



United States Government

Department of Energy

memorandum

Carlsbad Field Office
Carlsbad, New Mexico 88221



DATE: November 18, 2004

REPLY TO
ATTN OF: CBFO:QA:ALH:LC:04-1887:UFC:2600.00

SUBJECT: Audit A-05-03 of the RCRA Performance Demonstration Program

to: Kerry Watson, Assistant Manager, Office of National TRU Waste Program

The Carlsbad Field Office (CBFO) conducted an audit of the RCRA Performance Demonstration Program on November 10, 2004. The audit team concluded that, overall, the RCRA Performance Demonstration Program (PDP) as implemented by Environmental Resource Associates (ERA) is adequate in accordance with the CBFO Quality Assurance Program Document. The audit team also concluded that previous work performed by ERA was satisfactory and that the quality program and plans were adequate for future work. The CBFO audit report is attached.

There were no CBFO Corrective Action Reports issued as a result of the audit. One condition adverse to quality was corrected during the audit and one observation is presented for management review.

If you have any questions or comments concerning this report, please contact me at (505) 234-7423.

Ms. Ava L. Holland
Quality Assurance Manager

Attachment

- cc w/attachment:
- L. Piper, CBFO *ED
 - M. Brown, CBFO *ED
 - L. Chism, CBFO *ED
 - S. Zappe, NMED *ED
 - C. Watkins, CTAC *ED
 - B. Oates, CTAC *ED
 - N. Frank, CTAC *ED
 - CBFO QA File
 - CBFO M&RC

*ED denotes electronic distribution



**U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE**

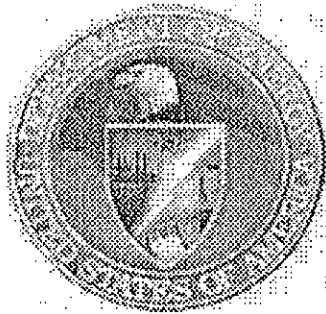
AUDIT REPORT OF

**ENVIRONMENTAL RESOURCE ASSOCIATES
6000 West 54th Avenue
Arvada, CO 80002-4021**

AUDIT NUMBER A-05-03

November 10, 2004

**PREVIOUS WORK PERFORMED
AND
CAPABILITY FOR CYCLE 12a**



Prepared by:

Norman Frank
Norman Frank, CTAC
Audit Team Leader

Date:

11/15/04

Approved by:

Ava L. Holland
Ava L. Holland, CBFO
Quality Assurance Manager

Date:

11/18/04

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office (CBFO) conducted Audit A-05-03 of Environmental Resource Associates (ERA) to evaluate the adequacy of previous work performed for Cycles 10A and 11A of the Resource Conservation and Recovery Act (RCRA) Performance Demonstration Program (PDP) and to verify capability to perform work required for Cycle 12A. The audit team reviewed the laboratory facilities along with records of previous work and the current Quality Systems Documents. The audit was conducted at the new ERA facilities in Arvada, Colorado on November 10, 2004.

ERA is the Sample Preparation Contractor for the RCRA PDP, whose work consists of the preparation of the PDP sample matrix and spiking solution, verification analyses, distribution of the PDP samples to Waste Isolation Pilot Plant (WIPP) RCRA PDP participants, and maintenance of an archive of surplus samples from past cycles.

One isolated deficiency concerning incorrect calibration due dates for a calibrated weight set was corrected during the audit (see CDA #1). One observation concerning the adequacy of the training program documentation for ERA is provided for management review (see Observation #1).

The adequacy of past work performed for the PDP was determined to be acceptable. The ERA facilities were determined to be adequate and the ERA quality program was determined to be adequate and effectively implemented for performing RCRA PDP Cycle 12A.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of selected QA processes related to the RCRA PDP Program. The Statements of Work (SOW) for Cycles 11A and 12A, and DOE/CAO-95-1077, "Performance Demonstration Program Plan for RCRA Constituent Analysis of Solidified Wastes", Revision 5, were the basis for the audit.

The audit team also evaluated the ERA facilities to verify capability to perform work for RCRA PDP Cycle 12A.

3.0 AUDIT TEAM AND OBSERVERS

CBFO AUDIT TEAM

Norman Frank	Audit Team Leader, CBFO Technical Assistance Contractor (CTAC) / S. M. Stoller Corporation
B. J. Verret	Auditor and Technical Specialist, CTAC / Portage Environmental, Inc.

OBSERVERS/INSPECTORS

Berta Oates RCRA PDP Coordinator, Portage Environmental, Inc.

4.0 AUDIT PARTICIPANTS

A preaudit conference was held in the ERA facilities on November 10, 2004. The audit was concluded with a postaudit conference held in the ERA facilities on November 10, 2004. Participants in the audit are shown below.

Name	Title	Preaudit Meeting	Contacted During the Audit	Postaudit Meeting
Craig Huff	Director, Inorganic Chemistry	X	X	X
John Laferty	Manager, Custom Products	X	X	X
Curtis Wood	Director, Quality Assurance	X	X	X
Berta Oates	PDP RCRA Coordinator	X		X
Jeff Lowry	Director, Organic Chemistry & Proficiency Testing	X	X	
Tony Ciacco	Inorganic Chemist		X	
Heidi Senft	Inorganic Chemist		X	
Matt Graves	Organic Chemist		X	

SUMMARY OF AUDIT RESULTS

Program Adequacy, Implementation, and Effectiveness

The audit team evaluated ERA records and the ERA Quality Manual for work previously performed against the requirements from the SOWs for Cycles 10A and 11A. The audit team also evaluated ERA facilities, personnel qualifications and training, instrumentation, and the Quality Manual for future work against the requirements of the SOW for Cycle 12A. The audit team concluded that ERA records, Quality Manual, facilities, instrumentation, and personnel were adequate, that the ERA quality program was adequate and effectively implemented for the RCRA PDP Cycle 10A and 11A

work, and that the facilities, Quality Manual, personnel, instrumentation, and plans for Cycle 12A are adequate to meet requirements.

One isolated deficiency concerning incorrect calibration due dates for a calibrated weight set was corrected during the audit (see CDA #1). One observation concerning the adequacy and implementation of the training program for ERA is provided for management review (see Observation #1). These are further explained in Section 6.0 of this report.

QA Program Audit Details

The ERA Quality Assurance Program Plan consisting of the Quality Manual and the Statement of Qualifications was reviewed and determined to be adequate for the RCRA PDP work. The work plan for Cycle 11A was reviewed and determined to meet the requirements for the Cycle 11A SOW. The work plan for Cycle 12A was in draft form with only a few changes from Cycle 11A.

The Quality Manual, Statement of Qualifications, Standard Operating Procedures, and Work Procedures are on an Intranet hard drive and are accessible to each employee. Only approved documents are placed on this hard drive. Records of review and approval are retained as part of the document control system.

Training provided to individuals performing RCRA PDP work was reviewed. Training consists of initial training in company and quality policies and manuals, proficiency training in the work to be performed, and follow-up training. Follow-up training consists of reading a new revision when notified that a new revision has been issued. One Observation concerning the training program is provided for ERA managements review (see Observation #1).

Technical and Facility Audit Details

The ERA facility is a new facility located in Arvada, Colorado. Incorporated into the design are a cold storage room for archive samples, a room for temporary storage of records prior to forwarding to the customer, and extensive laboratory space. Laboratory instruments used for RCRA PDP work include Agilent Gas Chromatograph (GC)/Mass Spectrometers (MS), a Hewlett-Packard Gas Chromatograph with Flame Ionization Detector (FID), Perkin Elmer and Thermo Elemental X Inductively Coupled Plasma (ICP) Units, a CETAC Mercury analyzer, a Hewlett-Packard High Performance Liquid Chromatograph (HPLC), and calibrated O'Haus scales with Troemner National Institute of Standards and Technology (NIST) traceable calibrated Class "S" weights. These were each evaluated for adequate use of NIST traceable standards for calibration and for recording of work done on the instrument. Additionally, analytical standard traceability was verified for both organic and inorganic calibrations and analyses.

The reporting packages provided for both Cycles 10A and 11A were reviewed for adequacy. All records are retained either by Portage Environmental, Inc. or by the CBFO. Thus, all records currently in the possession of ERA are considered to be

temporary, in-process records. These records are forwarded to the RCRA PDP Coordinator at the end of each cycle.

The audit team evaluated the calibration and adequacy of the laboratory instruments and equipment and verified that ERA has the capability to successfully perform the work required for RCRA PDP Cycle 12A. One isolated condition adverse to quality concerning an incorrect calibration due date was corrected during the audit (see CDA #1).

CARs, CDAs, OBSERVATIONS, AND RECOMMENDATIONS

Corrective Action Reports (CARs)

During the audit, the audit team may identify conditions adverse to quality (CAQs) and document such conditions on CARs.

Condition Adverse to Quality (CAQ) – Term used in reference to failures, malfunctions, deficiencies, defective items, and nonconformances.

Significant Condition Adverse to Quality – A condition which, if uncorrected, could have a serious effect on safety, operability, waste confinement, TRU waste site certification, compliance demonstration, or the effective implementation of the Quality Assurance (QA) program.

No conditions adverse to quality requiring corrective action were identified during the audit.

Deficiencies Corrected During the Audit (CDA)

During the audit, the audit team may identify CAQs. Once a determination is made that the CAQ is not significant, the audit team member, in conjunction with the ATL, determines if the CAQ is an isolated case requiring only remedial action and therefore can be corrected during the audit. Upon determination that the CAQ is isolated, the audit team member, in conjunction with the ATL, evaluates/verifies any objective evidence/actions submitted or taken by the audited organization and determines if the condition was corrected in an acceptable manner. Once it has been determined that the CAQ has been corrected, the ATL categorizes the condition as a CDA according to the definition below.

CDAs – Isolated deficiencies that do not require a root cause determination or actions to preclude recurrence. Correction of the deficiency can be verified prior to the end of the audit. Examples include one or two minor changes required to correct a procedure (isolated), one or two forms not signed or not dated (isolated), and one or two individuals that have not completed a reading assignment.

One deficiency requiring remedial action only was identified during the audit.

CDA #1:

The calibrated weight set used for the calibration check of scales used for RCRA PDP work was incorrectly marked with calibration due dates of June 2004 and August 2004. Actual due dates were June 2005 and August 2005. The label was corrected to show the correct due dates. Calibration dates of the weights were verified by examination of the weight calibration certificates.

6.3 Observations and Recommendations

During the audit, the audit team may identify potential problems or suggestions for improvement that should be communicated to the audited organization. The audit team members, in conjunction with the ATL, evaluates these conditions and classifies them as Observations or Recommendations using the following definitions:

Observation – A condition that, if not controlled, could result in a CAQ.

Recommendations – Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing requirements.

Once a determination is made, the audit team member, in conjunction with the ATL, categorizes the condition appropriately.

One Observation is presented for review by ERA management.

Observation #1:

The ERA training program has a form, signed by each individual, stating that the individual will read and follow any procedure / policy "upon notification". There have been several revisions to procedures, including the Quality Manual since the original training provided by ERA. Although notifications are provided to the individuals, no record of the notification is retained as a quality record nor is there a record that the individual read the document. People interviewed during the audit were familiar with the current procedures, which indicated that they had read and understood the documents as issued. ERA management should consider retaining the notifications as quality records and require documentation of performance of training to prevent a possible future deficiency.

Recommendations

None.