required procedures. In addition, records packages for Non-destructive Assay PDP results were reviewed and were satisfactory. See Recommendation 7.

5.3.2 Acceptable Knowledge

The LANL AK procedure was evaluated for adequacy and implementation for the debris waste stream being generated at TA-55. Quality Procedure, QP-1.1-021, R.1, is the detailed document controlling the development of the AK. The audit team noted inadequacies in the AK procedure: it did not specify the responsible party(ies) for each of the tasks identified in the procedure; the Records section did not list the documents generated as a result of implementing the procedure; and the procedure had not received the approval of the Waste Certification Official as required.

The implementation of the procedure was satisfactory. However, the audit team noted that a crucial table within the AK documentation package was not substantiated by references. This situation was corrected and verified by the audit team during the audit. Overall the AK package was determined to be traceable and compiled into an auditable package.

The AK process was evaluated through review of the only AK documentation package generated to date, *Acceptable Knowledge Summary Report* dated May 7, 1997 and through interviews. The process was determined to be marginally effective. The AK package was determined to have two purposes: 1) to confirm/assign RCRA Hazardous Waste Codes and 2) provide isotopic distributions for use in Passive Active Neutron (PAN) to determine the specific radioisotope content. The AK package with respect to assigning RCRA Hazardous Waste Codes was found to be marginally effective. The AK information presented in the package was not sufficient to supply radioisotope data for use in PAN and to quantify radioisotope content. The processes which generate this waste stream include those that concentrate specific radionuclides, therefore the use of stream averages, corrected for decay, was determined to be unsatisfactory to support this application of AK. See CAR 97-050, 97-058, Observation 9, and Recommendation 14.

5.3.3 Data Validation, Usability, and Reporting

The process for data review, validation and verification at the data generation level and at the project level was evaluated by the review of completed data report packages. Eleven of fourteen packages, covering headspace gas analysis and RTR visual examination packages were reviewed. One headspace analysis batch data report missed the data generation level supervisory review. This oversight was not noted at the project level review. The remaining data packages were reviewed, validated and verified satisfactory. See CDA 13 and Observation 1.

5.3.4 Headspace Gas Sampling/Visual Examination

The sampling of two drums of TRU waste was witnessed during the audit. This sampling was performed in the Waste Characterization, Reduction, and Repackaging Facility (WCRRF) at Technical Area (TA) 50. The sampling personnel were observed collecting field blanks, field reference samples, performing sampling equipment leak checks, and obtaining actual headspace samples from TRU waste drums. The sampling personnel followed the written procedure and were found to be knowledgeable of the requirements. The sampling procedure was found to be technically satisfactory. See Recommendation 6.

5.3.5 Drum Handling and Sampling

The process for the handling and tracking of TRU waste drums was evaluated and determined to be effective in tracking the location of waste drums in the custody of the TWCP. The electronic inventory and tracking form used by the TWCP provides appropriate controls to ensure that the most current status of drums can be determined and the distribution is satisfactory to ensure that this information is available to those TWCP personnel who need the information. See Observation 8 and Recommendation 13.

5.3.6 Real Time Radiography

The Real Time Radiography (RTR) process was evaluated by the audit team. The team observed the performance of the RTR in the image intensifier mode (real time) utilizing the mobile RTR unit adjacent to the TA55 facilities. Operational checks of the system and several cycles of RTR for TRU drums were performed to demonstrate the operation. The audit team determined that the RTR process was effective. See CDA 8 and Recommendation 1.

5.3.7 Nondestructive Assay

The Non-destructive Assay (NDA) calibration and assay processes were evaluated by the audit team. LANL uses a mobile Passive Active Neutron (PAN) system for NDA. The assay operation is controlled and data are processed by the assay software and a series of integrated computer spreadsheets that allow an almost completely automated operation. The evaluation included observation of background and system operational checks, passive and active system operation verification checks, and the assay of TRU waste drums. In addition, assay data packages for batches completed to date were reviewed and discussed with the process technical lead. NDA processes were determined to be effective. See Observation 7 and Exemplary Practice 2.

5.3.8 Visual Examination

Observation of the visual examination performed by LANL was accomplished by viewing the visual examination demonstration. Visual examination was performed on the debris waste within one drum. The drum was sealed to a glove box and the contents emptied and examined by the visual examination expert. The technical procedures for this process were implemented effectively. See CDA 9 and Recommendation 8.

5.3.9 Headspace Gas Analysis Activities

The LANL headspace gas sampling and analysis activities were observed and evaluated. Sampling and analysis were conducted at the same location using gas-tight sample syringes and an "at-line" GC/MS analysis process. Sufficient procedures are in place and are being satisfactorily implemented. The Headspace Gas run logs and laboratory notebook were reviewed and found to be satisfactory. Drum headspace gas sample collection, GC/MS calibrations, gas analysis processes, QA sample analysis, maintenance of operating logs and run logs, and the data package contents are also being effectively implemented.

Six Record of Variances (ROVs) associated with the headspace sampling and analysis were reviewed to ascertain whether the technical justifications for the changes were adequately presented. Discussions with the Operations Leader confirmed that the changes had a satisfactory technical basis, but there was insufficient documentation presented in the ROV.

The data packages, Headspace Gas 1 and 2 and Hydrogen/Methane 1, were reviewed. The packages were assembled consistent with the procedure and easily traceable. One instance of the procedure not being followed was noted and the completion of the data review sheets requires improvement.

The audit team observed the analyst performing Headspace Gas Analysis (for both VOC's and hydrogen/methane). The analyst was very knowledgeable and performed the analysis in accordance with the procedure. The method used and the implementation were determined to be technically satisfactory. See CAR 97-049 and CDA 2, Observations 5 and 6, and Recommendations 5 and 11.

5.3.10 Software

The implementation and effectiveness of the software quality assurance process requirements for the control of software used for analysis, measurement and data activities were evaluated. The evaluation included a review and evaluation of the

software classification and code development processes, a review of the configuration management controls on completed software baselines, a review of controls on commercial spreadsheets, and the technical review process of completed software baselines. At the time of the audit, completed software life-cycle documentation was available for only two codes used in the certification and characterization process in the PAN and HGAS systems. Commercial spreadsheets were used with both of these processes.

A review and evaluation of the completed software baseline documentation for the PAN and HGAS systems was performed. The audit team concluded that the code classification, software baseline documentation, configuration management and testing activities were marginally effective. The overall effectiveness of the software QA processes was not determined because parts of the software control procedure had not yet been implemented (due to the recent issue of the procedure) and the limited number of completed software baselines. See CAR 97-052, CDA 6, and Recommendations 2 and 3.

6.0 CORRECTIVE ACTIONS, OBSERVATIONS & RECOMMENDATIONS

The audit team identified twenty three deficiencies during the audit, requiring the issuance of ten Corrective Action Reports; 13 deficiencies that required only remedial action were corrected during the audit (CDAs).

A brief description of the Corrective Action Reports are detailed below. The CARs have been transmitted under separate letter.

6.1 Corrective Action Reports

CAO CAR 97-049

Three Continuing Calibration Checks for Headspace Gas (HGAS) analysis were out of compliance with the performance criteria. No Nonconformance Report (NCR) was prepared, nor was a new five point calibration performed as required by the procedure.

CAO CAR 97-050

The acceptable knowledge (AK) for radionuclide distribution is not adequate to support the Passive Active Neutron assay to confirm the radionuclide inventory and to obtain the total activity in the TRU waste.

CAO CAR 97-051

The technical supervisory review for an HGAS data batch report was not documented on the data review checklist. The completed second level (project) review did not identify the absence of the supervisor review.

CAO CAR 97-052

Software code "EnviroQuant", used in HGAS analysis: was not installed in accordance with the installation and checkout (I/C) form; was not properly classified; and was "qualified for use" prior to the I/C form being completed. In addition, commercial software used in support of lab notebooks was not properly identified and documented.

CAO CAR 97-053

The documentation of initial training and retraining was not satisfactory to determine if training was up-to-date. Deficiencies in this area were identified during the LANL internal audit AA-2-97-07 (Finding Number 3) on April 7 -11, 1997, but they have not yet been addressed.

CAO CAR 97-054

Quality Procedures and Detailed Technical Procedures were not prepared in accordance with the requirements of the Quality Procedure.

CAO CAR 97-055

The management assessment which LANL conducted April 7 - 11, 1997 was not performed in accordance with the Quality Procedure requirements.

CAO CAR 97-056

Several deficiencies were identified in the implementation of the Nonconformance Report (NCR) process as required by the Quality Procedure.

CAO CAR 97-057

Procurement requirements were not fully implemented in accordance with the Quality Procedure.

CAO CAR 97-058

Sealed containers larger than four liters are prohibited waste items in accordance with the WIPP Waste Acceptance Criteria. The existing radiography data form used in the RTR process does not list sealed containers over four liters as a prohibited item and RTR and acceptance knowledge (AK) personnel do not check for this prohibited item.

6.2 Deficiencies Corrected During the Audit (CDA)

Those deficiencies that are considered isolated in nature and only require remedial action may be corrected during the audit. The following 13 deficiencies were corrected during the audit:

1. The audit team noted during the review of Grading Questionnaires that there was no objective evidence that the Site Project Manager (SPM) reviewed and approved the questionnaires as required by the Quality Procedure QP-1.1-029, R.0. In response the SPM prepared a memo stating that the SPM had reviewed and approved the grading levels by reviewing and approving the TWCP Matrix which includes the grading levels for the work breakdown structure (WBS). In addition, a Record of Variance (97-ROV-051) was prepared and reviewed by the audit team to revise the procedure to reflect this method of review rather than requiring the SPM to review and approve each individual Grading Questionnaire.

2. Table 1 of Technical Procedure DTP-1.2-018, R.0 lists the Program Required Quantitation Limit (PRQL) for m-Xylene and p-Xylene as 10 ppm each. The audit team determined that the data are being reported at a PRQL of 20 ppm for the combination of the two constituents. This could allow one of the constituents to be greater than the PRQL of 10 ppm. The audit team verified that none of the analyses had resulted in a total concentration of greater than 10 ppm, therefore the PRQL had not yet been violated. The audit team verified that the analysis reporting Form 1A was changed to reflect the appropriate reporting level of 10 ppm.

3. The audit team determined that three ROVs (ROV-97-022, ROV-97-024, and ROV-97-041) were not in the records file as required by the Quality Procedure. ROV-97-041 was located in the records office and placed in the ROV file. ROV-97-022 was determined to have become obsolete and was not approved. Cancellation of this ROV was noted on the ROV index. ROV-97-024 was determined to still be in the negotiation process with the procurement personnel.

4. Ten ROV forms reviewed by the audit team had Operations Leader/Supervisor signature blocks that were left blank instead of identifying the signature as "not applicable". LANL evaluated the ROVs and determined that the supervisor

review was not required. The audit team verified that these omissions were corrected and that each blank was annotated "N/A".

5. The audit team reviewed the NCR file for completeness and determined that on five of the 18 NCRs that had been issued, opaque tape had been used to apply type-written NCR identification numbers over existing hand-written identification numbers. This appeared to be a type of correction tape that is not allowed be used on QA records. The audit team verified that the tapes were removed and the assigned NCR identification numbers were entered into the appropriate block of the NCR form for all five NCRs.

6. Quality Procedure QP-1.1-006 specifies that the Software Configuration Management (SCM) Coordinator maintain a baseline software list for each applicable code, that the list be made available upon request, and that it contain specific information. Although a software baseline list had been prepared, the list dated 5/6/97 did not contain all required information and had not been made available to users (issued). The audit team verified the SCM Coordinator prepared and issued a revision to the baseline list that contained all of the required information.

7. Quality Procedure QP-1.1-003, R.1 requires that "training activities are documented with copies of training materials in the training files..." A review of training record files by the audit team identified isolated examples of missing or mis-filed materials. One file was missing a "required reading list", some files contained documentation that was applicable to another individual, and one file was missing a training exemption form. These omissions were corrected and verified by the audit team.

8. Technical Procedure DTP-1.2-008, R.2 requires that each RTR operator scan a training drum once each quarter, and that the videotape of the training scan be reviewed by a supervisor to ensure that operator's interpretations remain consistent and accurate. The lead RTR operator reviewed the videotape for all three qualified operators (as the supervisor), including his own training scan. This did not satisfy the requirement for supervisor review of the lead operator's videotape. During the audit, the lead operator's performance was evaluated and documented in a memorandum by the TRU Waste Project Leader.

9. The audit team noted during the review of the visual examination data package for batch LA97-3.4.1-001 that pages 14 & 20 referenced an NCR but did not identify the NCR by number. The Visual Examination Expert investigated the nonconformance and determined the NCR number. The addition of the NCR number was made to the record package and verified by the audit team.

10. During a review of the logbook for the RTR operation, the audit team noted that the use of the new revision to the RTR Technical Procedure was not identified in the logbook. This a specific requirement of Quality Procedure QP-1.1-012, R.2. The audit team verified that the correct revision of the Technical Procedure was being used so that the oversight in the logbook had no effect on the operation. The logbook was annotated and verified by the audit team.

11. Quality Procedure QP-1.1-007, R.2 requires that NCRs identify corrective actions to prevent recurrence. One NCR (97-018) did not identify corrective actions to prevent recurrence. The NCR involved computer system data backups. Corrective action had been taken but not annotated on the NCR. Corrective actions to prevent recurrence included the procurement of a "ZIP" drive for system backups and a modification to the procedure which requires daily system backups. The auditor verified that this information was added to the NCR.

12. Quality Procedure QP-1.1-002, R.1 requires the maintenance and updating of a Master Controlled Document List and a Master Controlled Document File. The Master Controlled Document List contained a small number of inaccuracies in the areas of current revision numbers and effective dates. The Master Controlled Document File had one document mis-filed and one document missing. The audit team verified that the Master List was updated and that the documents missing from Master Files were located.

13. Technical Procedure DTP-1.2-025, R.0, Headspace Gas (HGAS) Analysis Batch Data Report Preparation, Attachment I, requires that the HGAS Hydrogen and Methane Analysis data packages have a list of analytical batch samples. The audit team determined that the Hydrogen/Methane analysis packages contained only the associated VOC Analytical Batch Sample List which is not complete for the hydrogen/methane sample batch list. The audit team verified that this omission did not effect analysis results and that a hydrogen/methane sample batch list was placed in the existing batch files (#1, #2, and #3).

6.3 Observations

The following nine observations resulted from the audit and are presented to LANL management for consideration. Written response by LANL to Observations 2, 4, 5, 7, 8 and 9 is required

1. The HGAS Analysis Data Review Checklist in some cases utilizes check marks instead of a yes or no answer, leaving ambiguity as to what the reviewer's response was. The reviewers should provide a yes or no answer, or the checklist should be modified to have "yes" and "no" columns so that check marks are defined.

2. Data generation level review is not accomplished in accordance with Quality Procedure QP-1.1-011, R.2, but instead the data review is being accomplished in accordance with each specific technical procedure (for example DTP-1.2-008 and 025). As a result, some of the attributes of the Quality Procedure may not accomplished since they are not part of the DTPs. For example, data validation, quantitative determinations to the QAOs specified in the QAPP, and HGAS QA review are not included in the DTPs.

3. The "Training Requirements by Position" form used by LANL does not contain sufficient information to document the analysis of job positions. For example:
   - Several instances were identified where the forms were not clear or did not address all the training or certification/qualification requirements identified in the QAPP or the Methods Manual: for the Visual Examination Operator there was missing classroom training, missing evidence of an examination for certification, and missing apprenticeship requirements; for the Radioassay Operator there were several missing training items that are required in the Methods Manual (Section 9.2); and for the Acceptable Knowledge Expert the record did not clearly incorporate all QAPP training requirements (Section 4.4).
   - The form does not address minimum education, experience, and training prerequisites for initial entry into the position.
   - The process for using this form is not documented in the TWCP training procedure.

4. Standard certification and traceability information is not available for the hydrogen/methane standards gas, because no such material exists for the gas stock standard. Therefore the requirement for traceability to NIST SRM or NIST/EPA approved CRM can not be met. Technical procedure DTP-1.2-018, R.0 and the Methods Manual require that liquid stock standards "must be from pure standard materials or purchased as certified solutions." SW-846 Method 8260 on which the methods manual was based, has a more recent revision (Rev.1, September 1994). In the latest revision of 8260A, the requirement is that "commercially prepared stock standards may be used at any concentration if they are certified by the manufacturer or by an independent source." It appears that with the exception of the methanol used in the standard, documentation sufficient to satisfy the revised 8260A requirements may be satisfied.

5. Based on a review of the file of completed ROVs, the audit team determined that the ROVs frequently do not have sufficient detail to allow technically qualified personnel to understand the rationale for the variance and associated process change. This is particularly important when implementing a change based on an equivalent process or method. For example, one ROV that allows the use of the

syringe HGAS sampling method gives no details of why it was done or justification of it being an equivalent method. Also, the ROV that allowed the deletion of a field blank before each HGAS sample was not accompanied by a justification for the deletion.

6. Based on a review of HGAS lab notebooks and discussions with HGAS analysis personnel, the audit team determined that lab notebooks need to be more explicit and descriptive. The HGAS lab notebook did not contain sufficient information to allow an understanding or interpretation by knowledgeable reviewers. For example, the preparation of the calibration standard could only be ascertained by conversation with analysis personnel and knowing that the activity was actually being performed.

7. Based on a review of PAN system data the audit team noted that data indicates that Quality Assurance Objectives (QAOs) for precision and accuracy were satisfied in the active mode, but were not satisfied in the passive mode. Although passive assays have not been selected for record purposes in these ranges, it is only because the current software default settings select the active results in drums containing less than 10 grams Pu. However, more positive action needs to be taken to prevent the inadvertent assay of waste in a mode where the QAOs have not been met.

8. Technical Procedure DTP-1.2-020, R.0 requires that the location of the TRU waste containers be known. In the LANL system, the location of individual waste containers is determined from the most current revision of the Waste Container Tracking Form. However, the forms are frequently revised, and a forum revision number is not required. In order to assure the traceability of waste containers, the file name, revision number, and date that the form was revised should be included in the waste container tracking form.

9. Based on a review of the Quality Procedure for AK documentation, QP-1.1-021, R.1, and interviews with AK process personnel, several areas of improvement in the procedure were identified by the audit team. For example: Section 5 does not clearly address the responsibility of the preparer of the AK report, nor are the duties of the Newly Generated Waste Generators with respect to this procedure; and throughout Section 6, responsibilities for each step is not specified; and the process for amending AK records needs to be established and added to the procedure. In addition the Waste Certification Official is required to approve the AK procedure; this approval was not documented. A previously assigned RCRA Hazardous Waste Code was unassigned without sufficient documentation that the discrepancies process was followed.

6.4 Recommendations

The following fourteen recommendations resulting from the audit are presented for LANL management consideration:

1. The RTR operator manually enters the drum number into the video record with no cross-checking for transfer errors. Provisions are being made to directly read the bar-code label into the record. Until this upgrade is implemented, a second person should verify that the drum number was correctly entered.

2. It was noted that LANL uses a number of spreadsheet applications while performing waste characterization activities. It is recommended that Quality Procedure QP-1.1-006, R.4 "Software Management" be revised to include a reference to Quality Procedure QP-1.1-012, R.2 "Laboratory Notebooks and Logbooks" where these types of applications are implemented through the lab notebook of logbook.

3. It is recommended that AP-CST7 GRP-004, R.0 "Software Methodologies used by CST-7 in compliance with DOE Order 1330" be canceled and deleted from the LANL controlled documents list. LANL software requirements are implemented by Quality Procedure QP-1.1-006.

4. The checklist used for the site project quality assurance (SPQAO) project level data review of data batch reports should specify that this review includes checking two additional items: the APQQAO review of the generation level review independent review checklist; the QA validation checklist.

5. The process operators and analysts should be trained to use the same terminology in their logbook entries as is in the applicable technical and quality procedures. For example, the HGAS procedure refers to "field blanks" while the logbook refers to these samples as "ambient air".

6. Technical Procedure DTP-1.2-017, R.0 needs to be updated to reflect the current definition of "field duplicate" implemented by LANL.

7. Quality Procedure QP-1.1-022, R.0, specifies a review of PDP results. LANL stated that this is no longer required by the PDP plan, and it was not planned to perform the reviews. However, the LANL procedure has not yet been updated. It is recommended that LANL remove this review from their procedure or delete the procedure in its entirety and handle the PDP utilizing their existing procedures.

8. Visual Examination Reports are being used as addenda to the original Visual Examination Reports without consistently being identified as such. It is recommended that LANL develop a procedure for data package preparation that includes a requirement to annotate the Visual Examination Report used as addenda and the reason for the addenda.

9. Data summaries for visual examination generated at the project level use a matrix format. Matrix elements are frequently left blank. Interpretation of these blanks is left to the reader to decide if the data entry is zero, not applicable, or incomplete. It is recommended that blanks not be used in the data summary tables.

10. Technical Procedure DTP-1.2-0025, R.0, for Headspace Gas Analysis Batch Data Report Preparation, provides a checklist to ensure that all required data sheets are included in the batch data report. The Form 7A, "Continuing Calibration Form", should be included in the batch data reports for Headspace Gas VOC Analysis, but is not included on the checklist. It is recommended that the checklist be revised to include the Form 7A.

11. The Run Logs for HGAS analysis do not consistently contain a unique identification of the calibration standards used. The Run Logs should include this information to be consistent with the need to identify consumable standards.

12. TWCP training records contained objective evidence demonstrating compliance with training requirements, but the information was not compiled in a way that was easy to verify. In many cases, the satisfaction of a training requirement could only be determined based on interpretation of the material provided (title of classes on attendance sheets, title of procedures on reading assignment lists, etc.) and input from the training coordinator. The following improvements are recommended: organize training records to clearly demonstrate the satisfaction of specific training requirements; classroom training, certification/qualification requirements, on-the-job training, apprenticeships, and site specific training; clarify the relationship between the required training and the training received using a matrix presentation; consistently use training plans. These plans should be detailed enough to clearly show that requirements are being satisfied; and revise certification documentation to address satisfaction of all requirements.

13. Technical Procedure DTP-1.2-020, R.0 identifies the Waste Container Tracking (WCT) form as a QA record. This form is new and its use has been limited and retention of the forms as QA records has not yet been fully initiated It is recommended that a specific records package be opened and existing WCT forms be routed to the records center for retention.

14. The audit team recommends the following improvements in the AK process: an evaluation of procurement records should be included in the AK process; the preparer of the AK package should ensure that the experiences of the personnel interviewed cover the entire range of time covered by the AK; the AK interviewer should provide the interviewee with a summary of RCRA regulated items (e.g. RCRA code listings) as a "refresher" before conducting the interview.

6.5 Exemplary Practices

1. The area of TWCP quality records management has progressed significantly towards a fully documented and effectively implemented process since the last CAO evaluation. The records system now in place is effective in implementation of quality requirements.

2. Non-destructive Assay (NDA) calibration and qualification of the mobile PAN system have been performed in a professional manner. New techniques have been developed to evaluate PAN performance reliability, (e.g. to identify indications of changes in PAN performance). Work continues to qualify the Gamma Tomographic Scanner and the High Energy Neutron Counter (HENC) as acceptable assay devices. The PAN, HENC, and Gamma Scanner have successfully performed in the NDA PDP. The Gamma Scanner will become more important as the need to identify isotopic ratios increases.

3. The audit team noted that significant progress has been made since the last CAO evaluation towards the full implementation of the TWCP Quality Assurance Program. Quality and technical procedures have been revised and improved. Personnel have been trained and characterization processes have been established in accordance with procedures. With the resolution of the items cited in this report, the program should be fully implemented and effective.

7.0 LIST OF ATTACHMENTS

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

NAME	ORGANIZATION	A	B	C
Dave Baggett	NMED	X		X
Tom Tatkin	NMED	X		
Kyle Rogers	EPA	X		X
Ines Triay	LANL	X	X	X
Bruce LeBrun	DOE-LAAO	X		X
Patrick Kelly	SC&A/EPA-ORIA	X		
Howard Finkel	ICF/EPA-ORIA	X		X
Paula Hugo	A. T. Kearney	X		
Julie Shanahan	A. T. Kearney	X		
James M. Channell	EEG	X		X
Ben Walker	EEG	X		X
Marty Mitchell	Weston FMU 64 QA	X		
Frank Primozic	FMU-64 QA BEC	X		
Kristen Schlesser	CST-7	X	X	X
Rick Stupka	CST-7 WACO	X	X	
George Vigil	CST-7	X	X	X
David Yeamans	Visual Exam. Ops. Leader	X	X	X
Joe Sowers	CST-7 QA	X	X	X
Jack Vigil	CST-7 NDE	X	X	X
Sandy Wander	CST-7 QA	X	X	X
Florie Caporuscio	Benchmark	X		
Don Langmuir	Outside Consultant	X		
Greg Choppin	Florida State University	X		
Chris Leibman	CST-12	X	X	
Leo Beckstead	CST-7	X		X
Fabiola Lucero	CST-25	X	X	X
David Janecky	CST-7	X	X	X
Gene Mroz	CST-7	X	X	X
Dan Taggart	CST-7	X	X	X
Johnny Harper	CST-7	X		
Steve Zappe	NMED/HRMB	X		X
Steve Yanicar	NMED/DOE OB	X		X
Ken Hargis	LANL EM/WM	X		X
Marta Oakley	LANL AA-1	X		
Cathy Stanhope	(LANL) CST-7	X	X	X
Derek Harris	ESH-1	X		
Bob Weeks	CST-25	X		
Loren Abercrombie	CST-25	X		X
Dennis Brown	DOE-CAO	X		

NAME	ORGANIZATION	A	B	C
Butch Stroud	DOE-CAO	X		X
Jeff May	CTAC	X		
John Pelletier	CTAC	X		X
Don Watkins	DOE-CAO	X		X
Tom Todd	DOE-LAAO	X		
Vann Bynum	SAIC	X		X
Bill Weston	Westinghouse/WID	X		X
Rich Hicks	CTAC	X		X
Mike Eagle	EPA	X		
Robert Paedon	CTAC	X		X
John Goode	A. T. Kearney/EPA	X		
Jim Oliveo	U9 EPA	X		
Samuel Vega	DOE-CAO	X		X
Pamela Rogers	LANL, CST-7	X	X	X
Marji Gavett	LANL, CST-7	X	X	X
Marshall Maez	LANL-NMT-7	X		X
John Ptacek	CAO/CTAC/QA	X		X
Linda Cox	CST-7	X		
Lee D'Anna	AA-1			X
Bob Weeks	CST-25			X
Michael Le Scovarnec	NMED/NRMB			X
Tim Michael	DOE-OB/NMED			X
James Bresson	CTAC			X
Andrew Montoya	LANL			X
K.M. Gruetzmacher	LANL			X
Dave Martinez	LANL/CST-7 NDE		X	
Krystyna Dziewinska	LANL		X	
Ricky Buros	LANL/CST-7		X	
C. Fresquez	LANL/BJS		X	
A. Gavler	LANL/ESH-9		X	
T. Moxley	LANL/ESH-9		X	
Flavio Martinez	LANL/CST-7 NDE		X	
Carlos Rael	LANL/CST-7 NDA		X	

CAO AUDIT A-97-01 DETAIL SUMMARY

REQUIREMENTS			DISPOSTION				EVALUATION		
PROGRAM ACTIVITIES	Procedures	Checklist Pages	CARs	CDAs	Obs	Rec	Adeq.	Impl.	Effect.
Organization/QA Program	QP-1.1-029	8		1				S	
Qulification/Training	QP-1.1-003	4	97-053	7	3	12		M	
Quality Improvement	QP-1.1-007	4	97-056	5,11				M	
	QP-1.1-008	4							
	QP-1.1-009	3							
	QP-1.1-019	3		3,4	5				
	QP-1.1-020	2							
	QP-1.1-026	3							
	QP-1.1-030	4							
Documents	QP-1.1-001	4	97-054					M	
	QP-1.1-002	2		12					
	QP-1.1-017	3							
Records	QP-1.1-004	3						S	
Experiment (Notebook & Logbook)	QP-1.1-012	4		10	6	5,11		S	
Procurement	QP-1.1-005	8	97-057					M	
Inspection/Testing	QP-1.1-016	3						S	
Measuing & Test Equipment	QP-1.1-018	7			4			S	
Assessments	QP-1.1-013	15	97-055					M	
	QP-1.1-027	4							
Data Documentation	QP-1.1-010	3				4		M	
	QP-1.1-011	6	97-051		2				
	QP-1.1-023	4							
	QP-1.1-024	1							
	QP-1.1-028	1							
Software Control	QP-1.1-006	15	97-052	6		2,3		M	

CAO AUDIT A-97-01 DETAIL SUMMARY

REQUIREMENTS			DISPOSTION				EVALUATION		
TECHNICAL ACTIVITIES	Procedures	Checklist Pages	CARs	CDAs	Obs	Rec	Adeq.	Impl.	Effect.
Program Demonstration Plan	QP-1.1-022	2				7			E
Acceptable Knowledge	QP-1.1-021	9	97-050 97-058		9	14			M
Data Validation	DTP-1.2-025	Procedure		13	1	10			E
Sampling Design	DTP-1.2-013 DTP-1.2-014 DTP-1.2-015	1 3 5							E
Drum/Sample Handling	DTP-1.2-020	5			8	13			E
Headspace Gas Sampling	DTP-1.2-017	3				6			E
Real Time Radiography	DTP-1.2-008	8		8		1			E
Non-destructive Assay	DTP-1.2-009 DTP-1.2-010	7 3			7				E
Visual Examination	DTP-1.2-001 DTP-1.2-002	8 5		9		8, 9			E
Headspace Gas Analysis	DTP-1.2-006 DTP-1.2-018 DTP-1.2-019	6 2 2	97-049	2					E
Software	QP-1.1-006	13							I
TOTALS/OVERALL EVALUATION	41	196	10	13	9	14	I	M	E

CAR..... Corrective Action Requests
Recs..... Recommendations
OBS..... Observations
Adeq..... Adequacy
Impl..... Implementation
Effect ..... Effectiveness

CDAs.....Corrected During Audit
S.....Satisfactory
M.....Marginal
E.....Effective
I.....Indeterminate