



Audit Report Number 91A-011

Dates of Audit 8/25-29/91

Audit Subject INEL Activities

EG&G Idaho and ANL-West

WIPP Library

**WASTE ACCEPTANCE CRITERIA
CERTIFICATION COMMITTEE**

AUDIT REPORT

WIPP PROJECT OFFICE

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Date

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AUDIT OF THE TRU WASTE CERTIFICATION ACTIVITIES
IDAHO NATIONAL ENGINEERING LABORATORY
AUGUST 25-29, 1991

I. INTRODUCTION

This report presents the results of the audit conducted by the Waste Isolation Pilot Plant (WIPP) Waste Acceptance Criteria Certification Committee (WACCC) at the Idaho National Engineering Laboratory (INEL) on August 25-29, 1991.

Specifically, the audit included the characterization and repackaging activities of contact-handled transuranic (TRU) waste by Argonne National Laboratory-West (ANL-W) and EG&G Idaho, Inc. (EG&G), prior to shipment to WIPP as part of the WIPP Pretest Waste Characterization Program.

The audit team was composed of: Les Gage, DOE/AL, Lead Auditor; Jim Hines, DOE/AL, Associate Lead Auditor; members of the Westinghouse Waste Isolation Division Staff, and specialists from contracted consulting organizations. Audit observers included: Dr. Elizabeth Gordon and Dr. Gilbert Gonzales, State of New Mexico Environment Department; Tony Gallegos, Environmental Evaluation Group; Mark Duff, DOE/HQ Waste Management Projects; Don Engelman and Darrell Hinckley, DOE/ID; Hal Davis, DOE/WIPP, Chairman of the WIPP WACCC; and specialists from consulting organizations.

The audit consisted of interviews, tours of the EG&G and ANL-W facilities, and document reviews -- each of which presented opportunities for verification of adequate program implementation. The scope of the audit is summarized in Section II, and an executive summary is provided in Section III. Audit findings and observations are detailed in Section IV. The status and adequacy of corrective actions to previous audit open items were reviewed and are detailed in Section V.

An opening meeting was held on August 25, and it was attended by members of the audit team, observers, and personnel from EG&G and ANL-W. The close-out meeting was held on August 29 to present preliminary findings and observations as well as status of previous WACCC audit open items. Attendees from the opening meeting were present for the close-out meeting.

II. AUDIT SCOPE

The audit was performed to evaluate INEL compliance with the following documents:

1. The INEL EGG-WM-9526, "INEL Project Office Quality Assurance Project Plan," (QAPJP), dated July 23, 1991.
2. The INEL EGG-WM-9527, "Radioactive Waste Management Complex Quality Assurance Project Plan," (QAPJP), dated July 23, 1991.
3. The ANL-W WO660-0038-QP, "Analytic Laboratory Quality Assurance Project Plan," (QAPJP), dated July 23, 1991.
4. The ANL-W WO096-0042-ES, "Hot Fuel Examination Facility Quality Assurance Project Plan," (QAPJP), dated July 23, 1991.
5. The INEL EGG-WM-9570, "Environmental Chemistry Unit Quality Assurance Project Plan," (QAPJP), dated July 23, 1991.

An additional audit-team task was to evaluate the INEL responses to selected findings and observations (deemed to be of immediate concern, by the WIPP WACCC) that resulted from the previous audit (WACCC 91A-009), at the INEL facility, on August 12-15, 1991. These findings and observations were the following items identified in the audit report: paragraph numbers IV.2.1; 2.2; 2.3; 2.4; 2.5; 2.6; 2.7; 2.8; 2.9; 3.2; 3.4; 3.6; 3.11 through 3.15; 3.17; 3.18; 3.19; and 3.20.a, c, and d (from the August 12-15 audit report).

III. EXECUTIVE SUMMARY

This audit of the INEL facility was performed prior to the first scheduled shipment of TRU waste to the WIPP. It resulted in 10 findings and 48 observations.

In general, the findings and observations are the result of a lack of (or an incompleteness in) procedures. The procedures are considered necessary in order to insure complete and repeatable actions to comply with WIPP requirements.

None of the items found by the audit team were determined to be "critical impactors": conditions which could result in the cancellation of the first planned shipment of TRU waste to WIPP. (See Section IV 1.0 - Definitions)

All of the INEL corrective actions for the immediate-concern audit findings and observations from the audit of August 12-15 were evaluated. All were determined to be satisfactory. Five of the corrective actions (2 findings and 3 observations) had not yet been completed; the incompleteness of each was evaluated, and it was determined not to be an item which could result in the cancellation of the first planned shipment of TRU waste to WIPP.

IV. DEFINITIONS: AUDIT CRITICAL IMPACTORS, FINDINGS, AND OBSERVATIONS

1.0 Definitions

CRITICAL IMPACTORS (CI)

A critical impactor is a condition which can result in the cancellation of a planned shipment of a bin of TRU waste to the Waste Isolation Pilot Plant (WIPP). The conditions that can result in an audit item being defined as a critical impactor are:

- o The records, or the systems which produce the records, do not support a conclusion that the WIPP waste acceptance criteria have been met.
- o The records, or the systems which produce the records, do not support a conclusion that the "No Migration Determination" requirements have been met.
- o There is documented evidence of deliberate fraud or malfeasance in the production of the data audited, relevant to the shipment of a bin of TRU waste.

FINDING (F)

A finding is a direct noncompliance to a program or procedural requirement which, if left uncorrected, could result in questionable waste shipments or possible violations to environment, safety, or health. It requires a response consisting of root cause, corrective action, and action to prevent recurrence. Action to prevent recurrence should be a solution to the root cause. Because the audit was a sampling of the activities, findings may be symptomatic of more extensive problems. Therefore, when the auditee investigates findings and develops corrective action, the entire program should be considered.

OBSERVATION (O)

An observation is a weakness or problem which, if left uncorrected, could become a significant condition adverse to quality. It also requires a response consisting of root cause, corrective action, and action to prevent recurrence. Action to prevent recurrence should be a solution to the root cause. Because the audit was a sampling of the activities, observations may be symptomatic of more extensive problems. Therefore, when the auditee investigates observations and develops corrective action, the entire program should be considered.

2.0 Critical Impactors (CI)

None of the items found by the audit team were determined to be critical impactors.

3.0 Findings (F)

3.1 Radioactive Waste Management Complex (RWMC) Area

3.1.1 Assay Data Accuracy (F)

No documentation was available to identify accuracy of the assay data. In addition, no documentation was available to trace sources to NIST.

DISCUSSION

Section 3.1 of the QAPjP requires the accuracy of the assay be known within $\pm 0.5g$. (95% confidence level) per waste drum for replicate processing and for waste drums containing approximately one gram of weapons grade material with guidelines on precision stated in Table 3.1. Section 6.2 of the QAPjP requires the calibration standards be prepared from primary standards traceable to the National Institute of Standards & Technology (NIST) when available. If not available, the actual standards shall be calibrated against primary standards traceable to NIST.

3.2 Environmental Chemistry Unit (ECU) Area

3.2.1 Bin Headspace Sampling Equipment (F)

The bin headspace sampling equipment does not contain a temperature sensor.

DISCUSSION

The QAPjP, Section 4.3.2, page 29 states:

"Bin headspace sampling equipment consists of a timer, ambient pressure and temperature sensors, a pump, flow controlling device(s), a flow-indicating device, valves, a pneumatic recirculation loop, sample canister(s), and pressure regulating equipment."

3.2.2 Canister Cleaning Oven Thermocouple (F)

The canister cleaning oven has a digital read-out display of the oven temperature. The oven has also been used for thermal equilibration of sample canisters prior to laboratory analysis. The temperature measurement had not been certified, nor has its NIST traceability been established.

DISCUSSION

The QAPjP, Section 6.2.3.2, requires that the temperature measurement be certified, traceable to NIST standards.

3.2.3 Computer Software Validation (F)

Computer software is utilized for data analysis, as required by the QAPjP. However, the software has not been tested.

DISCUSSION

NQA-1, Supplement 11S-2 (Supplementary Requirements for Computer Program Testing), requires that computer software be tested and documented.

3.2.4 Records for the Preparation of Standards (F)

In tracking the preparation and storage of analytical standards, a number of conditions were observed wherein activities were not completely performed and documented or were performed too late to accomplish their intended purposes. These activities included incomplete labels on standards, failure to keep preparation details in a bound notebook, failure to review preparation data in a timely fashion and failure to maintain records to show tracibility of analytical standards to EPA and NIST. The most common labeling deficiency was the failure to indicate an expiration date. (The printed labels clearly indicated the need for one.) Details of preparation are not being kept in a bound notebook

as required by the QAPjP, Section 6.4.4. (They are instead kept on forms in a three-ring binder (Notebook 9).) In addition, some of the details specified in Section 6.4.4 are not recorded on the same forms, but are cross-referenced to a database of chemicals procured.

DISCUSSION

The forms used in Notebook 9 have places for the analyst's signature and that of a witness. Instances were found where the signature of the witness was dated days or weeks after the actual standards preparation. In a few cases, even the analyst's signature was not dated the same day as the preparation. For example, the forms for the standards used in the method performance demonstration, VQA-WP-6-09-77 and -78, were not witnessed until August 20, 1991. The analyses had been completed by August 14. In another case, standards were prepared and used over a three-week period (April 29 - May 22, 1991) before any were witnessed. The requirement for witnessing of calculations by personnel other than those performing the original calculation of analytical data is referenced throughout the QAPP, QAPjP, and ECU QAPP, but the implementation of this specific form is not discussed in any document reviewed during the audit. (However, no instances of errors in the calculations were noted.) Attempts to trace standards back to the original certification of analysis for several standards as required in QAPjP, Section 6.4.1, was not accomplished due to the inability to find the records in the ECU file system.

3.3 ANL-W Analytical Laboratory

3.3.1 IIR Responsibility (F)

The Independent Technical Reviewer (IIR) action was identified as non-compliant with the QAPP and QAPjP requirements. In the below-referenced data package, the NO_x analyst signed off for the IIR (which is non-compliance) and provided review for the Quality Assurance Reviewer (QAR) (which is not NQA-1 accepted practice).

DISCUSSION

For bin data package (IDRFBN9100001, Vol. 1, dated August 22, 1991) the NO_x analyst also provided the IIR and QAR sign-offs. This action is prohibited by Section 8.0 of the QAPP, Section 8.2 of the QAPjP, and Section 2.3 of WO660-0034-OP. Discussions with the ANL staff indicated that a different laboratory staff member

conducted the ITR review for NO_x and Gas Chromatography, and that the data package will be amended to reflect this condition. A related problem was also found: No updated procedure exists to complete the data package and assure that the ITR responsibility is adequately maintained and documented in the data package.

3.3.2 Field Reference Standard (F)

A field reference standard was not provided and analyzed as part of the bin #1 head space gas sample, which is required by the QAPP and the QAPjP. This deficiency was not identified in either a variance or IDR (Inspection/Disposition Report) within the bin data package (IDRFBN9100001 Head Space, dated August 22, 1991).

DISCUSSION

A minimum of one field reference standard is required for each bin head space sample, as identified in the QAPP, Section 9 (Table 9.3) and the QAPjP requirements (Section 8.3). Additionally, the ANL data packages shall contain (for a single bin data associated with field blanks) LCSS and QA/QC samples. Discussions with the AL staff indicated they expected to receive field reference samples from EG&G but had only received the field blanks and actual samples. No apparent procedure exists to identify this non-compliance nor take corrective action to assure the QAPP/QAPjP requirements are implemented. In addition, the process and procedures for identification of this deficiency and the issuance of a variance and/or an IDR is not in place to assure the data package reflects a condition where field reference standards were not performed.

3.4 ANL-W Hot Fuel Examination Facility (HFEF)

3.4.1 Document Control (F)

The HFEF document control system is in noncompliance with the QAPjP requirement to approve documents important to QA prior to formal implementation.

DISCUSSION

Section 1.4.1 of the QAPjP, Revision 00, requires that documents important to QA be approved prior to formal implementation. Discussions with HFEF staff and review of QA records indicated that an unapproved draft of OMM 6825, "WIPP," has been used consistently to receive waste drums and associated documents and to generate data while performing characterization of WIPP test waste.

3.4.2 Design Control (F)

The HFEF design control system is in noncompliance with the QAPjP requirement to control designs with Fuel Cycle Division (FCD) Engineering Practices and with the FCD QA Program requirement for designation of quality levels.

DISCUSSION

Section 1.5 of the QAPjP, Revision 00, requires that the design of items be controlled in accordance with the FCD Engineering Practices and the FCD QA Program. Discussions with the HFEF engineering staff indicated that designs had been performed, but the FCD Engineering Practices had not been approved for use. In addition, Section 2.4 of the FCD QA Program requires that quality levels of items be classified either "A", "B", or "C" (and Section 3 defines these levels). Discussions with HFEF engineering staff and examination of design documents indicated that design levels had been designated as "vital" or "non-vital" instead of the required "A", "B", or "C".

3.4.3 Evaluation and Close-out of Noncompliances and Nonconformances (F)

The HFEF internal assessment system has no formal means to ensure that identified noncompliances and nonconformances are evaluated for significance and properly closed out in accordance with QA program requirements.

DISCUSSION

Section 10 of the QAPjP requires that internal assessments will be performed periodically and corrective actions made. An assessment was performed and documented on a memorandum from K. Miyaski to C. C. Dwight on August 22, 1991. There were three procedural noncompliance documents, two with OMM 6801 and one with OMM 6813. These were not identified on the memo as nonconformances or noncompliances, and no follow-up action was requested on

the memo. Discussion with the HFEF QA and coordination staff indicated that the noncompliances were not reported on Inspection/Disposition Reports, nor was there any other correspondence to ensure follow-up actions. In addition, the staff indicated that there is no formal system in place to ensure that nonconformances and noncompliances identified by internal assessments are evaluated for significance and properly closed out in accordance with QA program requirements.

4.0 Observations (O)

4.1 Radioactive Waste Management Complex (RWMC) Area

4.1.1 Procedure Reference (O)

The SWEPP procedure DOP-RO-4.2.4 TRUPACT-II Receipt, Inspection, and Loading Operation contains a reference to RWMC procedure PD-RS-3.1, "Logkeeping Practices and Checklists." The RWMC procedure PD-RS-3.1, however, has been canceled.

DISCUSSION

Procedure DOP-RO-4.2.4 must have the canceled procedure reference removed. If a different procedure dealing with logkeeping and checklists is to be substituted, the text of DOP-RO-4.2.4 must be reviewed to ensure text compatibility.

4.1.2 Responsibilities of Certification Specialist/Certification Official (O)

The SWEPP procedures DOP-RO-4.2.4 TRUPACT II Receipt, Inspection and Loading Operation and DOP-RO-4.2.5 TRUPACT II Payload Assembly contain a reference to RWMC procedure PD-RS-1.2, "RWMC/SWEPP Operation Responsibilities" which contains the responsibility for the Certification Specialist (CS) but does not contain the responsibilities for the Certification Official (CO). Procedures DOP-RO-4.2.4 and DOP-RO-4.2.5 also contain a step for CO sign-off. This falls within the listed responsibilities for the CS.

DISCUSSION

The step needs to be changed from CO to CS sign-off to remain consistent with the responsibilities identified in PD-RS-1.2 for the CS.

4.1.3 Translation of QAPjP Requirements into
Implementing Documents (O)

The following RWMC QAPjP requirements are not contained in implementing documents:

- a. RWMC QAPjP
Section 1.5: The following records generated by the SWEPP shall be retained in accordance with RWMC PD-RS-8.2, "WIPP Experimental Program Record Management and Retention."
 - o RA data form
 - o RTR videotape
 - o Reports
 - o Reference materials relevant to this project
 - o Dosimetry records
 - o Data reduction, validation, and reporting records

- b. RWMC QAPjP
Paragraph 6: Calibration records kept in the project files should include the revision number of the calibration procedure.

- c. RWMC QAPjP
Paragraph 10.2: A quarterly review of the program shall be performed by the RWMC Quality Engineer, as identified in RWMC PD-RS-5.7, "Quality Program Monitoring and Surveillance."

- d. RWMC QAPjP
Paragraph 13.1: Verify that the nonconformance request (NCR) includes action to prevent reoccurrence.

- e. RWMC QAPjP
Paragraph 14: The RWMC Quality Engineer summarizes, in a monthly report to the INEL Project Office, the following:
 - o Number of containers examined or shipped during the reporting period

- o Estimated exposure of facility personnel as a result of the project
- o Changes in this QAPjP
- o Significant QA/QC problems, recommended solutions, and results of corrective actions
- o Discussion of whether or not the QA objectives were met and the resulting impact on decision making
- o Limitations on use of the measurement data
- o Nonconformance Report
- o Results of audits and surveillances
- o Summaries of radioassay QC data
- o Deficiencies

4.1.4 Training Records (O)

A review of the qualification/training records of RWMC health physics and radiological engineers indicated that a Ms. MacLeod had an incomplete "new employee" checklist.

DISCUSSION

The training manual defines an individual as qualified as someone who "has demonstrated and documented possession of experience, physical attributes, training, knowledge, and skills required to perform a specific function." In an 8/20/91 Interoffice Correspondence, Ms. MacLeod was cited as being "qualified" to review and sign RWMC/SWEPP documentation for ... the Radiological Safety Discipline. She had signed off on a DOP on 2/21/91 (4.0 SWEPP, 4.3.1 "Experimental Waste Retrieval Operations"). However, the training manual only allows two months for a new employee at the RWMC facility to complete the checklist. Ms. MacLeod has been at the facility for at least six months (2/21/91 - 8/27/91).

4.1.5 Operations Procedure DOP-RO-4.3.1 (O)

This SWEPP operations procedure presently contains inconsistent text, resulting from incorrect incorporation of changes resulting from two document reviews.

DISCUSSION

Procedure DOP-RO-4.3.1 underwent a revision in 4/91. The original revision, a red-lined copy of the 2/21/91 issue, was attached to the Document Revision Request (DRR) as the revision instructions. Subsequent to the issuance of the DRR, additional black-line changes were added to the red-lined copy without deleting non-applicable text or (amending the DRR). As a consequence, the current issue of procedure DOP-RO-4.3.1 contains inconsistent text.

4.1.6 Radiation Source Traceability (O)

The traceability of the following radiation sources (used to calibrate the RWMC radiation detection instrumentation) to the National Institutes of Standards & Technology (NIST) was not available for review:

1. Cesium 137 source used to calibrate the beta emitting Chlorine (# H-7CL003 and H-7CL004), Technetium (# H-1TC002), Strontium (# H-1SR002), and Cesium (# H-2CS002, H-2CS003 and H-2CS007) sources.
2. Cobalt 60 source used to calibrate the two Cobalt sources used (# H-2C0005 and H-2C0006).

4.1.7 Content Code Correction (O)

A drum designated for bin #2 had raschig rings and a bag of absorbed material. The basis for changing the content code is 50% of contents. The question raised "was it content volume or content weight"?

DISCUSSION

Procedure 3.1 defines the criteria for assigning a correction of the content code. The basis is stated as 50% of contents. The EG&G past practice was based on volume. To ensure consistent interpretation in the future, DRR #WM-RW-229 was issued to clarify it was waste volume.

4.1.8 Data Clarifications (O)

Data clarifications, issued to clarify questions raised during project data package review, were not added to the master Detailed Operator Procedure (DOP) that documented the RTR examination.

DISCUSSION

The clarifications issued to resolve the differences observed on the videotape and the data package were not added to the master DOP. For example, the data package indicated 80 pints and the videotape showed 800. Eighty pints was the correct value. (The software for the RTR incorrectly moved the decimal point.) The software deficiency has been corrected and documented to prevent reoccurrence. Adding the clarifications to the DOP maintains documentation of the changes in the master procedure.

4.2 Environmental Chemistry Unit (ECU) Area

4.2.1 Approved Procedures Not Part of Controlled Documentation (O)

Approved procedures, listed in the QAPjP, for:

- a. procurement
- b. document control
- c. record and data archiving

are not a part of controlled documentation.

DISCUSSION

The ECU QAPjP, Section 1.3, states that controlled procedures will be used for ECU Operational SOPs involved in the WIPP Program. The QAPjP, Section 1.6.2 references Table 1-6, which lists the ECU SOPs involved. Also, Table 1-5 lists Project Directive WETP-PD-14 for procedure transmittals to the Site Project Office for record files. This PD has not been issued yet.

4.2.2 Quarterly Reading Notebook (O)

The requirement listed in ECU SOP 1.7.3, "Quarterly Reading Notebook" for the routing of the notebook during the first month of each quarter was not accomplished.

DISCUSSION

Two Quarterly Reading Notebooks were reviewed. The dates of these notebooks were 11/90 and 4/91. The 4/91 notebook record cannot be located to verify that required review has been accomplished within three working days, as required by SOP 1.7.3. (The routing process should have begun in July 1991.)

4.2.3 Signed-off Data Packages (O)

Data packages were reviewed, and packages #910070 and #910057 were not signed off.

DISCUSSION

Section 8.2.1 of the QAPjP states that "all original data shall be signed and dated in ink."

Note: This may be an isolated instance. EG&G has signed off all other data packages that were audited.

4.2.4 Training for Servicing Personnel (O)

There was no documentation to verify that personnel performing servicing functions (maintenance or repairs) have received training to qualify them.

DISCUSSION

The QAPjP, Section 11.6.3, page 108 states:

"If service repair is to be conducted in-house, then staff shall be adequately trained to provide that service. Adequate training and experience is a prerequisite before any in-house ECU staff member attempts repair."

4.2.5 Records Storage (O)

A procedure, covering proper storage of records, has not been issued.

DISCUSSION

NQA-1 requires that, prior to storage of records, a storage procedure must be prepared. The minimum requirements are specified in Supplement 17S-1.

4.2.6 Flammability Testing (O)

Calibration of the flammability analysis instrument is not complete.

DISCUSSION

The flammability analysis instrument has been delivered to the ECU. Two flammable standards have been ignited in the instrument. However, per the QAPjP, Section 6.2.4.2 and Table 6.3, a calibration curve must be run. This has not been accomplished.

4.2.7 Reporting of Nonconformances (NCRs) (O)

Nonconformance Reports are not being reported in complete accordance with the requirements.

DISCUSSION

The ECU QAPjP, Section 13.2.2.1 (Initial Actions for Nonconformance), page 129, dated July 23, 1991, states:

"When a nonconforming result is discovered or suspected, the occurrence shall be reported immediately and the details of the event noted in a laboratory notebook. Since the source of the nonconformance may be found at various stages throughout the analytical process, notations in addition to lab notebooks are required. The ECU Nonconformance Event Review Report (NERR) (Figure 13-1) is the required report."

The following data was reported for the sampled NCRs:

	<u>NCRs</u>		
	<u>NCRW1PP910708001</u>	<u>NCRW1PP910708002</u>	<u>NCRW1PP910710001</u>
Nonconformance date:	6/13/91	5/3/91 & 5/6/91	5/22/91
Report date:	6/28/91	7/8/91	7/8/91
QAO logged:	7/8/91	7/8/91	7/10/91
Discovered by:	Data Reporting	Analysis Measurement	Data Reporting
CAR required:	No	No	Yes
Notations made:	No	No	No

This data shows noncompliance to the requirement of reporting the nonconforming occurrence immediately, and noncompliance to the requirement of using notations in addition to lab notebooks. Also, none of the three reported nonconformances were reported in the required ECU NERR form (Figure 13-1 of the QAPjP), but were reported on an ECU lab QC Nonconformance Report form.

- o In addition, Section 13.2.2.2, page 132, alludes to using a specific Corrective Action Request (CAR) (Figure 13-2) form if the CAR is initiated. The actual requirement is stated in Section 13.3.2, page 137, as:

"Long-term corrective action taken for recurring problems shall be initiated by the use of the CAR (Figure 13-2), which shall be completed as follows: ..."

The specific CAR form was not used with NCRW1PP910710001.

- o Section 13.3.2, page 138, also requires that the CARs being processed be recorded in the Corrective Action Master Log (Figure 13-4). This Log was not used.

4.2.8 Safety & Health Alternate Coordinator (O)

There is no current Safety & Health Alternate Coordinator. The most recent appointment of the Alternate was Kelley Deming, who no longer works at the ECU Facility.

DISCUSSION

The ECU SOP 1.4.1, Section 4.1.1 requires a Safety & Health Alternate Coordinator from within the ECU, who must be documented by an appointment letter. The Safety & Health Alternate Coordinator is required (by ECU SOP 1.4.1, Section 4.3.2) to be certified (as a minimum) to Level I HP Technician. The current appointment letter designates Kelley Deming. K. Deming is no longer in the ECU Facility. When she was there, she was not a certified Level I HP Technician.

4.2.9 Critical Target Compounds (O)

In the first round of the WIPP Performance Demonstration Program, the ECU failed to achieve the required performance criteria for three critical target compounds (two target compounds using the modified TO-14 method and one target compound using the modified 8240/8260 method). No evidence was provided that the three reported failures were addressed in formal corrective actions, nor were such actions reported in the monthly reports.

DISCUSSION

The requirement is contained in the QAPjP, dated July 23, 1991, Section 14.3.5.

4.2.10 Gas Chromatography (GC) Analyst Qualifications (O)

The GC Analyst, Adrian D. Chapman, at the ECU Facility, has an A.S. degree with less than one year's experience. The WIPP QAPP, Section 1.8 requires the GC Analyst to have a B.S. degree with at least six months' experience.

DISCUSSION

Adrian D. Chapman, the GC Analyst at the ECU Facility had a Variance - (JTB-39-91) signed off by the Site Project Manager on May 16, 1991. However, sample analyses were run by Mr. Chapman, beginning April 22, 1991, prior to the final approval of the variance.

4.3 INEL Project Office Area

4.3.1 Control and Protection of Records (O)

A procedure for control of records related to bin prep activities has not been issued. Record storage is presently achieved in a one-hour fire-rated container, not the required two-hour rated container.

DISCUSSION

The QAPjP, paragraph 1.6.1, states that a procedure for control of records will be prepared, in accordance with NQA-1, Supplement 17-S1. A draft procedure has been prepared, but it does not meet all of the elements identified in the NQA-1 supplement, including records validation, records corrections, and records receipt control.

In addition, per NQA-1, Supplement 17S-1, a two-hour fire-rated container is required for storage of records. INEL fire-rated container is for only 1 hour.

4.3.2 Adequacy of the QA Program (O)

As of this audit date, a self-assessment of the project office QA program has not been performed.

DISCUSSION

The INEL QAPjP, paragraph 10.2, requires that each facility must regularly assess the adequacy of their QA program. Procedure WMDP-1.4 has been prepared and approved (May 15, 1991) to be used as the method for self-assessment.

4.3.3 NCR Transmittals (O)

Nonconformance reports must be transmitted to the site QA Officer within a specified time period. There is no verification to indicate that the time period is being adhered to.

DISCUSSION

Procedure WEIP-PD-2.2 requires that a copy of all NCRs be transmitted to the site QA Officer within one day. The INEL QAPjP requires that a copy of all NCRs be transmitted to the site QA Officer within two days. The two documents are not consistent. In either case, a review of the NCR log revealed that there is no provision to document when the NCRs are received by the site QA Officer. Therefore, the required time for submittal to the site QA officer cannot be verified.

4.3.4 Review and Approval of Variances (O)

The QAPjP (dated July 23, 1991), in paragraph 2.1.4, requires the Site Project Manager (SPM) to review and approve variances. The project directives WEIP-PD-1.7, "Duties of Site Project Office Personnel," dated June 10, 1991, and WEIP-PD-2.2, "Variance and Nonconformance Reporting," dated August 22, 1991, only require the SPM to review variances.

4.3.5 RTR Videotape Review (O)

Procedure WEIP-PD-2.5, "Bin Case Data Review Checklist," dated August 22, 1991, requires the Site Quality Assurance Officer (SQA) to compare the RTR examination videotapes to the visual examination data, to validate the RTR data. The SQA has not had the training to qualify him to read RTR videotapes.

DISCUSSION

The QAPP (July 15, 1991) paragraph 1.7.5, "Control of Processes," states:

"... non-destructive examinations (RTR and RA) shall be performed by qualified personnel using approved procedures in accordance with specified requirements."

4.3.6 Updating Procedure WETP-PD-3-1 (O)

Procedure for "Project Level Data Validation and Verification" WETP-PD-3.1 was issued on June 10, 1991 (prior to issuance of the QAPjP). Some elements of the procedure are therefore not consistent with current requirements.

DISCUSSION

Table 7 (PD-3.1) references an early position paper for a list of flammable VOCs. Two compounds from that list are no longer considered flammable, and two additional compounds have been added to the table in the QAPP.

Section 8.2.2 of the QAPjP now indicates that the signature release of the Project Manager must ensure that:

1. Project level reduced data have been evaluated for compliance with regulatory requirements of NMD.
2. Data has been evaluated for compliance with data quality objectives from the QAPP.

4.4 ANL-W Analytical Laboratory

4.4.1 Records Control (O)

The ANL-W AL laboratory records-control and permanent-file systems are in non-compliance with the QAPjP and QAPP requirements, which state that all laboratory records shall be maintained in accordance with the National Enforcement Investigation Centers (NEIC) guidelines.

DISCUSSION

The QAPP (Section 8.2) and QAPjP (Section 8.0) require that all laboratory records shall be maintained in permanent files according to NEIC guidelines. A review was made of implementing procedures including WO660-0034-OP, WO660-0024-OP, and WO660-0031-OP, with no identification of nor reference to the NEIC requirements and guidelines. The application of these guidelines also applies to chain of custody and software data base record storage.

4.4.2 Data Reporting (O)

The Data Reduction, Reporting and Data Package Preparation procedure (WO660-0034-OP-00) does not contain the current QAPP and QAPjP requirements. For example: calculations, forms, result qualifiers, custody tags, reporting and schedule requirements.

DISCUSSION

The QAPjP, Section 8.0 and QAPP, Rev. 1.0 require several new reporting requirements. For example: calculations shall be included to allow independent verification of final results. The referenced implementing procedure does not reflect these new changes and does not contain requirements for the new forms, sample canister tags versus copies, analytical report submittal to the Site Document Control Officer (SDCO), example of actual calculations, etc.

4.4.3 GC and NO_x Data (O)

No controlled procedure exists for collecting and storing required Gas Chromatography (GC) and NO_x raw data and results.

DISCUSSION

No procedure was provided, after a review of procedures WO630-0004-KP-00 and WO630-0005-KP-00, which describes the requirement for GC and NO_x data and results collection per the QAPjP requirements, Section 8.1. Requirements for collecting this data on computer disk or hard copy and a system process for retrieval and storage should be addressed.

4.4.4 DOE Review (O)

The DOE-CH Operation Office review requirement and sign-off was not identified.

DISCUSSION

The INEL QAPjP and ANL-W QAPjP state that the DOE-CH Operation Office shall review and sign off the site INEL QAPjP per the requirements of EGG-WM-9526 (Section 2.1.2). No evidence was identified demonstrating this review. (This requirement relates to the understanding and acknowledgment of the ANL-W facility interface responsibilities and commitments.)

4.4.5 Sampling Time Constraints (O)

The time constraint (34 days) on measurements of three sample blanks for bin #1 gas sampling (including a manifold blank) was exceeded.

DISCUSSION

The measurement of the bin data package sample blanks (ID032791AW205, ID040391AW208) and the associated manifold blank was performed approximately 120 days after sampling. The requirement in the QAPP (Section 4.1.4) and the QAPjP establishes a total 34-day administrative turnaround time: field sampling (four days), transfer time (two days), and sample analysis (28 days). Additionally, no variance or Inspection/Disposition Report was provided for not meeting this requirement.

4.4.6 F- and Q-tests (O)

No controlled implementing procedures were identified which consider the requirements of F-test (precision assessment) and Q-tests (rejection of suspect results) as identified in the QAPjP, Sections 12.6.3 and 12.6.4, respectively. The Q-tests formula and table for rejecting suspect results is in error for both the QAPP and QAPjP.

DISCUSSION

The referenced QAPjP sections are currently not being implemented via a controlled procedure. Additionally, the Q-test identified in the QAPP and QAPjP was found to be incorrect in both the formula in Section 12.6.4 and the table in 12.1, for result rejection with 90% confidence levels. The formula should consider the outlier value and not be exclusive of it, and the table reflects values for a 95% confidence instead of the reported 90% value. (Additionally, the Q-test may not be applicable for use at INEL.)

4.4.7 Performance of Replicate Reference Standards (O)

The requirement to conduct 30 replicate reference standards for precision and accuracy of the gas analyses systems per QAPjP, Section 12.6 and QAPP, Section 9.2 was not implemented prior to performing bin #1 drum gas samples.

DISCUSSION

The gas analysis on drum samples measured prior to August 15, 1991, did not reflect QAPP and QAPjP requirements for performing 30 laboratory standards as part of qualifying the GC system for conducting bin head space gas samples. Performing this as a post-laboratory demonstration analysis may be appropriate, but no note of a variance or Inspection/Disposition Report (IDR) was identified in the completed data packages for bin #1 drum head-space and inner bag samples.

4.4.8 PC System (O)

No security access and software control was identified in the location and use of the PC systems software Chrom Perfect 2 for gas analysis per the requirements in the QAPP, QAPjP, and per the references to the NQA-1 and NEIC applications of software validation, verification, and security control.

DISCUSSION

There was no objective evidence that controlled access to the PC system (which controls the GC peak integration and analysis program) was demonstrated or considered in the use of Chrom Perfect 2. While the laboratory calibration checks may identify major problems and tampering with the software, no demonstrated evidence exists to support the

conclusion that such identification is possible. Software access control, validation/verification, and use of current revisions should be considered to assure correct PC system performance.

4.4.9 Special WETP Sample Requirements (O)

Procedure WO660-0012-QP describes Chain of Custody (COC) requirements, some of which do not apply to the WIPP Experimental Test Program (WETP) samples. (Procedure 0012 is the reference in the QAPjP for COC practices.)

DISCUSSION

Procedure 0012 applies to all samples accepted at the ANL-W, not just WETP samples. The WETP samples can have different requirements from other samples. Examples are listed below:

1. Section 2.5 describes uses of the ANL-36 that are not applicable to WETP samples.
2. Section 9.4.2 describes sample label content that is different from that required by the form in QAPjP, Section 5.2 for WETP samples.
3. Section 9.4.1 describes sample seal content that does not apply to WETP samples.

4.4.10 Implementing Procedures Versus the QAPjP (for Samples) (O)

Implementing procedures for samples do not track the QAPjP. Examples are listed below:

1. WO660-0034-OP describes information that should be on the sample tag. The sample tag example in QAPjP, Section 5 does not provide space for the drum number and sample signature mentioned in procedure 0034.
2. WO660-0034-OP requires measurement of pressure and temperature within 24 hours of sample receipt. The QAPjP, Section 7.1 states that pressure and temperature are to be recorded at the time of analysis.

4.4.11 Lab ID Number (O)

The Lab ID number is not being placed at the top of the Chain of Custody (COC) as required in the implementing procedure WO660-0026-OP, 3.2.7.2.

4.4.12 Interlaboratory Transfer Form (O)

The form for interlaboratory transfer referenced in implementing procedure WO660-0034-OP, Section 3.6 is not the form currently used.

4.4.13 Document Control (O)

Contrary to requirements of Procedure WO660-0001-AP, Revision 00, paragraph 5.0, which states that "Controlled copies of AL procedures are maintained by the ANL-W Document Control Department," examples were found of procedures that were not so maintained.

DISCUSSION

Procedures Number WO660-0028-OP, WO660-0029-OP, WO660-0030-OP, WO660-0016-TP and WO660-0004-KP have not been issued through the Document Control Department. These procedures were approved in March 1991 and are currently being used by ANL-W Analytical Lab personnel.

4.4.14 QA Reporting (O)

1. Contrary to the QAPjP, Section 14, the monthly AL QA Report prepared by the ALQAR has not been approved by the WETP Project Manager.
2. In addition, contrary to the QAPjP, Section 2.2, the WETP QAO has not prepared any QA Project Reports. (These are supposed to be issued monthly.)

4.4.15 Records Storage & Protection (O)

Areas of noncompliance with procedural requirements of WO660-0024-OP were found, such as not having fire-rated files, failure to identify records storage in each lab procedure (per paragraph 4.1) using sample number instead of lab number for identifying data, storing records in openfaced and unlocked files, and not maintaining a logbook at storage locations.

4.4.16 Record Control Procedures (O)

Deficiencies were found in implementing procedure WO660-0031-OP regarding issuance and control of laboratory logbooks/notebooks. The logbook that is used for issue of notebooks was neither numbered nor contained entries; returned logbooks were not signed and dated by the custodian; and monthly checks were not made to verify if the Record Control Logbook is current.

4.4.17 WO660-0026-OP Paragraph References (O)

Paragraph references in WO660-0026-OP, paragraph 3.2.6.2 are incorrect (to paragraphs 3.2.1.1, 3.2.5.1, and 3.2.1.2). One of the errors would cause a backup to the sample logging database to fail.

4.4.18 LOGIN Computer System (O)

- o WO660-0026-OP, 4.1.5 calls for three alternating sets of backup diskettes. Actual operation has been using two sets of diskettes.
- o WO660-0026-OP, 6.0 calls for a LOGIN program trainee's Section Leader to be notified of the trainee's password. This is not being accomplished.

4.4.19 Samples (O)

- o There is no written record of LOGIN database training, as required by WO660-0026-OP, paragraph 4.1.7.
- o WO660-0027-OP, 3.1 specifies a sample storage cabinet labeled "WIPP Sample Storage Cabinet." This cabinet is not so labeled.
- o WO660-0027-OP, 4.1 indicates that a sample is taken to the ANL Radiation Safety Technician to check for external contamination. This is done instead by the person delivering the sample.
- o WO660-0027-OP, 4.2-4.4 require that entries in the WIPP Sample Storage Logbook must include time and initials. Actual entries are missing these.

4.5 ANL-W Hot Fuel Examination Facility (HFEF)

4.5.1 Monthly QA Report (O)

The HFEF QA reporting system is in noncompliance with the QAPJP requirement to issue a monthly QA report.

DISCUSSION

Section 1.4 of the QAPJP, Revision 00 requires the issuance of monthly QA reports. Discussions with HFEF QA and coordination staff indicated that no monthly QA reports have been issued.

4.5.2 Updating the WIPP WAC in OMM 6822 (O)

No provision exists to assure that future issues of the OMM 6822, Appendix E will reflect the most recent revision of the WIPP Waste Acceptance Criteria (WAC).

DISCUSSION

QAPJP, Revision 00, Section 7.2.2, states, "The examination of the contents shall confirm the results of the RTR conducted at the SWEPP facility, and shall verify that the waste conforms to the WIPP WAC." The section also states that OMM 6822 is the governing procedure. The procedure, Appendix E, extracts data from the WIPP WAC for the hot cell operators to use to verify the waste. There does not appear to be a document control system which ensures that Appendix E will be updated if the WIPP WAC is updated.

4.5.3 Bin Certification (O)

Bins #1 and #2 have been loaded, but a bin certification notice is not on file.

DISCUSSION

Section 1.6.3.2 of the QAPJP requires that WIPP provide ANL-W with a notice certifying each bin shipped to ANL-W at least 10 days prior to shipping. The required notice has not yet been received; the first bin was received over a month ago.

4.5.4 Headspace Sampling (O)

A QAPjP conflict appears to exist between taking only one sample per innermost layer of confinement and taking field duplicates of innermost layers of confinement.

DISCUSSION

Section 4.2.2 of the QAPjP states, "Only one sample shall be collected for each innermost layer of confinement." The preceding Tables 4-4 and 4-5 and Section 4.2.1.4 states a different frequency to be used in taking field duplicate samples for quality control purposes.

4.5.5 Recording of Survey Data (O)

Radiation survey and contamination data are not consistently recorded on the data forms in the OMMs as required in Section 1.6.3.1 of the QAPjP to verify that waste received is consistent with the shipping documentation.

DISCUSSION

- o Radiation survey or containment smear data collected by the Radiation Safety (RS) organization is recorded on forms found in a number of OMMs. Examples were found where smear data for alpha contamination was placed on the line designated for beta-gamma readings and vice-versa. Other forms were observed that did not have the required RS signatures on all lines. There were also examples where corrections had been made but not initialed (as required in Section 8 of the QAPjP and WO96-0042-ES). These discrepancies were noted on Appendix A forms of OMM 6813 for drums numbered 011120, 022558, 010422 and 021420; minor discrepancies were noted on Appendix A forms of OMM 6815 for Bin #1.
- o No formal, written guidance has been provided as to the format for reporting radiation and contamination data on the data forms in the OMMs. Some forms in OMMs contained contamination data reported as less than applicable limits (e.g., < 500 dpm/100cm² beta-gamma and < 20 dpm/100cm² alpha), some forms had actual numerical values, and some contained data of both types. This inconsistency was recognized by project personnel and verbal guidance was provided to RS staff on how to record data, but no written instructions were found. Examples of these inconsistencies were found on Appendix A forms of OMM 6813 for drums which went into Bin #1.

V. OPEN ITEMS FROM PREVIOUS AUDITS

On August 12-15, 1991, the WIPP WACC conducted an audit (Audit Report # 91A-010) of the Stored Waste Examination Pilot Plant (SWEPP) site. The audit report identified nine findings and 21 observations. Six findings and 12 observations were deemed of immediate concern. Additionally, the remaining three findings were considered for review. Therefore, as a part of this present audit, a team of auditors reviewed the corrective actions of EG&G personnel responsible for addressing these 21 items. All the corrective actions were found to be satisfactory; two of the finding and three of the observation corrective actions (identified in the following paragraphs) were not completed; none of the incomplete actions were deemed to be "critical impactors" by the audit team.

Note: The following paragraphs are provided with the same paragraph numbers that appeared in the original WACC Audit Report 91A-009.

2.1 Inspecting for Water (F)

The SWEPP O&MM, Section 3.10 has been revised per DRR WM-RS-210 to include the inspection of the vessel for the presence of free liquids. The procedure requires that the loading operation be stopped if free liquids are detected and not continued until the liquid has been removed. The procedure for the removal of the liquid will be developed by the site on a case by case basis and is dependent on the amount and type of free liquid. This work is handled through the use of a facility Site Work Release and is based on the actual conditions found. (COMPLETED)

2.2 TRUPACT-II Venting (ICV) (F)

The SWEPP O&MM, Section 3.10, has been revised (DRR WM-RS-230) and includes the checking, torquing, and inspecting requirements that were identified in the audit finding. (COMPLETED)

2.3 TRUPACT-II Venting (OCV) (F)

The SWEPP O&MM, Section 3.10, has been revised (DRR WM-RS-230) and includes the inspecting and torquing requirements that were identified in the audit finding. (COMPLETED)

2.4 Leak Testing of TRUPACT (F)

The SWEPP O&MM, Section 3.10, has been revised (DRR WM-RS-217) and includes the installation of the main O-ring seals in the ICV lower seal flange, which was identified in the audit finding. (COMPLETED)

2.5 Leveling of the TRUPACT Trailer (F)

The SWEPP O&MM Section 3.10 has been revised per DRR WM-RS-217 to include the leveling operation of the TRUPACT-II. This requirement was originally required for the TRUPACT-I operation and was carried over to the TRUPACT-II operations. No specific guidance is available from WIPP for performing this activity. At the RWMC, a level is used on the side of the TRUPACT to insure that the TRUPACT is vertical to within 1/8 inch. WIPP is currently reviewing this requirement and it may be deleted from the TRUPACT-II O&MM. (COMPLETED)

2.6 Carbon Composite Filters (F)

The SWEPP O&MM, Section 3.13, Drum Venting System (DVS) is being changed to ensure that filters are procured per Section 1.3.5 of the TRUPACT-II SAR. This change has been initiated by DRR No. WM-RS-223 (8/23/91).

A new Project Directive, PD-RS-8.7, was written to verify the procurement specifications for the filters on bins, drums and containers. This new PD was issued as WM-RS-189 (7/22/91). (COMPLETED)

2.7 Calibration of Weighing Devices (F)

The "Standards and Calibration Laboratories' Test and Measuring Equipment Calibration Procedure" Number 3558 (which is the calibration procedure that is used for the weighing station scales) was revised to ensure that the procedure meets the requirements of NIST (formerly NBS) Handbook 44 (1990), Section 2.0. This procedure revision was completed on August 27, 1991. (COMPLETED)

2.8 RWMC Load Management System (F)

Project Directive PD-RS-8.8 has been completed and provides the guidance for the WIPP Bin Waste Handling Operation. This document provides an interim guidance procedure which will be used at the facility until the Detailed Operating Procedure can be written and approved. The Detailed Operating Procedure has been added to the Commitment Tracking System (CTS 3257) and is scheduled to be completed by October 1, 1991. The Project Directive provides a flow diagram for the facility operation and includes individual sign-offs for each operation.

3.4 Qualified Procedures, Personnel, and Equipment (O)

Special processes were defined and identified (in QPP-130, Rev. 2, Section 5.9.6). They included:

- o Real Time Radiography System Operation
- o Assay System Operation
- o Container Integrity System Operation
- o Drum Venting System
- o Leak Testing of the TRUPACT-II Shipping Container

Evidence was provided that each of the special-process equipments were tested to meet their qualification requirements.

Evidence was provided of qualified procedures for each of the identified special processes (SWEPP O&MM, Sections 3.1, 3.2, 3.3, 3.10, and 3.13).

Evidence was provided of personnel qualifications for each of the identified special processes. (Training folders were audited to verify the qualifications.)
(COMPLETED)

3.6 TRUCON Codes (O)

SWEPP O&MM 3.10, "TRUPACT Operations," and O&MM 3.16, "Load Management System" have been revised (DRRs WM-RS-230 and WM-RS-225, respectively) to incorporate the TRUCON codes (DOE/WIPP 89-004) as the specific reference for content codes. Changes to other documents are not appropriate. (COMPLETED)

3.11 Radiation Surveys (O)

SWEPP O&MM, Section 3.10 has been revised (DRR WM-RS-230) to include surveillance requirements. (Completed)

3.12 Certification of Shipments (O)

The Safety Analysis Report (TRUPACT-II User Requirements Document, Rev. 1, dated May 1989), states: "For purposes of DOE-site applied controls, the WAC requires a site certification official ... For purposes of TRUPACT-II payload control, a similar position is established: transportation certification official ... At some sites, one person may fulfill both functions ..."

3.18 Payload Weights (O)

The procedure, to make the addition of errors a part of the payload-container weight determination, will be included in Project Directive PD-RS-8.8, which is being prepared. (INCOMPLETE)

3.19 Dose Rate Measurements (O)

SWEPP O&MM, Sections 3.10 and 3.16 have been revised (DRRs WM-RS-230 and WM-RS-225, respectively) to combine the gamma and neutron readings for the highest dose rates. The data management system program will be revised by October, 1991 (commitment tracking system #3183) to reflect this. (INCOMPLETE)

3.20 Training (O)

a. Transportation Official

RWC Training Manual, WM-PO-88-03, has been incorporated in the Waste Management Department Training Program Manual as Appendix C. This new manual was distributed August 21, 1991, and supersedes all individual Facility Training Program manuals, including WM-PO-88-03.

The Waste Department Training Program Manual, issued August 21, 1991, is being revised to include the training requirements for the TRUPACT-II Transportation Certification Official. (INCOMPLETE)

c. Helium Leak Testing

1. The Certification (recertification form) was properly signed by J. R. Bishoff on August 23, 1991.
2. The examination date incorrectly typed as October 4, 1991, was corrected to read October 4, 1990, on August 26, 1991.
3. The Level III Certificate Records for Jeffrey Cook were reviewed and found to be in order. (These records were not available during the original audit because they were located at the Willow Brook facility.)

All certification records/requirements were reviewed for correctness/consistency. (COMPLETED)

d. Personnel Training Records

The four missing personnel training records were available in the Training Section, Building 622. The records were found to be current, with proper signatures. The records contained both the certification requirements and the course completion information. (COMPLETED)