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**ACCEPTANCE OF THE FERNALD ENVIRONMENTAL MANAGEMENT
PROJECT APPROVED LABORATORY LIST**

08/12/94

**DOE-2253-94
DOE-FN USEPA
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REPORT**



Department of Energy
Fernald Environmental Management Project
P. O. Box 398705
Cincinnati, Ohio 45239-8705
(513) 648-3155

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AUG 12 1994

DOE-2253-94

Mr. James A. Saric, Remedial Project Director
U.S. Environmental Protection Agency
Region V - 5HRE-8J
77 W. Jackson Boulevard
Chicago, Illinois 60604-3590

Dear Mr. Saric:

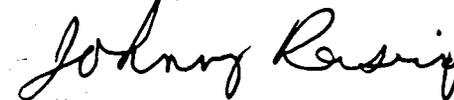
**ACCEPTANCE OF THE FERNALD ENVIRONMENTAL MANAGEMENT PROJECT APPROVED
LABORATORY LIST**

As requested in your voice mail message of August 4, 1994, enclosed are copies of laboratory audit reports from all audited laboratories, as well as check lists from two of the audited laboratories. Approved laboratory list revisions will be generated approximately every four months.

Your message also indicated the desire of the United States Environmental Protection Agency (U.S. EPA) to review and/or audit the Fernald Environmental Management Project (FEMP) Analytical Laboratory. We welcome the opportunity to have the U.S. EPA audit the lab and would like to further discuss with you a schedule for the audit.

Please contact John H. Trygier at (513) 648-3154 to discuss the upcoming audit or if you have questions concerning the material provided.

Sincerely,

fu 
Jack R. Craig
Fernald Remedial Action
Project Manager

FN:Trygier

Enclosure: As Stated

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cc w/o enc:

K. H. Chaney, EM-423/QO
D. R. Kozlowski, EM-423/QO
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FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

QUALITY ASSURANCE AUDIT NO. E93-15

Roy F. Weston Laboratory

DATE OF AUDIT: September 28 - October 1, 1993

DATE OF REPORT: October 28, 1993

REISSUED: February 23, 1994

AUDIT LOCATION: Weston
Lionville, PAAUDIT TEAM MEMBERS: D. H. Price FERMCO QA Lead Auditor
D. Davis, NFS, Technical Representative
T. J. Sheehan, NFS, Technical Representative

PURPOSE AND SCOPE:

Assess the adequacy, effectiveness, and implementation of FERMCO and DOE quality assurance requirements and contractor performance as required by FERMCO contract RFP92616. Investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program Description, RM-0012, FERMCO contract RFP 92616- RCRA/CERCLA Statement of Work, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ).

AUDIT SUMMARY:

Weston has the necessary licenses, certifications and controls, (i.e., quality program, policy statement, operating procedures) necessary to provide quality data packages to the FEMP in accordance with FERMCO Quality Assurance Program Description and FERMCO contract 92616 Statement of Work except for radiological analysis.

POST AUDIT REVIEW:

A post audit review was conducted in addition to the facility audit to include information pertinent to determining the capability of the laboratory to perform specified analyses. FERMCO Analytical Laboratory Support (ALS) personnel and FERMCO Quality Control (QC) personnel provide information related to the laboratory performance capabilities.

Weston did not bid Tables 17 and 18 of the Statement of Work, nor do they participate in DOE or EPA radiological intercomparison studies. Therefore, no radiological data is available for this report.

Weston does participate in FERMCO's intercomparison program for chemistry. Weston has performed determinations for metals on nine samples. A:

results were considered to be within the range considered acceptable by FERMCO.

AUDIT CONDUCT:

A formal announcement of the intended audit was sent to Weston, September 10, 1993. The FERMCO auditors held an opening meeting October 1, 1993 with Weston representatives. Following introductions, a tour of the laboratory was conducted that lasted approximately 2 hours.

Check lists were developed by the audit team for use during the audit to aid in review of the laboratory for compliance with the identified requirements. These check lists are maintained in the FERMCO Quality Assurance audit file.

The audit was to be a performance based audit of Weston Laboratory however, at the time of the audit, Weston had not received samples from FERMCO. Samples from some of their customers were reviewed.

Daily meetings were held to discuss evaluations of processes. Inadequacies that could be corrected during the audit, were corrected and noted. Paper work for Class S Primary Standard Weights was forwarded from another Weston Facility to immediately calibrate working standards and balances.

Interviews were conducted with various laboratory personnel and managers; procedures, program plans, Chemical Hygiene Plan, and record files were reviewed; laboratory operations, health and safety practices, and waste management activities were observed. Concerns and findings noted during the audit are stated in Section 1 and 2 of this report, respectively. Detailed findings are identified in Section 3.

The following people were contacted during the audit:

- Sue Durkee
- + Lisa DeLong - QA Specialist - Weston
- + Debbie Racioppi - QA Specialist - Weston
- + Pat Feldman - QA Specialist - Weston
- + Peg Beaty - Section Manager - Weston
- * + Dianne Therry - QA Technical Manager - Weston
- * + D. Kirk Cromer - Organics Section Manager - Weston
- * + Peter Hershey - Laboratory Manager - Weston
- * + Ray Siery - Inorganics Section Manager - Weston
- * + Keith Ryan - QA Section Manager - Weston
- + Glenn Roberts - Health & Safety Officer - Weston
- + Gail DeRuzzo - Project Manager - Weston
- + Carter Nulton - Project Manager - Weston
- + Carol Talbert - Sales Manager - Weston
- + Connie Taylor - BNA Unit Leader - Weston
- * + Tim Sheehan - Auditor - FERMCO-NFS
- + John D. Davis - Auditor - FERMCO-NFS
- * + David H. Price - Lead Auditor - FERMCO

- + Attended Closing Meeting
- Attended Opening Meeting

The audit team held a close out meeting on October 1, 1993 with Weston Laboratory and administrative personnel. During the close out meeting the five concerns and seven findings were reviewed and discussed to assure there were no misunderstandings.

AUDIT OBSERVATIONS

This section of the audit report is formatted to relate observations made during the audit as related to functional categories and criterion required by the FERMCO Quality Assurance Project Plan (RM-0012).

A. FUNCTIONAL CATEGORY A: MANAGEMENT

1.0 Criterion 1 - Program

Weston has developed and maintains a written quality assurance program, (QAP) following the appropriate requirements of NQA-1. Requirements of FERMCO's FD-1000, Sitewide CERCLA Quality Assurance Project Plan (SQ), including ANSI/ASQC E4-19XX, are specified in the contract and applicable portions are included in Weston's FERMCO specific QA program. A matrix is included in the FERMCO Quality Assurance audit file which depicts correlation between DOE Order 5700.6C, RM-0012, and ANSI/ASQC E4-19XX.

Weston's Quality Assurance Plan is binding on all personnel, and operating procedures describing how the elements are applied, are referenced in each section. A policy statement, signed by management personnel and a "stop work" policy are included in the document.

Employment at Weston is approximately 115 people.

A list of equipment was submitted during the Procurement process prior to award of contract. Weston has sufficient equipment to perform organic and inorganic analyses necessary to support the Statement of Work.

Housekeeping practices were judged to be adequate.

2.0 Criterion 2 - Personnel Training and Qualification

Weston is supportive of the concept that personnel shall be trained and qualified to perform their assigned work. The audit team recognizes the technical expertise of the staff to be excellent. Resumes were reviewed to ensure analysts and management met educational and training requirements established by Weston. Records indicated that analysts participated in performance evaluation programs and a system is in place for retraining should it be required.

3.0 Criterion 3 - Quality Improvement

The Weston QA program implements processes to detect and prevent quality problems and promote continuous quality improvement.

A corrective action reporting (CAR) system is in place, documents related to deviation reporting and corrective actions are retrievable and traceable, however, their system does not address customer notification (See Finding 1).

4.0 Criterion 4 - Documents and Records

A log book system is in place to control preparation, review, approval, issuance, use, and revision of documents.

Records containing data used to support CERCLA decision making follow the requirements of the FERMCO SCQ and reporting requirements listed in the Statement of Work. Records are maintained for preventive maintenance, calibration, procedures, and other documentation as needed, to meet SCQ requirements.

Weston provides the analysts with written procedures for specific tasks. Logbooks are used extensively for specific instructions, however, the instructions are not tied to a controlled document (See Concern 3).

Archived quality records are maintained in an area, with limited person (2) access. A master inventory list is maintained in log books, and a sampling of documents indicated that records matched the inventory.

Weston relies mainly on manual entries (logbooks) with virtually no back-up systems. Weaknesses of the system include no real-time verification of data input and loose document control of the logbooks. (See Concern 4 and Finding 7)

B. FUNCTIONAL CATEGORY A: PERFORMANCE

5.0 Criterion 5 - Work Performance

This criterion describes work related instructions, procedures, and other forms of direction including, but not limited to, waste handling packaging, certification and shipping, and environmental data operations

Weston's Chemical Hygiene Plan is being revised. Each laboratory has a information point near the entrance; labeling is in effect, and safety equipment is installed in or near all laboratories. (See Concern 1)

A preventative maintenance (PM) program for analytical instrumentation is in effect and is operating adequately as indicated in the PM log.

TCLP Extractions by SW-846 Method 1311 requires that the rotary extractors operate at 30 ± 2 RPM during TCLP extractions and that this data be documented, however, this data was not being documented. (See Finding 6)

The Statement of Work and Weston's procedures require that the percen

solids determinations for TCLP analysis be recorded on the TCLP extraction run sheet; this documentation was not completed. (See Finding 5)

Double key entry from the field Chain-of-Custody into the Laboratory Information Management (LIM) system is performed. However, the Chain-of-Custody does not make provisions for Chain-of-Custody on extracts. (See Finding 2)

This criterion also describes the identification and control of items, handling, storing, and shipping of waste, and calibration and maintenance of monitoring and data collection equipment.

Problems were encountered with the Class S Primary Standard Weights that were corrected during the audit, however, several uncalibrated thermometers had been used to record temperature. (See Finding 3)

Weston does not provide radiochemistry analytical services such as those required for Tables 17 and 18 as described in the SCQ. Weston will subcontract samples for these parameters for return of FERMCO waste only (not for field samples).

6.0 Criterion 6 - Design

This criterion states that data collection processes for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. Computer programs are to be proven through previous use, or verified through testing or simulation prior to use. A system is in place that defines computer program testing and documentation, and software control and software security. The auditor noted that several personal computer programs in use had not been validated. (See finding 4)

Weston relies on the manufacturer for software reliability. A self-audit sample data management procedure is used to verify that data entry is valid. Weston relies mainly on manual entries (logbooks) and cannot software application. Group Leaders oversee this process.

Building Design:

The structure of the building is specifically designed for laboratory use. Limited access to the facility is maintained by key and card access. Security is adequate to ensure that sample chain of custody is not compromised.

7.0 Criterion 7 - Procurement

Weston has established a program to ensure that purchased items and services meet established requirements and perform as expected. The auditor will audit their vendor and suppliers.

8.0 Criterion 8 - Inspection and Acceptance Testing

This criterion describes requirements and responsibilities for labs conducting chemical analyses, and producing analytical data for environmental projects. Weston produced an equipment list identifying measuring and test equipment which is calibrated against nationally recognized standards. Records are maintained indicating that standards are traceable to NIST. However, not all calibrations were up to date as noted. (See finding 3)

Quality control standards and data quality objectives that laboratories are required to meet, are described in the SCQ. However, Weston did not accept FERMCO QC samples requiring radiochemistry analysis. Weston's performance in quarterly round robin programs is maintained and tracked. Weston continues to perform competently as indicated by review of sanitized data packages and logbooks for documentation of required quality control elements. A CLP data package was examined. Review of the CLP package and routine data packages provided evidence that Weston is capable of producing data for ASLs B, C, and D.

Laboratory equipment inspections are scheduled and logbooks indicated inspections took place and that results were satisfactory.

C. FUNCTIONAL CATEGORY C: ASSESSMENT

9.0 Criterion 9 - Management Assessment

This criterion describes a planned and periodic program of management assessments.

A formalized program is not evidenced. However, quality is promoted throughout the laboratory and quarterly reports based on laboratory processes are generated and forwarded to the Weston Laboratory Director.

10.0 Criterion 10 - Independent Assessment

Weston has implemented a program for the planning and performance of independent assessments. An audit schedule was produced indicating that internal assessments are performed. Performance evaluation (PE) samples are processed, blind duplicates are processed and a tracking log exists for blind duplicates and performance evaluation samples. The information gleaned from PE and blind duplicates is forwarded to FERMCO to be incorporated into the interlaboratory comparison program.

Weston participates in external performance evaluation programs and undergoes audits from the EPA, state, and various auditing organizations. This area was reviewed to ensure independent assessments are being conducted, but evaluation results were not reviewed by the audit team.

Nine (9) items in the Best and Final Offer were discussed with Weston's management. These items were responded to by Weston but have not yet been evaluated and answered by FERMCO.

A number of items were identified, these included five (5) concerns and seven (7)

findings that need formal written corrective action.

CONCERNS - Section 1

1. Chemical Hygiene Officer had not been formally designated as identified in 29 CFR part 1910.1450.
2. Paperwork for the flow meter that is used to check air flow of chemical laboratory fume hoods was not in order.
3. System for signing out Quality Records from Quality Assurance files needs to be reviewed to provide better control.
4. Verification of transcribed data is not clearly documented.
5. Data dealing with radioactive inventory totals needs a review - this item was addressed during the course of the audit.

FINDINGS - Section 2

1. Corrective Action - Non Conformance/Deviation Present procedure does not make any allowance or provisions for customer notification.
2. Chain-of-Custody - There were no provision for maintaining C-O-C on sample extracts.
3. Calibration - Program needs a review - several thermometers in use that had not been calibrated.
4. Data Review and Verification - Validation- Several personal computer programs were in use which had not been validated.
5. Percent solids determination for TCLPs was not documented on TCLP extraction run sheets.
6. Checking of rotary extraction RPMs for TCLP not documented.
7. Hand entered data was not reviewed to estimate transcription error rates

CONCLUSION AND RECOMMENDATIONS:

The staff and management of Weston were very cooperative and candid in the review of their data and in the discussions and addressing of the audit concerns.

The audit team was taken on a tour of the facility and during the course of the audit provided with the following items;

- QA Manual
- Equipment list
- Listing of personnel (complete)
- Organization charts
- Procedure index & any requested procedures

The evaluation showed that Weston has adequate facilities, equipment and a management system that can, with a few modifications, meet the requirements of FERMCO RFP 92616.

The following recommendations are offered:

- Write a Project Specific Plan
- Review the Quality Assurance Manual & Program to assure that it meets all the criteria of the Statement of Work.
- Review the calibration program to assure that the requirements of the SOW for RFP 92616 are consistently met.

SECTION 3
FINDING
E93-15-1

REQUIREMENT:

Statement of Work, page C16-J, says the following:

- J. Non-conformance/Deviations
In all cases where a result of an internal quality control sample exceeds acceptable criteria or any non-conformance or deviation from established procedures occurs, the Seller shall inform FERMCO in the following manner:
1. If the non-conformance directly impacts the quality of the results, and resampling is required, FERMCO shall be notified by phone and a non-conformance report with root cause and corrective actions shall be sent to FERMCO within 3 working days.
 2. If the non-conformance does not require resampling, but there is a deviation from established procedures, a written non-conformance report with root cause and corrective action shall be sent to FERMCO with the data package. However FERMCO reserves the right to reject the data and request resampling.

FINDING:

Contrary to the above Weston's corrective action/non-conformance procedure doe not address customer notification.

SECTION 3
FINDING
E93-15-2

REQUIREMENT:

Quality Assurance Project Plan (SCQ) - Section 7-Page 8 & 9 Paragraph 7.2 - Item 7.2.1 - Number 8 says the following;

8. Each laboratory must follow its established system for assuring that sample custody is documented for all movements of both the sample and its extracts/digestates. Each laboratory shall have an approved, controlled SOP that gives stepwise intralaboratory custody procedures complete with copies of documentation to be used. This SOP shall be approved by the FEMP project contact before use. Any changes to the SOP shall be approved by the FEMP project contact before installing. Transfers that shall be documented include:
- from sample receiving to sample preparation,
 - return of original sample to sample receiving,
 - from sample extraction to digestion,
 - from digestion to analysis,
 - from analysis to storage of both original sample and extract,
 - from sample storage to disposal.

FINDING:

Contrary to the above, Weston's Chain-of-Custody procedure and system make no provision for Chain-of-Custody on extracts.

SECTION 3
FINDING
E93-15-3

REQUIREMENT:

Quality Assurance Project Plan (SCQ) Section 8 - page 1 Calibration Procedures and Frequency says the following;

CALIBRATION PROCEDURES AND FREQUENCY

Measuring and test equipment used in the field and the laboratory shall be controlled by formally prescribed calibration requirements. Equipment shall be of the type, range, accuracy, and precision necessary to provide data compatible with the Analytical Support Level (ASL) (Section 2) specified in applicable Data Quality Objectives (DQO) (Appendix C) or Project-Specific Plans (PSPs). Calibration of measuring and test equipment shall be performed using documented and approved procedures. When available, accepted procedures published by the American Society for Testing and Materials, the EPA, the National Institutes of Standards and Technology, or manufacturer equipment manuals shall be used. Variance from these procedures shall be justified and documented in PSPs.

FINDING:

The calibration of primary standard Class S weights used to calibrate working standards had expired.

Calibrated Class S Primary Standard Weights were forwarded from another Westco Facility to immediately calibrate working standards and balances.

Calibration documentation for working standard weights did not site the unique ID number of the NIST traceable primary standard.

Milligram weights in the WT10 working standard weight set were missing. Some analytical balances in Building 256 were not calibrated in the milligram range as required. Uncalibrated thermometers were used to record temperature in the TCLP lab and in the mercury digestion procedure.

SECTION 3
FINDING
E93-15-4

REQUIREMENT:

Statement of Work - Section C.IV Quality Assurance page C-14 - Item C says the following;

C. Data Review and Verification

The Seller shall establish a review program to verify and assure the integrity of reported data. An SOP shall be prepared to describe the above review program. Verification of compliance with all contract requirements shall be provided with every release.

For samples analyzed under the Data Quality Objective level D, data validation shall be completed by the Seller as defined in the CLP SOW.

Additionally SCQ Appendix D page 8 paragraph D.2.2.2 says the following;

D.2.2.2 Laboratory Checklist Development. Checklists for validating chemical analyses shall be directly traceable to appropriate requirements and industry standards [e.g., American National Standards Institute (ANSI), American Society of Mechanical Engineers (ASME), EPA]. Laboratory data validation criteria are determined by analytical methods and ASLs specified for the data. Checklists shall include, but not be limited to, the following criteria.

The paragraph goes on to identify the criteria for Organic materials, Inorganic Materials and Radiochemical and Analytical Support Levels that make for a standardized approach.

FINDING:

Technical data reviewers do not use a standard data validation checklist when reviewing organic analysis.

"MACROS" developed by individual users to generate or manipulate reportable data were not validated using a standardized software validation procedure.

SECTION 3
FINDING
E93-15-5

REQUIREMENT:

RFP92616 Statement of Work-Appendix 2 page 20, SW-846, Method 1311 and Weston SP#21-15-1311.1 and OP#21-15-1311.2 require the documentation of all percent solids.

FINDING:

The percent solids determinations for TCLPs were not recorded on the TCLP Extraction Runsheets.

SECTION 3
FINDING
E93-15-6

REQUIREMENT:

Per the SCQ the TCLP Extractions by SW-846 Method 1311 requires that the rotary extractor operate at 30 ± 2 RPM during TCLP extractions and that this data be documented.

FINDING:

RPM checks of the rotary extractor had not been recorded.

SECTION 3
FINDING
E93-15-7

REQUIREMENT:

Statement of Work-Section CI-I-I Specific Requirements page c-1 Item A Program Description reference Level D says the following;

Level D: The method, detection limits, and quality control to be employed in the processing of these samples shall be the EPA CLP SOW. The data package required shall be described in the CLP SOW.

Additionally CLP Users Guide Chapter 6 - G says the following;

Data manually entered from hard-copy must be reevaluated through quality control measures and the error rates estimated. Systems should prevent entry of incorrect or out-of-range data and alert data entry personnel of errors. In addition, data entry error rates must be estimated and recorded on a monthly basis by reentering a statistical sample of the data entered and calculating discrepancy rates by data element.

FINDING:

Contrary to the above, error rates of hand entered data was not being estimated.

FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

QUALITY ASSURANCE AUDIT NO. E93-16

Data Chem Laboratories

DATE OF AUDIT: October 11-15, 1993

DATE OF REPORT: December 9, 1993

REISSUED: March 14, 1994

AUDIT LOCATION: Data Chem Laboratories (DCL)
Salt Lake City, UT

AUDIT TEAM

MEMBERS: David T. McCulley, Lead Auditor, FERMCO QA
Doug Davis, Nuclear Fuels Services, Technical Representative

PURPOSE AND SCOPE:

Assess the adequacy, effectiveness, and implementation of FERMCO and DOE quality assurance requirements and contractor performance as required by FERMCO contract RFP 92616. Investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program Description, RM 0012, FERMCO contract RFP 92616 RCRA/CERCLA Statement of Work, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ) as related to providing analytical laboratory services for radiological constituents.

AUDIT SUMMARY:

DCL has the necessary licenses, certifications and controls (e.g., quality program, policy statement, operating procedures) necessary to provide quality data packages for radiochemical analyses to the FEMP in accordance with FERMCO Quality Assurance Program Description and FERMCO contract 92616 Statement of Work except for thorium analysis.

POST AUDIT REVIEW:

A post audit review was conducted in addition to the facility audit to include information pertinent to determining the capability of the laboratory to perform specified analyses. FERMCO Analytical Laboratory Support (ALS) personnel and FERMCO Quality Control (QC) personnel provided information related to the laboratory performance capabilities.

During the previous audit, E93-08, checklists based on the USEPA Contract Laboratory Program (CLP) Statement of Work were used (Combined Organic/Inorganic Laboratory On-site Audit Plate). The CLP requirements were incorporated into the SCQ, therefore, DCL can perform analyses in accordance with the SCQ. Analysis results received during the past

months indicate that DCL can also meet the requirements specified in Statement of Work 92616 with exceptions noted below.

At the time of this audit report, the FERMCO intercomparison program could not provide data for uranium and thorium for DCL. A follow up audit at DCL will be conducted within the next few months and intercomparison data for uranium and thorium will be evaluated. However, in the DOE Environmental Measurement Laboratory (EML) program, up to three uranium measurements are made on each of four possible matrices (water, soil, air, and vegetation). The DOE EML intercomparison studies for round 93-03 indicate that for 17 determinations, approximately 98% of the results were within reported EML acceptable range. It is noted that thorium is not included in intercomparison programs sponsored by DOE and EPA due to its limited use at other DOE or commercial sites. Until data for thorium analysis, by DCL, can be evaluated, DCL should not be used for thorium analysis.

AUDIT CONDUCT:

A formal announcement of the intended audit was sent to DCL on September 21, 1993. The FERMCO auditors held an opening meeting the afternoon of October 11, 1993 with DCL representatives.

Check lists were developed by the audit team for use during the audit to aid in review of the laboratory for compliance with the identified requirements. These check lists are maintained in the FERMCO Quality Assurance audit file.

Findings from Audit E93-08 requiring verification were reviewed and will be evaluated during an upcoming surveillance. However, based on information provided by the FERMCO Technical Representative, those inadequacies do not affect the overall quality of data. Daily meetings were held to discuss evaluations of processes and to discuss inadequacies noted.

Interviews were conducted with various laboratory personnel and managers; procedures, program plans, and record files were reviewed; laboratory operations, health and safety practices, and waste management activities were observed. Findings and concerns noted during the audit are stated in Sections 1 and 2 of this report, respectively.

T. E. Wachter	Health & Safety
L. Eggenberger	Quality Assurance
J. Johnson	Project Manager
C. Walker	Radiochemistry Manager

A close out meeting was held by the auditors, October 15, 1993, with DCL laboratory and administrative management personnel.

AUDIT OBSERVATIONS:

This section of the audit report is formatted to relate observations made during the audit to functional categories and criterion required by the FERMCO Quality Assurance Project Plan (RM-0012).

A. FUNCTIONAL CATEGORY A: MANAGEMENT**1.0 Criterion 1 - Program**

DCL has developed and maintains a written quality assurance program. (QAP) following the appropriate requirements of NQA-1. Requirements of FERMCO's FD-1000, Sitewide CERCLA Quality Assurance Project Plan (SCQ), including ANSI/ASQC E4-19XX, are specified in the contract. A matrix is included in the FERMCO Quality Assurance audit file which depicts correlation between DOE Order 5700.6C, RM-0012, and ANSI/ASQC E4-19XX.

DCL's Quality Assurance Plan is binding on all personnel, and operating procedures describing how the elements are applied, are referenced in each section. A policy statement, signed by management personnel and a "stop work" policy are included in the document.

A list of equipment was submitted during the Procurement process prior to award of contract. DCL has sufficient equipment, as well as personnel, to perform organic, inorganic, and radiological analyses, necessary to support the Statement of Work. However, they are performing only organic and inorganic analyses for data validation.

Housekeeping practices in the radiological area are indicative of working laboratory.

DCL has the following systems in place in order to fulfill regulator requirements:

- Safety & Health Plan (including a radiological safety section)
- Chemical Hygiene Plan
- Waste Management Plan

Verification of these systems found them to be adequate to support DCL processes.

See Section 2, Concern 1

2.0 Criterion 2 - Personnel Training and Qualification

DCL is supportive of the concept that personnel shall be trained and qualified to perform their assigned work. The audit team recognizes the technical expertise of the staff to be excellent. Resumes were reviewed to ensure analysts and management met educational and training requirements established by DCL. Records indicated that analysts participated in performance evaluation programs and a system is in place for retraining should it be required.

Resumes and training files were reviewed during conduct of Audit E93-08.

3.0 Criterion 3 - Quality Improvement

The DCL QA program implements processes to detect and prevent quality problems and promote continuous quality improvement.

4.0 Criterion 4 - Documents and Records

A system is in place to control preparation, review, approval, issuance, use, and revision of documents.

Records containing data used to support CERCLA decision making follow the requirements of the FERMCO SCQ and reporting requirements listed in the Statement of Work. Records are maintained for preventive maintenance, calibration, procedures, and other documentation as needed, to meet SCQ requirements.

DCL's system for maintaining documents and records was reviewed during conduct of Audit E93-08.

3. FUNCTIONAL CATEGORY A: PERFORMANCE

5.0 Criterion 5 - Work Performance

This criterion describes work related instructions, procedures, and other forms of direction including, but not limited to, waste handling packaging, certification and shipping, and environmental data operations

There are standard operating procedures available for pertinent processes including sample receipt, storage and processing. To ensure chain of custody, laboratory tracking systems are in place. A process for sample receipt (described in Section 7 of the SCQ) was not included in DCL procedure. Other operating procedures were found to be inadequate noted.

See Section 1. Findings 1, 2, 4, 5, 6, 8, 9.

The radiochemistry methods portion of the audit was performed by reviewing an example data package submitted to FERMCO on August 26, 1993, in order to comply with RFP requirements for a FERMCO sampling and analysis program (unrelated to RFP 92616). DCL has not, at the time of the audit processed any radiological samples for FERMCO, therefore, a FERMCO package could not be evaluated.

The DCL data package reviewed contained data for total uranium and alpha spectroscopy analysis performed on surrogate liquid waste samples. data in the report package was reviewed for compliance with appropriate performance requirements of the SCQ.

Isotopic uranium analyses were performed per alpha spectroscopy SOPs

DC-200, WR-DC-341, WR-DC-130, and WR-DC-131. The DCL data package contained documentation of percent overall tracer recovery analysis, matrix spike analysis, duplicate sample analysis, method blank evaluations, and laboratory control sample analysis. Analytical standards are traceable to certified standards through proper documentation in the standard logbooks.

Total uranium analyses were performed per DCL SOP WR-DC-342. The DCL data package contained documentation of matrix spike analysis, method blank evaluations, laboratory control sample analysis, and duplicate sample analysis. In all cases, the raw data confirmed the values reported in the sample summary reports. The transcription and verification of data and calculations into the report package were controlled per DCL SOP XX-RP-600 and XX-EP-900. All raw data and notebook entries clearly identified both the analyst/preparer and the reviewer. The overall quality of laboratory notebooks were impressive both in terms of legibility and content. Analytical standards are traceable to certified standards through proper documentation in the "Radioactive Material Inventory Service Log" and the "Radioactive Materials Inventory Intermediate Standard Log".

Review of data packages during the conduct of Audit E93-08 and this audit provided evidence that DCL is capable of producing data for ASLs B, C, and D.

A preventative maintenance program (PM) for analytical instrumentation is in effect and is operating adequately as indicated in the PM log.

6.0 Criterion 6 - Design

This criterion states that data collection processes for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. Computer programs are to be proven through previous use, or verified through testing or simulation prior to use.

See Section 2. Concern 2.

7.0 Criterion 7 - Procurement

DCL has established a program to ensure that purchased items and services meet established requirements and perform as expected, however a concern was documented during Audit E93-08.

8.0 Criterion 8 - Inspection and Acceptance Testing

This criterion describes requirements and responsibilities for conducting chemical analyses and producing analytical data for environmental projects. DCL produced an equipment list identifying measuring and test equipment which is calibrated against national recognized standards. Records are maintained indicating that standards are traceable to NIST.

0808

DCL's analytical procedures do not address the preparation of calibration standards. DCL has committed to promulgate a draft procedure "The Acquisition, Preparation, and Use of Radioactive Standard Reference Material".

See Section 1. Findings 3 and 7.

Laboratory equipment inspections are scheduled. Logbooks indicated inspections took place and that results were satisfactory.

C. FUNCTIONAL CATEGORY C: ASSESSMENT

9.0 Criterion 9 - Management Assessment

This criterion describes a planned and periodic program of management assessments.

The Management Assessment program was addressed during Audit E93-08 and inadequacies were noted under "Concern - 9.2".

10.0 Criterion 10 - Independent Assessment

DCL has implemented a program for the planning and performance of independent assessments. An audit schedule was produced indicating that internal assessments are performed.

However, inadequacies were noted during Audit E93-08 under "Concern - 10.2".

Intercomparison studies were previously discussed in the "Post Audit Review" section.

Section 1

FINDINGS
Audit E93-16

1. **Requirement:** SCQ Appendix 6, Tables 2 and 4
Finding: DCL analytical SOPs do not specify the QC performance specifications of SCQ Appendix G, Tables 2 and 4. DCL has committed to specifying the QC requirements of the SCQ in the "Project Protocol Worksheets" that will be prepared for this project.

The FERMCO Audit Team recommends that these documents be reviewed by the FERMCO technical representative prior to shipment of any samples requiring radiological analysis.
2. **Requirement:** SCQ Appendix 6, Table 4
Finding: DCL analytical SOPs do not address the determination of HAMDC, as required in SCQ Appendix G, Table 4. DCL has committed to develop a program to address the determinations of HAMDC, for each analytical method and to make provisions for the data from these determinations to be included in each analytical report package in order to meet SCQ data validation requirements.
3. **Requirement:** SCQ Appendix E Item 3
Finding: DCL's analytical SOPs do not address the preparation of calibration standards. DCL has committed to promulgate "The Acquisition, Preparation, and Use of Radioactive Standard Reference Material". The SOP will address the finding for all radiological analytical methods.
4. **Requirement:** SCQ Appendix E Item 3
Finding: The DCL analytical method for total uranium analysis WR-DC-342, does not describe the preparation of samples such as method blanks, matrix spikes, etc. DCL has committed to revise the SOP to include preparation of QC samples.
5. **Requirement:** RFP 92616 - Requires approval of Chain of Custody Procedure prior to awarding samples for analysis.
Finding: DCL's chain of custody procedure, XX-DC-006, does meet Statement of Work requirements concerning tracking of sample extracts and waste from analysis through the storage of the solutions. DCL has committed to issue a project specific SOP or address specific

chain of custody requirement on the "Project Protocol Worksheet".

6. **Requirement:** SCQ Appendix G, Table 4

Finding: DCL currently monitors the background response of the KPA-11 through the use of control charts, but does not routinely calculate HAMDCs as required per SCQ Appendix G, Table 4.
7. **Requirement:** SCQ Appendix G,

Finding: The total uranium SOP does not specify QC requirements, preparation of QC sample, and preparation of calibration standards.
8. **Requirement:** SCQ Appendix G

Finding: DCL routinely calculates instrument minimum detectable activity, but does not calculate HAMDCs as required by the SCQ.
9. **Requirement:** SCQ Appendix G

Finding: The alpha spectroscopy SOPs do not specify QC requirements or the preparation of calibration standards.

Section 2

CONCERNS
Audit E93-16

1. Several laboratories in the mixed-waste analysis area had floor drains. The drains present a concern based on the possibility of spilled FERMCO samples not being recovered for return to FERMCO. DCL has committed to develop a spill plan that addresses this concern.
2. The RMIT software used to track the inventory of radioactive material on a weekly basis is updated by manually entering changed in the inventory. The changes are not currently checked for accuracy by a second reviewer. DCL has committed to address this concern. The RMIT software was validated before being placed into service; however, this validation was only partially documented.

The Audit Team recommended that additional validation and documentation be added through the DCL QA department to strengthen the validity of the RMIT system.

BASELINE ASSESSMENT REPORT
AUDIT I94-04
ANALYTICAL LABORATORY SERVICES DEPARTMENT

DATE OF ASSESSMENT: January 25 - 28, 1994
DATE OF REPORT: February 24, 1994
ASSESSMENT LOCATION: FERMCO Analytical Laboratory Services (ALS)
ASSESSMENT TEAM MEMBERS: D. H. Price, Lead Auditor
D. V. Meredith, Auditor
D. Madsen, Auditor
M. A. Forrest, Auditor
D. McCulley, Auditor
C. K. Suits, Auditor

ASSESSMENT PURPOSE: To assess the adequacy, effectiveness and implementation of the operations of the Analytical Laboratory Services

ASSESSMENT SCOPE: To investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program, RM-0012, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ).

Analytical Laboratory Services Quality Assurance Management Plan Revision 0, (No. 776-V-P002)

Previous Audits:

Audit I91-08 Analytical Inorganic Section

Audit I93-03 - Organic Analysis Laboratory

ASSESSMENT SUMMARY:

A formal announcement of the intended assessment was sent to Analytical Laboratory Services Department, January 7, 1994.

The audit was conducted to evaluate Analytical Laboratory Services Department's (ALS) ability to perform in accordance with FEMP Sitewide CERCLA Quality Assurance Project Plan FD-1000 (SCQ) and other applicable procedures and documents.

This audit was performed using the same parameters and approach that had been used in six (6) previous laboratory audits.

The following areas were covered during the course of the audit making use of checklists:

- Chemical Hygiene Plan
- Satellite Accumulation Areas (SAAs)
- Health and Safety
- Analytical Laboratory Services
Quality Assurance Management Plan
(Document No. 776-V-P002)
- Sitewide CERCLA Quality Assurance Project Plan FD-1000
(SCQ)
- Previous Audits
(Audit I91-08 - Inorganic Section)
(Audit I93-03 - Organic Analysis Laboratory)
- RM-0012 Quality Assurance Program Description
- And applicable procedures

Analytical Laboratory Services Department has developed administrative controls, they have a Quality Assurance Management Plan; policy statement; operating procedures, etc. necessary to provide the FEMP with validatable data packages for EPA SW-846 methods and CLP Level B. At this time the laboratory has done very little work at Level C and D.

A preventive maintenance program is in place; logbooks are maintained for each instrument indicating the instruments are properly maintained.

AUDIT CONDUCT:

Throughout the audit, interviews were conducted with various laboratory personnel and managers; procedures, the Chemical Hygiene Plan, the Quality Assurance Management Plan, record files and training records were reviewed; laboratory operations, health and safety practices, and waste management activities were observed. Concerns and findings noted during the assessment are identified in attachments 1 and 2, respectively. A close-out meeting was conducted on January 28, 1994, (attended by the QA Baseline Assessment Team and appropriate Laboratory staff).

As a result of detailed investigation, team members recorded individual concerns and findings on their checklists. These

concerns and findings were consolidated into subteam findings that provided the basis for this report and overall evaluation of the Laboratory. Detailed requirements and observations to support the deviations can be found in Attachment 3. The deviations were then evaluated and classified based on severity and consequences as referenced in Attachment 4. Six findings and five concerns were presented and discussed at the close out meeting January 28, 1994. The following people were contacted during the course of the assessment:

People Contacted During Audit

+ ● Chris Sutton - Manager ALS Dept.
 + ● William D. Kelley - ACS-STR-ALS Dept.
 + * William Maple - QC
 + * Reinhard Friske - QC
 + * Larry Herrick - Supervisor EPM - ALS Dept.
 + * Robert Hellmann - Supervisor TMS - ALS Dept.
 + * Mike Rolfes - Environmental Lab Scientist - ALS Dept.
 + * Janet L. Angert - Senior Analytical Chemist - ALS Dept.
 + * Jo Anna Cole - Manager SMO - ALS Dept.
 + * Harold W. Humphrey - Supervisor Radiochemical Analysis ASL Dept.
 + ● Carl T. Bishop- Supervisor Low Level Environmental
 + * Rao B. Paturi - Supervisor DR & A - ALS Dept.
 + Michele Miller - Manager Analytical Facilities Administration ALS Dept.
 Betty Burk - Secretary - ALS
 May Blanton - Procedures
 David Ponke - QA
 Janet Neton - AA/ICP Analysis - ALS Dept.
 + Wanda Burk - Chemical & Equipment Control - ALS
 + Kathy Fisher - Training Coordinator - ALS Dept.
 + Ellen Hansmann - Procurements, Commitments Budget, & ALS Dept.
 + Dawn M. Webber - DRA Lead Clerk - ALS Dept.
 + * Raymond J. Danahy-Manager Rad & Isotopic-ALS Dept.
 + * Amy J. Meyer - Supervisor - AA/ICP analysis - ALS Dept.
 + * Richard M. Dain - Supervisor, ACS - ALS Dept.
 + * William J. Maple - QC
 Jim Phelan - Environmental/Lab Scientist I - ALS Dept.
 Paul Blake - ES&H
 Kathy McIntyre - Computer Operations
 Tom Strassell - Computer Operations
 ● Mary Ann Forrest - Auditor
 + * David Madsen - Auditor
 + ● David McCulley - Auditor
 + * David Meredith - Auditor
 + * Chris Suits - Auditor
 + ● David H. Price - Lead Auditor

+ = Attended Closing Meeting

● = Attended Opening Meeting

CHEMICAL HYGIENE PLAN

The Chemical Hygiene Plan - PL-FMPC-3001 dated January 15, 1991 is presently under review for revision. There is a Chemical Hygiene Committee that meets on a regular basis. They are currently reviewing the Chemical Hygiene Plan.

(See Attachment 2 and 3, Finding 4)

SATELLITE ACCUMULATION AREAS (SAA)

The satellite accumulation areas (SAA #13, #11A, and #11B) were visited during the course of the audit. A number of items were verified such as:

- EPA Waste Number
- Markings on the hazardous waste label
- Proper shipping name in the space provided
- Flammable Materials Cabinets
- Compatibility of Waste
- Condition of SAA containers
- Generators name and address
- Container condition requirements
- Proper signs posted
- Proper Training

In area #11A, a drum lid was not secured (insufficient information was encountered with SAA addition sheets and was corrected immediately), and this was reported to the proper personnel.

(See Attachment 2 and 3, Finding 5)

HEALTH AND SAFETY

In the health and safety area, a number of items were covered without any problems being encountered. Listed are some of the areas covered:

- Radiation Worker Training
- Laboratory Safety Training
- Chemical labeling
- Material Safety Data Sheets (MSDS)
- Safe handling, storage, and disposal of all waste
- Personal Protective Equipment
- Fire Extinguisher
- Fire alarm system
- Velocity flow rates of laboratory fume hoods

General housekeeping requires improvement. (See attachment 1- Concerns)

ALS - QA MANAGEMENT PLAN

Training, calibration and self assessment were covered in this area.

Training - In an attempt to verify/assure that analysts were trained to the procedures several documents were chosen from the procedure index, it was discovered that some of the procedures are not being used. A closer review of the procedure index indicates that there are three different numbering systems being used.

Calibration - While checking on calibration it was discovered that the balances had stickers on them that indicated that the next calibration was due December 1993. ALS personnel were made aware of this, further checking indicated they changed to an annual basis in accordance with SCQ paragraph 8.4.1, also a letter was obtained from Mettler-Toledo, the calibration and preventative maintenance company. The stickers will be corrected at the next calibration cycle.

Self-Assessment - At this time they have only conducted one self-assessment, January 18, 19, 20, 1994.

The Self-Assessment program needs to be continued and expanded.

FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ)

The Sitewide CERCLA Quality Assurance Project Plan (SCQ) program was developed for FEMP environmental sampling and analysis with a twofold purpose: (1) to establish minimum standards of performance for operational and analytical activities, and (2) to ensure standards are followed by parties covered by the program. The SCQ provides overall site-wide quality assurance planning for sampling and analysis activities planned or ongoing at the FEMP.

The following labs were audited:

Atomic Absorption/Inductively Coupled Plasma Lab (AA/ICP)
 Environmental Process Monitoring Lab (EPM)
 Isotopic Lab (IL)
 Low Level Environmental Monitoring Lab (LLEML)
 Laboratory Qualification (LQ)

I. DOCUMENTS AND RECORDS

A. SOP's/Methods

1. **Finding** - The following is a list of examples where procedures need to be updated:

- a. Environmental Process Monitoring Lab (EPM) - In Room 169, a CIO 92-143 for method 3002 (Total Uranium) has expired.
- b. Atomic Absorption/Inductively Couple Plasma Lab (AA/ICP)
 - (1) In Room 165, method 9012 (TCLP) needs revision to include a calculation worksheet that is used.
 - (2) In Room 192, method 9103 (Mercury-Cold Vapor) needs a revision to include SCQ ASL/QC criteria.
 - (3) In Room 163, method 9058 (CLP QC procedure) needs revision to include SCQ ASL C and D criteria for serial dilution in ICP metals analysis.
- c. Analytical Laboratory Services - SOP 9031, Data Management and Reporting, needs to be updated to reflect SCQ criteria for ASL reporting levels (as described in Appendix E, Section 7). This procedure does not adequately describe Data Review and Assembly (DR&A) nor Analytical Lab's activities for reporting. (See attachment 2 and 3, Finding 1 and 3)

B. Records/Files

1. The following is the list of items audited.
 - a. Documentation of QC samples - All items reviewed were satisfactory. Raw QC data was on computer printout.
 - b. Documentation of Instrument Detection Limits (IDL) - All items reviewed were satisfactory. Raw QC data was on computer printout.
 - (1) Observation - The current AA/ICP IDL's were being processed and not yet posted. The deadline is January 31, 1994.
 - c. Documentation of calculations and validation - All items reviewed were satisfactory. All labs used checklist and customized forms for consistency in calculations and validation activities.
 - d. Documentation of sample holding times - All items reviewed were satisfactory. Holding times are

calculated and tracked by the FACTS computer system.

- e. (AA/ICP) Documentation for ICP serial dilution (ASL C & D) - All items reviewed were satisfactory.
- f. (AA/ICP) Documentation for complete ASL C & D Package - Ward Scientific Software was purchased for processing these packages in the AA/ICP lab. They are processed according to CLP SOW requirements.
- g. (LQ) Documentation for Interlaboratory Quality Assurance Program Performance - All items reviewed were satisfactory. Documentation was verified against programs listed in 776-V-P002, Section 13.3. Corrective actions were initiated by official memo.
- h. (AA/ICP) Documentation for TCLP samples - All items reviewed were satisfactory. Documents for QC samples, tracking, storing, and calculations were verified.

C. Logbooks

- 1. All items reviewed were satisfactory. Working standards were traceable to certificates with the following exception.
 - a. **Concern** - (AA/ICP) In Room 192, a working standard was not traceable for a sample batch (MA2-93-067) that was analyzed in November 1993. The logbook format was changed to correct this problem during a self assessment on January 18, 1994.

This was evaluated to be an isolated incident.

D. Electronic Data Archiving - Administration Building (No findings.)

- 1. **Discussion** - Tom Strassel and Kathy McIntyre were interviewed to determine the storage locations of backup tapes and the file indexing system used for traceability of analytical data. The site VAX system (Facts & AnaLIS) is electronically transferred to the Sitewide Database and then downloaded to backup tapes on a daily (partial backup) and weekly (full backup) schedule. The tapes are sorted onsite in the computer vault in the Administration Building and offsite at Business Information Storage, Inc. in downtown

Cincinnati on a rotation basis. A hanging file library system containing printouts from the computer is used, with tape numbers, dates, and file information listed. Tape number 4073 containing analytical data was selected from the logbooks and was found to be traceable to the computer vault. A special software program is used to facilitate traceability from that number to essential information of tape contents and then to the analytical data.

This section of the audit report is formatted to relate observations made during the audit as related to functional categories and criterion required by the FERMCO Quality Assurance Project Plan (RM-0012).

Functional Category A: Management

1.0 Criterion 1- Program

Analytical Laboratory Services Department has a written Quality Assurance Management Plan that is based on compliance with DOE Orders and EPA requirements through adherence with the FEMP Quality assurance Program Description (QAPD) requirements (RM-0012) and the Sitewide CERCLA Quality Assurance Project Plan (SCQ) requirements FD 1000.

(See Attachment 2 and 3, Finding 6)

2.0 Criterion 2 - Personnel Training and Qualification

Records were reviewed to assure that analysts were trained to the various procedures. Some resumes of the personnel were not on file but were obtained during the course of the audit. Review of the resumes indicated analysts have the necessary credentials as described by FERMCO to perform their assigned tasks.

3.0 Criterion 3 - Quality Improvement

The laboratory has appointed an individual to handle quality related issues.

4.0 Criterion 4 - Documents and Records

Numerous procedures were obsolete and had not been reviewed within the prescribed time frame, also noted that a number CIOs had expired.

Document periodic review program needs to be followed. A records inventory list is in place, but needs to be updated.

(See Attachment 1 and 2, Finding 2 and 3)

Functional Category B: Performance**5.0 Criterion 5 - Work Performance**

This criterion describes work related instructions, procedures, and other forms of direction including, but not limited to, waste handling, packaging, certification and shipping, and environmental data operations.

A Chemical Hygiene Plan is in the process of being revised. The fume hoods are on a regular (PM) Program to assure that the air flow is adequate.

Safety equipment is installed in or near all laboratories.

A PM program for analytical instrumentation is in effect and is operating adequately as indicated in the PM log.

This criterion also describes the identification and control of items, handling, storing, and shipping of waste, and calibration and maintenance of monitoring and data collection equipment.

The calibration processes are traceable to NIST and records are maintained indicating standards traceability.

While checking on calibration it was discovered that the balances had stickers on them that indicated that the next calibration was due December 1993. ALS personnel were made aware of this, further checking indicated the calibration cycle was changed to an annual basis in accordance with the SCQ paragraph 8.4.1. Also a letter was obtained from Mettler-Toledo, the calibration and preventative maintenance company stating the balances are in calibration. New stickers will be attached to the instruments at the next calibration cycle.

(See Attachment 1)

6.0 Criterion 6 - Design

This criterion states that data collection processes for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. Computer programs are to be proven through previous use, or verified through testing or simulation prior to use.

Raw QC data was on computer printout. All labs used checklist and customized forms for consistency in calculations and validation activities. Sample holding times are calculated and tracked by the FACTS computer system. Ward Scientific Software was purchased for processing computer ASL C & D packages. The software is designed to meet CLP SOW requirements. Documents for QC samples, tracking, storing, and calculations were verified.

7.0 Criterion 7 - Procurement

Analytical Laboratory Services has established a program to ensure that laboratory materials, equipment and services meet established requirements. Audits will be conducted prior to award of a contract to outside labs and on an annual basis during the terms of the contract.

8.0 Criterion 8 - Inspection and Acceptance Testing

This criterion describes requirements and responsibilities for labs conducting chemical analyses, and producing analytical data for environmental projects.

Laboratory equipment inspections are scheduled and documented.

Documentation of QC samples and instrument detection limits was satisfactory.

Discussions were held with QC personnel who indicated they felt the laboratory was capable of producing acceptable data for ASL - B, C, and D.

9.0 Criterion 9 - Management Assessment

This criterion describes a planned and periodic program of management assessments. Self-Assessment Program falls under this criterion.

At this time the laboratory does not have a formal program, however self-assessments were conducted January 18, 19, and 20, 1994, prior to this baseline assessment.

10.0 Criterion 10 - Independent Assessment

Analytical Laboratory Services Department has been audited on a regular basis, this assessment helps to fulfill this requirement.

Listed below are additional audits that have been conducted:

- Audit I91-08 - Analytical Inorganic Section
- Audit I93-03 - Organic Analysis Laboratory
- Audit I94-06 - Site Sample Management

ALS is included on the QAE surveillance schedule.

Conclusions and Recommendations

The staff and all the Analytical Laboratory Services personnel were very cooperative and supportive in the review of their data.

It is felt that ALS has the capability to produce analytical results in compliance with the SCQ, although at this time, the Laboratory has for the most part only conducted work at the ASL Level B.

The facility, equipment, and personnel are quite adequate to operate in accordance with the SCQ.

It is recommended that the Analytical Services Laboratory be placed on the, "Approved Laboratory List", conditionally, pending resolution of the audit deviations/findings.

Attachment 1
CONCERNS

- A records inventory list is in place, but it needs to be updated.
- Access to the Analytical Laboratory service files and records is not properly restricted.
- Housekeeping can be improved in several areas:
 - RM-203 - Being converted
 - RM-163 - Emergency exit was blocked
 - RM-168 - Container's stacked - Area cluttered
 - RM-159 - Boxes stacked on top of cabinets
- Satellite accumulation area addition sheets did not indicate wastes were from immediate area - corrected immediately.
- In Room 192, a working standard was not traceable for a sample batch (MA-93-067) that was analyzed in November 1993. The logbook format was changed to correct this problem during a self assessment on January 18, 1994.

Attachment 2

FINDINGS

The findings will require a formal written reply.

1. "Both, the ICP instrument and the Graphite Furnance AA instrument, have two types of analytical methods; one for SW-846 (ASL B) and one for CLP (ASL C & D)." The method used is determined by the analytical support level (ASL) for the project/sample. The method of analysis is not noted or otherwise recorded in the analyst logbook.
2. Several blank spaces and boxes were observed on forms in laboratory logbooks. Abnormal conditions are recorded, however the remaining spaces were left blank. In order to reflect all work has been performed completely, all spaces should be filled in. Use N/A as necessary.
3. There is a need to complete the periodic review program for procedures in accordance with PO-D-007 (document periodic review program)
4. There is no indication that the Chemical Hygiene Plan, PL-FMPC-3001, has been reviewed or revised since January 15, 1991.
5. Satellite accumulation area addition sheets do not contain information required by headings on the form. No quantities were recorded for waste emptied into 5-gal containers.
6. Room 159 where CRU5 data packages are stored should be a limited access/controlled area was left unattended.
(1/27/94 -1:10 PM)

Attachment 3

Finding

I94-01-1

Requirement:

RM-0012, Quality Assurance Program Description Revision 2 -
Criterion 4 - Documents and Records Paragraph 4.2.6 says:

4.2.6 FERMCO shall establish and implement processes to ensure that records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

Finding:

"Both, the ICP instrument and the Graphite Furnace AA instrument, have two types of analytical methods; one for SW-846 (ASL B) and one for CLP (ASL C & D)."

The method used is determined by the Analytical Support Level (ASL) for the project/sample. The method of analysis is not noted or otherwise recorded in the analyst logbook.

Finding

I94-04-2

Requirement:

RM-0012, Quality Assurance Program Description Revision 2 -
Criterion 4 - Documents and Records Paragraph 4.2.6 says:

4.2.6 FERMCO shall establish and implement processes to ensure that records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

Finding:

Several blank spaces and boxes were observed on forms in laboratory logbooks. Abnormal conditions are recorded, however the remaining spaces were left blank. In order to reflect all work has been performed completely, all spaces should be filled in. Use N/A as necessary. This was observed in the AA/ICP Laboratory.

Finding
I94-04-3

Requirement:

RM-0012, Quality Assurance Program Description Revision 2,
Criterion 4 - Documents and Records:

4.2 REQUIREMENTS

4.2.1 FERMCO shall establish and implement a system to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design. The scope of the document control system shall be defined.

Additionally Department Procedure PO-D-007, Revision 0 -
Paragraph 6.1 Scheduling:

6.1.1 Each document shall be reviewed using a DRC (Document Review Cycle) of 12 to 24 months after the issue date of the document.

Finding:

Contrary to the above numerous work related instructions and procedures were obsolete and have not been reviewed within the prescribed time frame. The Analytical Document Index shows that there are three different systems for numbering documents/procedures, this makes for confusion. Listed are some examples of documents/procedures that are not in compliance with the DRC and do not meet the SCQ.

ANL-01-0049 - Chain of Custody for Environmental Samples

1001 - The Determination of Oil and Grease in Water and Waste

3001 - The Determination of Ammonia - Nitrogen in Wastewater using The Potentiometric Ammonia Sensing Electrode Method

4022 - The Radiometric Determination of Th-234 and PA-234M In Effluents

9001 - Gas Chromatography/Mass Spectrometry for Semi-Volatile

ANL-33-0028 - Radiometric Records and Sample Handling

9031 - Management and Reporting of Analytical Laboratory Results

THE TOTAL DOCUMENT/PROCEDURE SYSTEMS NEED A REVIEW AND REVISION.

Finding

I94-04-4

Requirement:

The Code of Federal Regulations - 29 CFR 1910.1450 requires that the laboratory have a Chemical Hygiene Plan, and that it be evaluated on an annual basis.

Finding:

Analytical Laboratory Services, Chemical Hygiene Plan, dated 1/15/91, references numerous obsolete procedures, organizations, and responsibilities.

Chemical Hygiene Plan needs a complete review and revision.

0000

Finding

I94-04-5

Requirement:

RM-0012, Quality Assurance Program Description Revision 2,
Criterion 5 - Work Performance:

5.1 SCOPE

This criterion describes the requirements and responsibilities for the control of processes affecting work performance. The purpose of work process control is to ensure that standard processes and special processes are accomplished under controlled conditions. These standard processes and special processes include, but are not limited to: waste handling, packaging, certification and shipping; environmental data operations; welding; heat treating; core drilling; or nondestructive testing.

Additionally 40 CFR 262.34 (c)1 requires that the material designated on the Addition Sheet match the material designation on the hazardous waste label and that the waste has come from the immediate area.

Finding:

Satellite accumulation area addition sheets do not contain information required by headings on the form. No quantities were recorded for waste emptied into 5-gal containers.

Finding

I94-04-6

Requirement:

Quality Assurance Project Plan (SCQ) Appendix E Page 2 of 10-E.2
Laboratory Approval:

E.2.1 Requirements for an Approved Laboratory

A laboratory which demonstrates compliance with the following requirements shall be considered approved to perform work for the FEMP for the ASL and types of analyses considered.

Item 4: Has adequate building security and Chain-of-Custody system with applicable SOPs.

Finding:

Room 159 CRUS data packages were stored in a room that is not classified as a limited access/controlled area and was left unattended on 1/27/94 at 1:10 PM. CERCLA data is to be maintained in a limited access/controlled area.

Attachment 4

Quality Assurance Baseline Assessment, I94-04
Assessment Deviation Evaluation Sheet

<u>Deviation I.D. Number</u>	<u>Organization</u>	<u>• Subject</u>
I94-04-01	Quality Assurance	Chemical Hygiene Plan/Program

* Subject Areas assessed: Chemical Hygiene Plan/Program; Satellite Accumulation Area; Health and Safety standards; FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ); Analytical Laboratory Services Quality Assurance Management Plan, 776-V-P002; Quality Assurance Program Description, Rev. 2, RM-0012 and previous audits (Audit I91-08, Analytical Inorganic Section and Audit I93-03, Organic Analysis Laboratory).

Date: January 25 - 28, 1994

Activity: Chemical Hygiene Plan Assessment

Referenced Data: Visual inspection

<u>Deviation(s)</u>		<u>Severity Category</u>				
1=	Potential Near-Term Significant Impact	1	2	3	4	5
2=	Potential Agreement NonComp					
3=	Potential Reg/DOE NonComp					
4=	Potential BMP NonComp			X		
5=	Noteworthy Compliance or Practice					

Chemical Hygiene Plan, PL-FMPC-3000, cover page indicates that the document has not been reviewed/revise on an annual basis. The effective date for this document is 1/15/91.

Discussion

As stated in 29 CFR 1910.1450(e)(4), the employer shall review and evaluate the effectiveness of the CHP at least annually and update it as necessary

Tentative Deviation(s)

The ALS Chemical Hygiene Plan is not adequately maintained.

Probable Root Cause(s)

There is a lack of quality control in the Chemical Hygiene Plan review process.

Quality Assurance Baseline Assessment, I94-04
Assessment Deviation Evaluation Sheet

Deviation I.D. Number	Organization	* Subject
I94-04-02	Quality Assurance	Satellite Accumulation Areas (SAA)

* Subject Areas assessed: Chemical Hygiene Plan/Program; Satellite Accumulation Area; Health and Safety standards; FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ); Analytical Laboratory Services Quality Assurance Management Plan, 776-V-P002; Quality Assurance Program Description, Rev. 2, RM-0012 and previous audits (Audit I91-08, Analytical Inorganic Section and Audit I93-03, Organic Analysis Laboratory).

Date: January 25 - 28, 1994

Activity: Satellite Accumulation Area Baseline Assessment

Referenced Data: Visual Inspection and Interviews

Deviation(s)	Severity Category				
	1	2	3	4	5
1= Potential Near-Term Significant Impact					
2= Potential Agreement NonComp					
3= Potential Reg/DOE NonComp				X	
4= Potential BMP NonComp					
5= Noteworthy Compliance or Practice					

Satellite Accumulation Area Addition Sheet does not contain information required by headings on the form and quantities and locations of waste not provided on all documents.

Discussion

As stated in SSOP-0035, Accumulating Hazardous Waste in Satellite Accumulation Areas and Interim Containers, Section 7.5.5, "Record addition of waste material to the accumulation container on the "Hazardous Waste Disposal Record".

Tentative Deviation(s)

The SAA Addition Sheets are not adequately maintained.

Probable Root Cause(s)

There is a lack of quality control in the SAA Addition Sheet preparation process.

**Quality Assurance Baseline Assessment, I94-04
Assessment Deviation Evaluation Sheet**

<u>Deviation I.D. Number</u>	<u>Organization</u>	<u>• Subject</u>
I94-04-03	Quality Assurance	ALS QA Management Plan

* Subject Areas assessed: Chemical Hygiene Plan/Program; Satellite Accumulation Area; Health and Safety standards; FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ); Analytical Laboratory Services Quality Assurance Management Plan, 776-V-P002; Quality Assurance Program Description, Rev. 2, RM-0012 and previous audits (Audit I91-08, Analytical Inorganic Section and Audit I93-03, Organic Analysis Laboratory).

Date: January 25 - 28, 1994

Activity: ALS Quality Assurance Management Plan Baseline Assessment

Referenced Data: Visual Inspection and ALS personnel interviews

<u>Deviation(s)</u>	<u>Severity Category</u>				
	1	2	3	4	5
1= Potential Near-Term Significant Impact					
2= Potential Agreement NonComp					
3= Potential Reg/DOE NonComp					
4= Potential BMP NonComp				X	
5= Noteworthy Compliance or Practice					

ALS procedures and identification/numbering system are outdated and require a review and revisions incorporated.

Discussion

As stated in ALS QAMP, Section 7.1, "The ALS shall have written SOPs (including analytical methods) detailing its operation and work performed. These SOPs encompass administrative, operational, and analytical aspects of the facility. SOPs reference source documents published by agencies such as the DOE, EPA, and the American Society for Testing and Materials (ASTM). They also are controlled documents and available to personnel at

the work station. The laboratory maintains a log of all SOPs in use and a file of all revisions of SOPs used in the past. SOPs are reviewed periodically on a two-year basis. Revisions are made to address changes in data quality requirements, technology and equipment changes, and/or regulatory requirements.

Tentative Deviation(s)

The ALS procedures and identification/numbering system are not adequately maintained.

Probable Root Cause(s)

There is a lack of quality control in the ALS procedures and identification/numbering process.

Quality Assurance Baseline Assessment, I94-04
Assessment Deviation Evaluation Sheet

Deviation I.D. Number	Organization	• Subject
I94-04-04	Quality Assurance	Quality Assurance Program Description, RM-0012
<p>* Subject Areas assessed: Chemical Hygiene Plan/Program; Satellite Accumulation Area; Health and Safety standards; FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ); Analytical Laboratory Services Quality Assurance Management Plan, 776-V-P002; Quality Assurance Program Description, Rev. 2, RM-0012 and previous audits (Audit I91-08, Analytical Inorganic Section and Audit I93-03, Organic Analysis Laboratory).</p>		

Date: January 25 -28, 1994

Activity: ALS Implementation of Quality Assurance Program Description, RM-0012 Baseline Assessment

Referenced Data: Visual Inspection and ALS personnel interviews

Deviation(s)	Severity Category
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1= Potential Near-Term Significant Impact	1	2	3	4	5
2= Potential Agreement NonComp					
3= Potential Reg/DOE NonComp					
4= Potential BMP NonComp				X	
5= Noteworthy Compliance or Practice					

Several incomplete spaces and boxes were observed in laboratory logbooks.

Discussion

As stated in RM-0012, Section 4.2.6, "FERMCO shall establish and implement processes to ensure that records are specified, prepared, reviewed, approved, and maintenance to accurately reflect completed work. The maintenance of records shall include provisions for retention, protection, preservation, traceability, and accountability".

Tentative Deviation(s)

The laboratory logbooks are not adequately maintained.

Probable Root Cause(s)

Personnel seem unaware of the significance of the logbook completeness.

Quality Assurance Baseline Assessment, I94-04
Assessment Deviation Evaluation Sheet

Deviation I.D. Number	Organization	* Subject
I94-04-05	Quality Assurance	FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000, (SCQ)

• Subject Areas assessed: Chemical Hygiene Plan/Program; Satellite Accumulation Area; Health and Safety standards; FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ); Analytical Laboratory Services Quality Assurance Management Plan, 776-V-P002; Quality Assurance Program Description, Rev. 2, RM-0012 and previous audits (Audit I91-08, Analytical Inorganic Section and Audit I93-03, Organic Analysis Laboratory).

Date: January 25 -28, 1994

Activity: Quality Assurance Baseline Assessment to ensure implementation of the FEMP Sitewide CERLCA Quality Assurance Project Plan (SCQ), FD-1000

Referenced Data: Visual Inspection and ALS personnel interviews

<u>Deviation(s)</u>		<u>Severity Category</u>				
1=	Potential Near-Term Significant Impact	1	2	3	4	5
2=	Potential Agreement NonComp					
3=	Potential Reg/DOE NonComp					
4=	Potential BMP NonComp				X	
5=	Noteworthy Compliance or Practice					

Two analysis methods are available for ICP/AA and Graphite Furnace Instruments, SW-846 and CLP methods. The method of analysis is not noted or otherwise recorded in the analyst logbook.

Discussion

FEMP Sitewide CERLCA Quality Assurance Project Plan (SCQ), FD-1000, Section 4.4.2.1 states that "hard copy records shall be legible, accurate, and complete; indexed to permit quick and accurate identification of items or activities to which they apply; and authenticated by preparer's signature and completion date".

Tentative Deviation(s)

The laboratory logbooks are not adequately maintained.

Probable Root Cause(s)

Personnel seem unaware of the significance of the logbook completeness.

Quality Assurance Baseline Assessment, I94-04
Assessment Deviation Evaluation Sheet

Deviation I.D. Number	<u>Organization</u>	<u>• Subject</u>
I94-04-06	Quality Assurance	Quality Assurance Program Description, RM-0012, Rev. 2

* Subject Areas assessed: Chemical Hygiene Plan/Program; Satellite Accumulation Area; Health and Safety standards; FEMP Sitewide CERCLA Quality Assurance Project Plan, FD-1000 (SCQ); Analytical Laboratory Services Quality Assurance Management Plan, 776-V-P002; Quality Assurance Program Description, Rev. 2, RM-0012 and previous audits (Audit I91-08, Analytical Inorganic Section and Audit I93-03, Organic Analysis Laboratory).

Date: January 25 - 28, 1994

Activity: ALS implementation of Quality Assurance Program Description, Rev. 2, RM-0012 Baseline Assessment

Referenced Data: Visual Inspection and ALS personnel interviews

<u>Deviation(s)</u>	<u>Severity Category</u>				
	1	2	3	4	5
1= Potential Near-Term Significant Impact					
2= Potential Agreement NonComp					
3= Potential Reg/DOE NonComp					
4= Potential BMP NonComp			X		
5= Noteworthy Compliance or Practice					

Room 159, where CRU5 data packages are stored, should be a limited access/controlled area. Room 159 was left attended (1/27/94 at 1:10 p.m.).

Discussion

As stated in RM-0012, Section 4.2.9, "Records containing data used to support CERCLA decision making shall meet the requirements defined in the Sitewide CERCLA Quality Assurance Project Plan. These records shall be contained in the Administrative Record, an official repository for programs and projects aimed at remediation of the FEMP. Contents of the Administrative records are determined by DOE and are accessible to the public".

Tentative Deviation(s)

The laboratory files are not adequately stored.

Probable Root Cause(s)

There is a lack of quality control in the management of ALS files.

FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION**FERNALD ENVIRONMENTAL MANAGEMENT PROJECT****QUALITY ASSURANCE AUDIT NO. E93-09****Clemson Technical Center**

DATE OF AUDIT: September 13-17, 1993

DATE OF REPORT: October 25, 1993

REISSUED: February 23, 1994

AUDIT LOCATION: Clemson Technical Center (CTC)
Anderson, South CarolinaAUDIT TEAM MEMBERS: Mary Ann Forrest, Lead Auditor, FERMCO QA
Keith Crutcher, NFS, Technical Representative
Bill Pearson, NFS, Technical Representative**PURPOSE AND SCOPE:**

Assess the adequacy, effectiveness, and implementation of FERMCO and DOE quality assurance requirements and contractor performance as required by FERMCO contract RFP 92616. Investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program Description, RM 0012, FERMCO contract RFP 92616 RCRA/CERCLA Statement of Work, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ).

AUDIT SUMMARY:

CTC has the necessary licenses, certifications and controls (e.g., quality program, policy statement, operating procedures) necessary to provide quality data packages to the FEMP in accordance with FERMCO Quality Assurance Program Description and FERMCO contract 92616 Statement of Work except for thorium analysis.

POST AUDIT REVIEW:

A post audit review was conducted in addition to the facility audit to include information pertinent to determining the capability of the laboratory to perform specified analyses. FERMCO Analytical Laboratory Support (ALS) personnel and FERMCO Quality Control (QC) personnel provided information related to the laboratory performance capabilities.

At the time of this audit report, the FERMCO intercomparison program could not provide data for uranium and thorium for CTC. A follow up audit at CTC will be conducted within the next few months and intercomparison data for uranium and thorium will be evaluated. However, in the DOE Environmental Measurement Laboratory (EML) program, up to three uranium measurements are made on each of four possible matrices (water, soil, air, vegetation). The DOE EML intercomparison studies for round 93-03 indicate that for 16 determinations, approximately 81% of the results were within reported EML acceptable range. It is noted that thorium is not included in intercomparison programs sponsored by DOE and EPA due to its limited use at other DOE or commercial sites. Until data for thorium analysis, by CTC, can be evaluated, they should not be used for thorium analysis.

USEPA Blind A and B Performance evaluation studies indicate that for 10 determinations performed by CTC, 100% of the results were within EPA acceptable range.

AUDIT CONDUCT:

A formal announcement of the intended audit was sent to Clemson Technical Center, September 2, 1993. The FERMCO auditors held an opening meeting the afternoon of September 13, 1993, with CTC representatives. Following introductions, a tour of the laboratory was conducted by Dr. E. Scott Tucker, Director.

Check lists were developed by the audit team for use during the audit to aid in review of the laboratory for compliance with the identified requirements. These check lists are maintained in the FERMCO Quality Assurance audit file.

All findings from Audit E92-10 requiring verification have been closed.

Daily meetings were held to discuss evaluations of processes. Inadequacies that could be corrected during the audit, were corrected and noted (See Section 2).

Interviews were conducted with various laboratory personnel and managers. Procedures, program plans, and record files were reviewed; laboratory operations, health and safety practices, and waste management activities were observed. Findings and concerns noted during the audit are stated in Sections 1 and 2 of this report, respectively.

The following people were interviewed during the course of the audit:

Scott Tucker	Director
William Baskin	Sr. Manager, QA
Wyly Cameron	Analytical Laboratory Manager
Richard Heirwegh	Group Leader
Richard Ayen	Vice President
Celeste Nauman	Systems Manager
John Leyba	Group Leader
Tim Fletcher	Group Leader

Martha Cahill	Project Manager
John Westcott	Sr. Group Leader
Ted Henry	Project Coordinator
Ann Clark	Quality Control
Dan Hogan	Safety Officer
Don Trott	Waste Management
Susan O'Connei	Laboratory Analyst
Bill Baggot	Analytical Chemist
Cindy Gibson	Analytical Chemist
David Slagle	Analytical Chemist
Bill Ingersoll	Analytical Chemist

A close out meeting was held by the auditors, September 17, 1993, with CTC laboratory and administrative management personnel.

AUDIT OBSERVATIONS:

This section of the audit report is formatted to relate observations made during the audit as related to functional categories and criterion required by the FERMCO Quality Assurance Project Plan (RM-0012).

A. FUNCTIONAL CATEGORY A: MANAGEMENT

1.0 Criterion 1 - Program

CTC has developed and maintains a written quality assurance program, (QAP) following the appropriate requirements of NQA-1. Requirements of FERMCO's FD-1000, Sitewide CERCLA Quality Assurance Project Plan (SCQ), including ANSI/ASQC E4-19XX, are specified in the contract and applicable portions are included in CTC's FERMCO specific QA program. A matrix is included in the FERMCO Quality Assurance audit file which depicts correlation between DOE Order 5700.6C, RM-0012, and ANSI/ASQC E4-19XX.

CTC's Quality Assurance Plan is binding on all personnel, and operating procedures describing how the elements are applied are referenced in each section. A policy statement, signed by management personnel and a "stop work" policy are included in the document.

Employment at CTC has increased from 43 person equivalents in 1992 to 9 person equivalents in 1993. Staffing continues to increase as contract increase.

A list of equipment was submitted during the Procurement process prior to award of contract. CTC has sufficient equipment to perform organic, inorganic, and radiological analyses necessary to support the Statement of Work. However, they are performing only organic and inorganic analyses for data validation.

Housekeeping practices are commendable.

See Section 2, Concern 4.

2.0 Criterion 2 - Personnel Training and Qualification

CTC is supportive of the concept that personnel shall be trained and qualified to perform their assigned work. The audit team recognizes the technical expertise of the staff to be excellent. Resumes were reviewed to ensure analysts and management met educational and training requirements established by CTC. Records indicated that analysts participated in performance evaluation programs, and a system is in place for retraining should it be required. Although some of the training files reviewed were incomplete, analyst qualifications were traceable to methods being performed.

See Section 1, Finding 1; Section 2, Concern 3.

3.0 Criterion 3 - Quality Improvement

The CTC QA program implements processes to detect and prevent quality problems and promote continuous quality improvement. During monthly meetings, safety, quality, and environmental compliance topics are discussed and documentation was reviewed to support the dialogue (meeting minutes).

A corrective action reporting (CAR) system is in place, documents related to deviation reporting and corrective actions are retrievable and traceable through log books. However, the CAR forms do not include space for consecutive numbering.

The auditors were assured by the evidence provided that personnel have assumed ownership of their processes, thus projecting a commitment to quality.

See Section 2, Concern 2.

4.0 Criterion 4 - Documents and Records

A log book system is in place to control preparation, review, approval, issuance, use, and revision of documents.

Records containing data used to support CERCLA decision making follow requirements of the FERMCO SCQ and reporting requirements listed in Statement of Work. Records are maintained for preventive maintenance calibration, procedures, and other documentation as needed, to meet requirements.

CTC provides the analysts with written procedures for specific tasks. Logbooks are used extensively for specific instructions, however, instructions are not tied to a controlled document (See Section 1).

Archived quality records are maintained in an area, with limited personnel access. A master inventory list is maintained in log books, and sampling of documents indicated that records matched the inventory.

CTC relies mainly on manual entries (logbooks), with virtually no back-up systems. Weaknesses of the system include no real-time verification of data input and loose document control of the logbooks.

See Section 1, Findings 2 and 14; Section 2, Concern 1.

8. FUNCTIONAL CATEGORY A: PERFORMANCE

5.0 Criterion 5 - Work Performance

This criterion describes work related instructions, procedures, and other forms of direction including, but not limited to, waste handling, packaging, certification and shipping, and environmental data operations.

CTC's Chemical Hygiene Plan is being revised. Each laboratory has an information point near the entrance; labeling is in effect, and safety equipment is installed in or near all laboratories. Entry areas are marked in braille as well as english.

A preventative maintenance (PM) program for analytical instrumentation is in effect and is operating adequately as indicated in the PM log.

There are standard operating procedures available for pertinent processes, including sample receipt, storage and processing. To ensure chain of custody, laboratory tracking systems are in place. A process for sample receipt (described in Section 7 of the SCQ) was not included in CTC's procedure. The FERMCO Contract Project Manager at CTC included the SCC requirement in the FERMCO specific project plan as indicated in the draft document presented to the audit team. The FERMCO Technical Representative approved the Chain of Custody procedure during the audit. Double key entry from the field Chain of Custody into the LIM system is performed.

A work list, prioritized by the Group Leader, is generated on the LIM system which supports the work schedule.

The FERMCO Statement of Work describes mandatory practices for waste management. CTC follows the sample receipt process and the waste management process described in FERMCO documents, therefore ensuring FERMCO that chain of custody is maintained from sample receipt through waste disposal.

This criterion also describes the identification and control of items handling, storing, and shipping, and calibration and maintenance of monitoring and data collection equipment.

A group of samples, requiring analyses by Table 17 as described in the Statement of Work, 92616, was analyzed to ensure that rad levels were within DOT guidelines. The information was used for information purposes only; no environmental decisions were made based on the data. The sampled waste was returned to FERMCO. The waste will undergo further sampling at FERMCO prior to shipment off site.

Logbooks are maintained indicating calibration standards are traceable to NIST, however, not all of the items checked were up to date.

See Section 1, Findings 3 thru 13, 17-19.

6.0 Criterion 6 - Design

This criterion states that data collection processes for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. Computer programs are to be proven through previous use, or verified through testing or simulation prior to use. A system is in place that defines computer program testing and documentation, and software control and software security. Group Leaders have change authority if procedures are to be altered.

CTC relies on the manufacturer for software reliability. A self audit sample data management procedure (CTC-1044) is used to verify that data entry is valid. CTC relies mainly on manual entries (logbooks) and canned software application. Group Leaders oversee this process.

The structure of the building is specifically designed for laboratory use. Air flow designs are posted in the building. Limited access to the facility is maintained by key and card access. Security is adequate to ensure that sample chain of custody is not compromised.

7.0 Criterion 7 - Procurement

CTC has established a program to ensure that purchased items and services meet established requirements and perform as expected. A FERMCO auditor checked one procurement purchase to verify procedures were followed. Documentation indicated the purchase did not meet the original requirements and the instrument was returned to the vendor.

8.0 Criterion 8 - Inspection and Acceptance Testing

This criterion describes requirements and responsibilities for labs conducting chemical analyses, and producing analytical data for environmental projects. CTC produced an equipment list identifying measuring and test equipment which is calibrated against nationally recognized standards. Records are maintained indicating that standards are traceable to NIST. However, not all calibrations were up to date as noted in Section 1.

Quality control standards and data quality objectives that laboratories are required to meet, are described in the SCQ. CTC's performance in quarterly round robin programs is maintained and tracked. An intercomparison report, "Gross Alpha-Beta in Water Intercomparison Study A Statistical Evaluation of the May 15, 1992, Data", indicated the results for both Gross Alpha and Gross Beta were well within all warning limits as well as control limits. CTC continues to perform competently as indicated by review of routine data packages and logbooks for documentation of required quality control elements. A "CLP-like" dat

package which CTC had compiled to demonstrate their capability to provide this type of information, was also reviewed. Review of the "CLP-like" package and routine data packages provided evidence that CTC is capable of producing data for ASLs B, C, and D.

Laboratory equipment inspections are scheduled. Logbooks indicated inspections took place and that results were satisfactory.

See Section 1, Findings 15 and 16.

C. FUNCTIONAL CATEGORY C: ASSESSMENT

9.0 Criterion 9 - Management Assessment

This criterion describes a planned and periodic program of management assessments.

A formalized program is not evidenced. However, quality is promoted throughout the laboratory as indicated in meeting minutes and discussions with laboratory personnel. Quarterly reports based on laboratory processes are generated and forwarded to the CTC Laboratory Director.

10.0 Criterion 10 - Independent Assessment

CTC has implemented a program for the planning and performance of independent assessments. An audit schedule was produced indicating that internal assessments are performed. Performance evaluation (PE) samples are processed, blind duplicates are processed and a tracking log exist for blind duplicates and performance evaluation samples. The information gleaned from PE and blind duplicates is forwarded to FERMCO to be incorporated into FERMCO's interlaboratory comparison program.

CTC participates in external performance evaluation programs and undergoes audits from the EPA, state, and various auditing organizations. This area was reviewed to ensure independent assessments are being conducted, but evaluation results were not reviewed by the audit team.

Intercomparison studies were previously discussed in the "Post Audit Review" section.

Section 1

FINDINGS

AUDIT E93-09

1. Requirement: RM-0012, 2.0 - "Personnel shall be trained and qualified to ensure they are capable of performing their assigned task."

Finding: Training files were lacking documentation for required training.
2. Requirement: RM-0012, 4.2.1. "...establish and implement a system to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design."

Finding: Revisions to controlled documents were initialed in two review blocks by the same person (QAP).
3. Requirement: RM-0012, 5.2.1. "Work related instructions..shall be provided to employees doing the work."

Finding: Written instructions, meeting requirements stated in the SCQ 7.2.1.5, and Statement of Work, were not available for sample processing (receipt, disposal, nonconformances) when FERMCC samples were received. (Sample Nos. 200013353, 200013351, 200013349, 200013789, 93098-086) The information was attached to the Sample Receipt procedure during the audit.
4. Requirement: RM-0012, 5.2.1. "Work related instructions..shall be provided to employees doing the work."

Finding: Analyte lists are inconsistent or inadequate for SW-84 Methods and/or SCQ requirements.
5. Requirement: SW-846-8260, Rev 5

Finding: Applicable analyte list does not include all analyte specified in SCQ Appendix G, Table G-2, Criterion 1a.
6. Requirement: SW-846-8260, Rev 5

Finding: Method detection limits are considerably above the limit specified in SCQ Appendix G, Table G-2, Criterion 1a.
7. Requirement: SW-846-8260, Rev 5

Finding: Method does not require laboratory control samples (LCS) specified in the SCQ Appendix G, Table G-2, Criterion 1a.

8. Requirement: SW-846-8080, Rev 3
 Finding: Applicable analyte list does not include all analytes specified in SCQ Appendix G, Table G-2, Criterion 3.
9. Requirement: SW-846-8080, Rev 3
 Finding: Method detection limits are above the limits specified in SCQ Appendix G, Table G-2, Criterion 3.
10. Requirement: SW-846-8080, Rev 3
 Finding: CTC does not document evaluation of degradation check sample analyses.
11. Requirement: SW-846-6010A, Rev 3
 Finding: CTC method is inadequate to meet SCQ Appendix G, Table G-2, Criterion 11. (Inadequate to perform the method without other documents.) CTC places instrument specific instructions in logbooks and the method does not independently address the quality control elements. SW-846 states that specific procedures must be written for the lab's operations.
12. Requirement: SW-846-7471, Rev 2
 Finding: CTC method is inadequate to meet SCQ Appendix G, Table G-2, Criterion 12. See a) above.
13. Requirement: CTC Method #CTC-0002, Rev 2
 Finding: Method does not address counting instrumentation or technique for gross alpha/beta.
14. Requirement: RM-0012, 4.2.4 "Control of superseded and cancelled document shall include measures to ensure that only correct documents are in use."
 Finding: Logbook instructions, in general, do not reflect parent procedure numbers, revisions, and Lab Manager approval. The instructions are not always traceable to controlled documents (Calibration, Analytical Methods)
 Comment: The Audit Team does not feel that sufficient controls are in place to ensure the consistency of reviews, approvals, and distribution of operating procedures.
15. Requirement: SCQ 8.4.1, "Laboratory equipment shall be calibrated at least annually or at the time of a repair that affects the function of the equipment."

Finding: Annual calibration was not performed for the following:
- thermometer #A06854
- 20 gram and 0.5 gram weight in set SC870326-1M

16. **Requirement:** SCQ Appendix E Item 3 and CTC-1049. 3.4. "...it will be reviewed and approved by the Lab Manager and placed in the instrument logbook."

Finding: The Lab Manager has not approved calibration instructions for the following:

- pipets
- balance # 37110155
- refrigerator #112191053

17. **Requirement:** SCQ Appendix E and Rad License No. 432. 21. issued by the State of So. Carolina. "The licensee shall conduct a physical inventory every six (6) months to account for all radioactive material received and possessed under the license."

Finding: Physical inventory has not been performed every six months.

18. **Requirement:** SCQ Appendix E and CTC Chemical Hygiene Plan, "...employees are to receive training..Right to Know"

Finding: No evidence was found that employees are apprised of the "Right to Know"

19. **Requirement:** SCQ Appendix E and CTC-1005, CTC-1035. D. "The maximum safe opening which provides 100 fpm face velocity shall be marked clearly and legibly on each fume hood with the date of test and initials of the tester."

Finding: There was no evidence of markers on any of the hoods observed by the Audit Team.

Section 2

CONCERNS

AUDIT E93-09

- 1) The Chain-of-Custody trail can be documented with CTC's logbook system, but consideration should be given to developing a backup system and a real time verification system.
- 2) Deviation Report forms do not have space for consecutive numbering. How do you ensure that a "closed loop" system is in place?
- 3) A training plan describing required training was not in evidence. It is suggested that, as a minimum, a checksheet listing required training and frequency, be included in each employee file.
- 4) It appears that the QA Manager has diverse responsibilities. Considering the anticipated workload, the Audit Team suggests that additional staff be added to the QA Division.

FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

QUALITY ASSURANCE AUDIT NO. E93-10

TCT-St. Louis

DATE OF AUDIT: September 13-17, 1993

DATE OF REPORT: October 25, 1993

REISSUED: February 23, 1994

AUDIT LOCATION: TCT-St. Louis (TCT)
St. Louis, MOAUDIT TEAM MEMBERS: David T. McCulley, Lead Auditor, FERMCO QA
Tim Sheehan, NFS, Technical Representative
Douglas Davis, NFS, Technical Representative

PURPOSE AND SCOPE:

Assess the adequacy, effectiveness, and implementation of FERMCO and DOE quality assurance requirements and contractor performance as required by FERMCO contract RFP 92616. Investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program Description, RM-0012, FERMCO contract RFP 92616 RCRA/CERCLA Statement of Work, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ).

AUDIT SUMMARY:

TCT has the necessary licenses, certifications and controls (e.g., quality program, policy statement, operating procedures) necessary to provide quality data packages to the FEMP in accordance with FERMCO Quality Assurance Program Description and FERMCO contract 92616 Statement of Work except for thorium analysis.

POST AUDIT REVIEW:

A post audit review was conducted in addition to the facility audit to include information pertinent to determining the capability of the laboratory to perform specified analyses. FERMCO Analytical Laboratory Support (ALS) personnel and FERMCO Quality Control (QC) personnel provided information related to the laboratory performance capabilities.

At the time of this audit report, the FERMCO intercomparison program could not provide data for uranium and thorium for TCT. A follow-up audit at TCT will be conducted within the next few months and intercomparison data for uranium and thorium will be evaluated. However, in the DOE Environmental Measurement Laboratory (EML) program, up to three uranium

measurements are made on each of four possible matrices (water, soil, air, and vegetation). The DOE EML intercomparison studies at core for round 93-03 indicate that for 18 determinations, approximately 89% of the results were within reported EML acceptable range. It is noted that thorium is not included in intercomparison programs sponsored by DOE and EPA due to its limited use at other DOE or commercial sites. Until data for thorium analysis by TCT can be evaluated, they should not be used for thorium analysis.

AUDIT CONDUCT:

A formal announcement of the intended audit was sent to TCT-St. Louis on September 7, 1993. The FERMCO auditors held an opening meeting on September 13, 1993 with TCT representatives. Following introductions a tour of the laboratory was conducted.

Check lists were developed by the audit team for use during the audit to aid in review of the laboratory for compliance with the identified requirements. These check lists are maintained in the FERMCO Quality Assurance audit file.

All findings from Audit E92-11 requiring verification have been closed.

Daily meetings were held to discuss evaluations of processes and to identify inadequacies that could be corrected during the audit.

Interviews were conducted with various laboratory personnel and managers; procedures, program plans, and record files were reviewed; laboratory operations, health and safety practices, and waste management activities were observed. Findings and concerns noted during the audit are stated in Sections 1 and 2 of this report, respectively.

The following people were interviewed during the course of the audit:

Amy Sumariwalls	Laboratory Operations
Mike Travis	Quality Assurance
Chuck Ward	Management Information
Jim Shetley	Receiving
Seleva Harris	Prep Lab
Bob Leible	TC Lab
Bill Lesko	Inorganic Lab
Paul Smith	Project Management
Fred Grabau	Technician
Srour Laila	Technician
Joann Kray	Technician

A closeout meeting was held by the auditors, September 17, 1993, with TC laboratory and administrative management personnel.

AUDIT OBSERVATIONS:

This section of the audit report is formatted to relate observations mac

during the audit as related to functional categories and criteria required by the FERMCO Quality Assurance Project Plan (RM-0012).

A. FUNCTIONAL CATEGORY A: MANAGEMENT

1.0 Criterion 1 - Program

Quality Assurance at TCT-St. Louis starts with the Twin City Testing (TCT) Corporate Quality Assurance Program which establishes the quality policy for the entire corporation. The TCT Quality Assurance Program, which was instituted in 1976, is specifically designed to meet the requirements of Appendix B to Title 10, Code of Federal Regulations, Part 50 Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants and ANSI/ASME NQA 1. The TCT-St. Louis Quality Assurance Plan defines how the TCT Quality Assurance Program will be implemented in the laboratories. This plan summarizes elements of quality assurance and quality control routinely used in their operations to obtain accurate and precise data consistent with project objectives. The plan has been designed to meet requirements of many client projects and specifically addresses all elements of the Environmental Protection Agency Quality Assurance Management Staff's "Guidelines and Specifications for Preparing Quality Assurance Program Plans," QAMS-004/80. While this plan establishes quality assurance and quality control procedures common to most, if not all, of TCT-SL's services, a Quality Assurance Project Plan (QAPjP) is used to define any project-specific quality requirements not contained in the plan.

See Section 1, Findings 1 and Section 2, Concern 3.

2.0 Criterion 2 - Personnel Training and Qualification

Each analyst or technician employed by TCT-SL undergoes a period of orientation and training for the tasks to which he or she will be assigned. This training ensures that the data obtained are of the highest quality and the safety and productivity of all personnel is maintained. The design of the training program is specific for each employee and laboratory section and depends on the education and experience of the individual and the employee's assigned responsibilities. A set of guidelines have been outlined in an SOP which addresses both general and technical training and is applicable to both present and new employees. A training verification form is used to document the training efforts. Tech-Check or performance samples are used to evaluate and validate technician's performance.

See Section 2, Concern 2.

3.0 Criterion 3 - Quality Improvement

Quality assurance at TCT is a system for integrating the quality planning, quality assessment, and quality improvement efforts of various sections and departments to enable operations to meet client requirements at a cost-effective level.

4.0 Criterion 4 - Documents and Records

All records associated with sample handling and analysis are systematic, complete, and permanent. Records are traceable by someone with no first-hand knowledge, to follow activities from sample receipt to data reporting and to establish the degree of confidence associated with the data. The reasons for thorough record keeping are:

- validation
- traceability
- data and sample security
- representativeness
- retrievability

Storage and Retention of Records

Original data records never leave the laboratory unless required by contractual or legal requirements. All laboratory records are confidential and are maintained in a climate and access controlled area. Long-term storage is provided off-site in a secure, temperature controlled warehouse.

In general, data records applicable to a specific project are maintained for a minimum of seven years. General chemical analysis data records (including bench sheets, instrument print-outs, etc.) that are not project specific are maintained for a minimum of five years.

Project Files

Documentation specific to a particular project is maintained in a separate project file and is identified with its unique project number. For significantly large projects, the files are separated into individual cases and identified with unique project/case numbers. Project-specific documentation includes:

- project QC plans/QAPjP
- project correspondence
- sampling records
- chain-of-custody records (originals or photocopies)
- shipping documents, traffic reports, and requests for analysis
- analytical data, including calibrations and QC
- project-specific logbooks and notebooks
- control charts
- corrective action reports
- final data reports

All documentation related to a specific project is confidential and subject to secure filing and storage. Unless other arrangements are made, project files are to be maintained in local filing cabinets at the TCT- St. Louis offices for approximately one year following project completion. After this time, the files are transferred in inventoried file storage boxes to a secure, climate controlled off-site warehouse for storage up

seven years. After seven years, all project-related documentation shall be destroyed by shredding.

See Sections 2, Concern 1.

B. FUNCTIONAL CATEGORY A: PERFORMANCE

5.0 Criterion 5 - Work Performance

A performance evaluation of the TCT-St. Louis Laboratory was conducted to determine if TCT has developed the basic program requirements and implemented the required procedures and administrative controls necessary to meet the requirements of RFP 92616. TCT's performance was evaluated in the following areas:

- Health and Safety
- Lab QA Plan - Lab Capacity/Personnel
- RM-0012 - Qualification of Analysts - Training
- Chemical Hygiene Plan - Waste Management Plan

The evaluation showed that TCT-St. Louis has developed the basic program requirements and implemented the required procedures and administrative controls necessary (with minor modification) to meet all the requirements of RFP 92616.

The SW-846, CLP-SOW, and radiochemistry methods portion of Audit E93-10 was performed by reviewing a TCT CLP DQO Level D report package, a TCT SW-846 DQO Level B report package, and a Core Laboratories report package containing data from total uranium and gross alpha/beta analyses. The data in these packages was reviewed for compliance with the appropriate QC performance requirements of the CLP-SOW, SW-846, and the SCQ.

TCT was found to be operating using analytical SOPs containing the QC requirements of CLP-SOW, SW-846 and SCQ. TCT was found to be meeting the QC requirements of their SOPs and producing data packages containing defensible analytical results.

Four specific findings were identified concerning TCT analytical methods:

TCT CLP DQO Level D package number 3555-CLP24 was reviewed for QC performance validation of VOA by GC/MS, pesticides/PCB's by GC, metals by ICP/AES, and total mercury in solids by CVAA.

- **VOA BY GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GM/MS)**

VOA analyses were performed by SOP 4200-METH-MS-03. This SOP contained all of the QC requirements of the CLP-SOW. The TCT CLP package contained documentation of ion abundance pattern evaluations, initial calibration: continuing calibration verifications, target compound identification: evaluations, method blank analyses, matrix spike/matrix spike duplicate analyses, surrogate standard additions, and internal standard

evaluations. In all cases, the raw data confirmed the values reported in the sample summary reports. Sample holding times were tracked and were in compliance with SCQ guidelines. Raw data from the GC/MS was processed directly into the CLP reports electronically. The data transfer system was validated per TCT SOPs 4200-DATA-GEN-10 and 4200-DATA-GEN-11.

Analytical standards are traceable and documented to certified standards. However, TCT was not placing a copy of the appropriate pages of the Standards Preparation Log in the CLP report package. This logbook is maintained in the GC/MS laboratory, but not protected as a vital record. This raised the concern that if this logbook were lost or destroyed, that the data affected would not have traceability to certified primary standards.

- **PESTICIDES/PCBS BY GAS CHROMATOGRAPHY (GC)**

Pesticide/PCBs analyses were performed by SOP 4200-METH-GC-06. This SOP contained all of the QC requirements of CLP-SOW. The TCT CLP package contained documentation of initial calibrations, continuing calibration verifications, method blank analyses, compound identification evaluations, matrix spike/matrix spike duplicate analyses, and surrogate standard additions. In all cases the raw data confirmed the values reported in the sample summary reports. Sample holding times were tracked and were in compliance with SCQ guidelines. Analytical standards are traceable and documented to certified standards. Copies of the appropriate pages of the standards preparation logbook were in the CLP report package. Raw data from the GC was processed directly into the CLP reports electronically. The data transfer system was validated per TCT SOP's 4200-DATA-GEN-10 and 4200-DATA-GEN-11.

The CLP package provided documentation of degradation check sample analyses. All degradation check samples were within limits except for an ending sample. The CLP-SOW 7.9 states that: "acceptable sample analyses must be bracketed by acceptable performance evaluation mixtures and instrument blanks." Conversation with GC laboratory personnel revealed that ending check standard limits were considered as advisory limits.

- **METALS BY INDUCTIVELY COUPLED PLASMA/ATOMIC EMISSION SPECTROSCOPY (ICP/AES)**

Metals analyses by ICP/AES were performed per TCT SOP 4200-METH-INO-05. This SOP contained all of the QC requirements of the CLP-SOW. The TCT CLP package contained documentation of initial calibration verification standards, method blank analyses, initial calibration blank/continuing calibration blank analyses, interference check sample analyses, laboratory control sample analyses, matrix spike analyses, serial dilution evaluations, and duplicate analyses. In all cases, the raw data confirmed the values reported in the sample and QC summary reports. Sample holding times were tracked and were within SCQ guidelines. Analytical standards are traceable and documented to certified standards. Copies of the appropriate pages of the standards presentation logbook were in the CLP

report package. Raw data from the ICP was processed directly into the CLP reports electronically. The data transfer system was validated per TCT SOPs 4200-DATA-GEN-10 and 4200-DATA-GEN-11. The determination of instrument detection limits was documented in the CLP report package. TCT determines detection limits on a quarterly basis.

- **MERCURY BY COLD VAPOR ATOMIC ABSORPTION (CVAA)**

Total mercury analyses of solid samples were performed per 4200-METH-INO-16. This SOP contained all of the QC requirements of CLP-SOW. The TCT CLP package contained documentation of initial verification standards, continuing calibration verification standards, method blank analyses, initial calibration blank/continuing calibration blank analyses, laboratory control samples, matrix spike/matrix spike duplicate analyses, and duplicate analyses. In all cases, the raw data confirmed the values reported in the sample and QC summary reports. The raw data from the analyses is transcribed manually into the CLP report software. All raw data and calculations were reviewed by shift supervisors. Sample holding times were tracked and were within SCQ guidelines. Analytical standards are traceable and documented to certified standards. Copies of the appropriate pages of the standards preparation logbook were in the CLP report package. The determination of detection limits was documented in the CLP report package. TCT determines instrument detection limit on a quarterly basis.

- **SW-846, METHOD 1311, TOXICITY CHARACTERISTIC LEACHING PROCEDURE (TCLP)**

TCT DQO Level B Report Number 3555-254, Release 2793 (March 3, 1993) was reviewed for compliance with the QC performance requirements of SW-846 for TCLP extractions.

TCLP extractions were performed per TCT SOP 4200-PREP-GEN-01. This SOP contained all of the QC requirements of SW-846, except for temperature monitoring and control. The TCT SW-846 package contained documentation of percent solids determinations. The TCT TCLP runsheet (Form 80/1) documented compliance with the requirements of SW-846, except for temperature monitoring. In all cases reviewed, a method blank was taken through the entire extraction process for each extraction batch. Sample holding times were tracked and documented through chain-of-custody forms TCLP extraction runsheets, and instrument runsheets.

TCT was not monitoring TCLP extraction temperatures. SW-846, Method 1311 7.2.11 and 7.3.12 define required ambient extraction temperatures a 22°/3°C and 23°/2°C for non-volatile and volatile extractions respectively

- **RADIOCHEMISTRY**

TCT subcontracts all radiochemical analyses to Core Laboratories. Core Laboratories Analytical Report, Job Number 930896 (August 16, 1993) was reviewed for compliance with SCQ performance specifications for tota

uranium and gross alpha/beta analysis.

- **GROSS ALPHA/BETA**

Gross alpha/beta analyses were performed by Core SOP CA-GLR-02.0. This SOP addressed all of the performance specifications of the SCQ. The Core report contained documentation of highest allowable minimum detectable activity determinations, percent matrix spike recovery, method blank evaluations, laboratory control sample evaluations, and duplicate analyses. Raw data from the gross alpha/beta analyzer was processed directly into report form electronically. The report contained a list of all calculations used by the report software.

- **TOTAL URANIUM**

Core Laboratories is not performing total uranium analyses by a SOP. The Core report contained documentation of matrix spike recovery determinations, method blank evaluations, laboratory control sample evaluations, and duplicate sample evaluations.

The Core analytical report was not in compliance with SCQ performance specifications in the following instances:

- The determination of highest allowable minimum detectable concentration was not documented. The Core report did not include the raw data required for this determination or any calculations. SCQ appendix G, Table G4, Criteria 27 and 28 define the calculations and raw data requirements needed to fulfill these performance specifications.
- Laboratory control samples were evaluated. However, the control limits used did not comply with SCQ Appendix G, Table G-4, Criteria 27 and 28.
- The matrix spike recovery determination contained a data transcription error, and the raw data for the spiked sample was not found.

See Sections 1, Findings 2, 3, 4, 5, 6, 7.

6.0 Criterion 6 - Design

The data management group is responsible for compiling the final Data Summary Report. Copies of the raw data, chromatograms, etc. will not be sent to the client unless requested. However, all QC sample data is included in the summary report. Results less than the limit of detection (DL) are recorded on forms as "<DL," the appropriate numerical value or DL, being used for each case.

The data validation and coordination group is responsible for validating the summary report against the laboratory data sheets. This is done prior

to submitting the data report to the project manager for review.

Laboratory bench sheets used for reporting data to the project managers are available for most analyses done at TCT-SL. Some analyses, such as those for GC/MS, provide computerized "quant" reports that may serve as the data reporting forms. However, the reporting forms in general include:

- analytical readings
- normalities of reagents (if applicable)
- description of analytical conditions (i.e., gas flow rates, column temperatures, etc.)
- correction factors
- dilution or concentration factors
- QC sample results
- data values

All data reporting forms are accompanied by the instrument printout. All data reporting forms and instrument printouts are signed and dated by the analyst and/or laboratory supervisor. The raw data is stored in the project-specific files.

See Section 1, Finding 9

7.0 Criterion 7 - Procurement

An SOP establishes procedures for the procurement of quality critical supplies, equipment, and services. A "quality critical" item or service is defined as, but not limited to, "those items or services directly affecting the operations of TCT-SL which, if the item or service did not meet specified requirements, would result in a significant adverse effect on either quality of services or TCT-SL's capability to provide services. The SOP establishes a system for the preparation, review, and approval of procurement documents to assure quality critical supplies, equipment, and services are adequately specified and obtained from quality vendors. A set of criteria for the qualification of vendors has been established and an approved vendor list developed which is periodically reviewed and updated. A second SOP, "Receipt of Supplies, Equipment, and Services, provides a system for assuring that purchased supplies, equipment, and services conform to specified requirements.

8.0 Criterion 8 - Inspection and Acceptance Testing

SW-846 criteria for quality control, detection limits, and related project requirements are routinely used when appropriate to customer requirements. Other standard criteria, such as USEPA's Superfund/CERCLA Contract Laboratory Program, Clean Water Act, and Safe Drinking Act, are also used as needed.

See Section 1, Findings 8 and 10.

C. FUNCTIONAL CATEGORY C: ASSESSMENT

9.0 Criterion 9 - Management Assessment

The Quality Assurance Manager of TCT-SL performs a laboratory audit every quarter. These audits review the laboratory functions and systems involved in the production of laboratory data. Any deficiencies found are documented and corrected. The corrections are documented upon reinspection. Additionally, Twin City Testing performs an annual audit of all its laboratories for conformance to the Corporate Quality Program.

10.0 Criterion 10 - Independent Assessment

TCT-SL participates in several laboratory certification programs including the states of New Jersey, Missouri, and Illinois; the Corps of Engineers; and the Naval Energy and Environmental support Activity (NEESA) Program. In addition to the performance samples analyzed by TCT-SL to earn and maintain the above certifications, TCT-SL also participates in the USEPA round-robin performance samples for Water Pollution (WP) and Water Supply (WS) analyses.

Intra-laboratory performance samples are analyzed at least quarterly and more frequently if quality evaluations indicate the need for additional performance assessments. Normally, QC samples prepared by a commercial vendor are used which have certified "true" values and statistically established limits for satisfactory performance.

If unacceptable values are reported for any performance, sample potential causes are investigated and suitable corrective action is initiated.

Section 1

FINDINGS

AUDIT E93-11

1. **Requirement:** SCQ Appendix E, Page 20F 10, Section e.2.1, Requirements For an Approved Laboratory Item, No. 6 states: "An approved lab shall have a QA Program which addresses the applicable requirements of the most recent version of ANSI/ASQC/E4-19xx and the FEMP SCQ."
- Section C statement of work states: "The seller shall have a QA Program which meets all requirements of ANSI/ASQC-E4-19xx (September 1991), applicable portions of FEMP Sitewide CERCLA Quality Assurance Plan (SCQ) and is accepted by FERMCO."
- Finding:** Quality Assurance Program Manual
- TCT's Quality Assurance Program Manual does not address all requirements of ANSI/ASQC-E4-19xx (September 1991). The following requirements need to be addressed.
- Part C design, construction and operation of engineered environmental system
 - Quality improvement (procedures)
2. **Requirement:** RM-0012 5.4.10, TCT Chemical Hygiene Plan
- Finding:** Eye Wash Station
- The eye wash station was missing in the Rad Lab.
3. **Requirement:** QC Performance Requirement of CLP-SOW, SW 846, and the SCQ
- Finding:** Pesticides/PCBs
- Pesticides/PCBs by GC - An ending degradation check standard was above CLP-SOW limits. The CLP-SOW state that acceptable sample analyses must be bracketed by acceptable check standards. Conversations with laboratory personnel revealed that they treated ending check standard limits on an advisory basis.
4. **Requirement:** QC Performance Requirement of CLP-SOW, SW 846, and the SCQ.
- Finding:** VOAs by GC/MS

VOAs by GC/MS - A copy of the appropriate pages of the standards preparation log was not included in the CLP report package. This logbook is maintained in the laboratory, but not protected as a vital record. Loss or destruction of this logbook would jeopardize the dependability of affected data since this data would not be traceable to certified primary standards. TCT has committed to include a copy of the appropriate logbook pages in future CLP report packages.

5. **Requirement:** QC Performance Requirement of CLP-SOW, SW 846, and the SCQ.
- Finding:** **TCLP Extractions**
- TCLP Extractions by SW-846, Method 1311 - The TCT TCLP extractions runsheet did not have a blank for recording extraction temperature. Review of TCT SOPs revealed that extraction temperature is not monitored. Method 1311 requires that ambient room temperature of 22°/3°C are maintained for all other TCLP extractions. TCT has committed to revise its TCLP SOP to require temperature monitoring and documentation.
6. **Requirement:** QC Performance Requirement of CLP-SOW, SW 846, and the SCQ.
- Finding:** **Core Laboratories-Total Uranium**
- The total uranium data was lacking in several key areas. Core is currently performing total uranium analyses without an SOP.
7. **Requirement:** The chain-of-custody and sample retention requirements are detailed in the SOW for RFP 92616 and the SCO section 7.2.1. TCT is implementing these requirements through its QA Plan and SOPs 4200-GENL-LOG-4 and 4200-GENL-LOG-5.
- Finding:** **Chain-of-Custody**
- TCT maintains cold sample and extract storage for up to six months as required. However, chain-of-custody for FERMCO samples was not maintained as required from sample receipt through sample disposal. Once the extracted sample was analyzed, extracts were usually cold stored in the applicable lab. After long term storage, sample extracts were sent to receiving for storage and disposal. Extracts were not returned to receiving using chain-of-custody documentation as required by the RFP 92616.

TCT Operations Manager agreed to maintain chain-of-custody documentation on FERMCO samples, including sample extracts, throughout the TCT analytical process from receipt to disposal. The TCT Operations Manager agreed to revise their chain-of-custody procedure before samples are shipped.

8. **Requirement:** The sample receiving requirements stated in the SCQ Section 7.2.1 are outlined in the TCT QA Plan Section 4.4 and implemented through TCT SOPs 4200-GENL-LOG4 and 4200-GENL-LOG-5.

Finding: Thermometer Calibration

Thermometers used to determine sample temperature at the time of receipt had not been calibrated or uniquely identified.

9. **Requirement:** The requirements for data management and data validation are detailed in the SCQ Section 11.2, D.2.2.2 and in the CPL User's Guide Chapter 6-G.

Finding: Entered Data and Approval

TCT hand enters some data into its LIMS. TCT does not estimate error rates of hand entered data as required by the CLP User's Guide. Also, the Laboratory Manager does not approve changes to originally submitted deliverables. Approval of changes to previously submitted data packages is done at a lower level.

10. **Requirement:** The calibration and standards traceability requirements stated in the SCQ Section 8 are outlined in the TCT QA Plan. TCT SOP 4200-GENL-SS-8 is a project specific procedure that implements calibration and preventive maintenance requirements on some other TCT contract.

Finding: Calibration Program

The TCT calibration program is not formalized in a comprehensive calibration SOP. Also, the responsibility for implementing the calibration program is not centralized.

Section 2

CONCERNS

AUDIT E93-11

1. Concern: OSHA Accident Reports

OSHA Accident Reports lack a controlled follow-up system (i.e., evaluation and identification of root cause) for corrective action.

2. Concern: RAD Analysts' Qualifications

The audit team was unable to verify that the RAD analysts assigned to the FERMCO project have the level and type of experience to successfully perform the work. The work is subcontracted to Core Laboratories. Note Findings 3.5.4 Core Lab has no SOP for doing total uranium.

3. Concern: Materials License

TCT's current materials license (24-17152-02) expires October 31, 1993. FERMCO will need an update of license status.

FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

QUALITY ASSURANCE AUDIT E93-11

LOCKHEED ANALYTICAL SERVICES

DATE OF AUDIT: September 27 - October 1, 1993
DATE OF REPORT: December 6, 1993
REISSUED: March 15, 1994
AUDIT LOCATION: Lockheed Analytical Services (LAS)
Las Vegas, Nevada
AUDIT TEAM MEMBERS: David T McCulley, Lead Auditor, FERMCO QA
Keith Crutcher, NFS, Technical Representative
Bill Pearson, NFS, Technical Representative

PURPOSE AND SCOPE:

Assess the adequacy, effectiveness, and implementation of FERMCO and DOE quality assurance requirements and contractor performance as required by FERMCO contract RFP 92616. Investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program Description, RM-0012, FERMCO contract RFP 92616 RCRA/CERCLA Statement of Work, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ).

AUDIT SUMMARY:

LAS has the necessary licenses, certifications and controls (e.g., quality program, policy statement, operating procedures) to provide quality data packages to the FEMP in accordance with FERMCO Quality Assurance Program Description and FERMCO contract 92616 Statement of Work except for thorium analysis.

POST AUDIT REVIEW:

A post audit review was conducted in addition to the facility audit to include information pertinent to determining the capability of the laboratory to perform specified analyses. FERMCO Analytical Laboratory Support (ALS) personnel and FERMCO Quality Control (QC) personnel provided information related to the laboratory performance capabilities.

At the time of this audit report, the FERMCO intercomparison program could not provide data for uranium and thorium for Lockheed. A follow up audit at Lockheed will be conducted within the next few months and intercomparison data for uranium and thorium will be evaluated.

The EPA EMSL-Las Vegas intercomparison studies indicate that 124 determinations were performed by Lockheed during 11-91 through 10-93. Approximately 98% of the results were within the range considered acceptable by EPA.

AUDIT CONDUCT:

A formal announcement of the intended audit was sent to LAS on September 21, 1993. The FERMCO auditors held an opening meeting the afternoon of September 27, 1993, with LAS representatives. Following introductions, a tour of the laboratory was conducted.

Check lists were developed by the audit team for use during the audit to aid in review of the laboratory for compliance with the identified requirements. These check lists are maintained in the FERMCO Quality Assurance audit file.

All previous concerns identified during surveillance 92-944 by FERMCO Quality Control on July 7, 1993 requiring verification have been closed.

Daily meetings were held to discuss evaluations of processes and to identify inadequacies that could be corrected during the audit.

Interviews were conducted with various laboratory personnel and managers procedures, program plans, and record files were reviewed; and laboratory operations, health and safety practices, and waste management activities were observed. Findings and concerns identified during the audit are stated in Sections 1 and 2 of this report.

The following people were interviewed during the course of the audit:

Sevda K. Aleckson	Quality Assurance
Michael J. Butler	Client Services
Paul A. Banfer	Computer Center
John R. Loyd	Program Development
Scott Perkins	Business Center
Ross K. Robeson	Support Services
Robert P. Johnson	Operations
Mathew S. Klainer	Document Control
Nathan Nunn	Safety & Health
Jimmy Morales	Radiation Safety
Dan C. Fishcher	Organic Analysis
Tuijauna Mitchell - Hall	Inorganic Analysis
Russell J. Stimmel	Radiochemical Analysis
Paul Sturtz	Sample Control
Fred Kent	Technical Lead
Dwight Parks	Pesticide Analyst
Jeff Linder	Metals Analyst
Ann Racel	Metals Analyst
Mel Lic	QA Specialist
Ron Callision	Technical Lead
Bernice Herbert	Sample Preparation

Mary Form
Bud Lowman
Charles Carter

Client Services
Instrumentation
Lab Director

A close out meeting was held by the auditors on October 1, 1993 with LAS laboratory and administrative management personnel.

AUDIT OBSERVATIONS:

This section of the audit report is formatted to relate observations made during the audit as related to functional categories and criterion required by the FERMCO Quality Assurance Program Description (RM-0012).

A. FUNCTIONAL CATEGORY A: MANAGEMENT

1.0 Criterion 1 - Program

The LAS Quality Assurance plan addresses the Quality Assurance requirements outlined in U.S. EPA QAMS-005/80, ANSI/ASQC-E4-19xx, DOE Order 5700.6C (1991 Edition), and NQA-1. A table identifying the sections of the plan in which requirements are addressed is located in the FERMCO Quality Assurance audit files.

Furthermore, LAS Quality Assurance Plan follows standards and requirements mandated by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); The Resource Conservation and Recovery Act (RCRA); The Superfund Amendments and Reauthorization Act (SARA); The Toxic Substances Control Act (TSCA); The Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA).

See Section 2, Concerns 1, 3, 4, 6, 7, 8.

2.0 Criterion 2 - Personnel Training and Qualification

Two distinct aspects of training ensure that the LAS staff consistently produce high-quality work: (1) the individual, regardless of his or her technical, managerial, or support role, is capable of performing the assigned task, has the proper level of education and background for the specific job classification, and has received the appropriate orientation and indoctrination into LAS operations and (2) proper mechanisms are in place to enhance employee skill levels. Quality assurance aspects of job performance are stressed in the training that LAS technical personnel receive.

Qualifications of all professional, technical, and support personnel are documented via resumes which include academic credentials, employment history, experience, and professional registration or certification, appropriate for the position. A data base provides essential information on the current status of the internal and external training each technical staff member has received.

Copies of all training records are forwarded to the Human Resources Department through the LAS Safety Officer and the Quality Assurance Department. Human Resources staff coordinate the entry and filing of the appropriate documents to the training data base and to Human Resources files.

3.0 Criterion 3 - Quality Improvement

Data Quality Objectives (DQOs) are established to meet method or client specific requirements and to ensure that the data collected are sufficient and are of adequate quality for their intended use (EPA, 1987a). EPA has established six primary analytical DQOs for environmental studies; precision accuracy, representative, completeness, comparability and detectability.

Typically, DQOs are identified during project scoping and during development of sampling and analysis plan however, LAS only addresses the analytical DQOs, because LAS does not have any jurisdiction over sample collection, shipment or other field-related activities.

LAS monitors performance with respect to the DQOs to identify areas for quality improvements.

4.0 Criterion 4 - Documents and Records

Accountability for analysis documentation begins with receipt of the samples. At LAS, laboratory personnel typically use bound logbooks with prenumbered pages or sample preparation and analysis bench sheets to record data. Validation of measurement data is accomplished by requiring the analyst to review, date and sign data for each analysis on the day completed. This validation is further strengthened by providing space for the laboratory supervisor's (or designee) signature indicating that he or she has witnessed the data production and the completion of the analysis. Hard-copy data generated by a computer is permanently affixed in the logbook; hard copy so affixed is acceptable as an original record of sampling and laboratory logging. All original raw data (e.g. chromatograms, logbooks) are maintained in the laboratory while in use then forwarded to Document Control for long-term storage.

Instrumentation maintenance records are maintained for each instrument documenting all routine and emergency maintenance, tuning, calibration and analytical activities conducted on the instrument. The project name the date that the analysis is performed, and the names of the analyst(s) who operated the instrument are recorded on each page.

Maintenance of logbooks are detailed in procedure LAS-90-SOP-0006. Logbook entries are completed in black or blue ballpoint ink. Complete information (e.g., dates, data, sample numbers, observations) are legibly entered so that an examination by a supervisor, auditor, or another analyst can easily determine what was done, by whom, when, and the results.

Loose sheets, such as computer printouts or certification information, are permanently affixed to the logbook provided that the analyst initials and dates over the pasted record.

Bound, numbered laboratory logbooks are issued by the Document Control staff. Each logbook is tracked by the Document Control staff and all completed logbooks are transferred to Document Control for long-term storage if they are not used as a reference document.

5.0 Criterion 5 - Work Performance

A performance evaluation of LAS was conducted to determine if LAS has developed the basic program requirements and implemented the required procedures and administrative controls necessary to meet the requirements of RFP 92616. LAS's operation performance was evaluated in the following areas:

- Health and Safety
- Lab QA Plan - Lab Capacity/Personnel
- RM-0012 - Qualification of Analysts - Training
- Chemical Hygiene Plan - Waste Management Plan

The evaluation showed that Lockheed laboratory has developed the basic program requirements and implemented the required procedures and administrative controls necessary (with minor modification) to meet all the requirements of RFP 92616. Findings and concerns with the Lockheed program are detailed in 3.4.1 through 3.4.4.

The audit team evaluated LAS's analytical capabilities to meet FERMCO's SCQ requirements by auditing interlaboratory performance evaluation study results and selected organic, inorganic, radiochemical and preparative methods. Since LAS had not started receiving samples for analysis under the SCQ requirements, only capabilities and comparable performances could actually be evaluated.

VOLATILE ORGANICS BY GC/MS

The audit team reviewed a sanitized (customer's identification removed) CLP data package and logbooks for documentation of LAS's performance on required quality control elements. An interview was conducted with F. Kent to assist in performing these evaluations and review. The preparation and analysis facilities were also visited during the audit to evaluate general instrumentation and facility adequacy.

PESTICIDE/PCB

The audit team evaluated the capability of LAS's pesticide/PCB organ procedure to meet the SCQ requirements for quality control. The aud

team reviewed a sanitized (customer's identification removed) CLP data package and logbooks for documentation of LAS's performance of required quality control elements. An interview was conducted with D. Parks to assist in performing these evaluations and reviews. The preparation and analysis facilities were also visited during the audit to evaluate general instrumentation and facility adequacy.

METALS INDUCTIVELY COUPLED PLASMA - ATOMIC EMISSION SPECTROSCOPY (ICP-AES)

The audit team evaluated the capability of LAS metals by ICP-AES procedure to meet the SCQ requirements for quality control. The audit team reviewed a sanitized (customer's identification removed) CLP data package and logbooks for documentation of LAS's performance of required quality control elements. An interview was conducted with T. Mitchell-Hall, J. Linder, and A. Racel to assist in performing these evaluations and review. The preparation and analysis facilities were also visited during the audit to evaluate general instrumentation and facility adequacy.

MERCURY BY COLD VAPOR ATOMIC ABSORPTION SPECTROSCOPY (AAS)

The audit team evaluated the capability of LAS's mercury by cold vapor AAS procedure to meet the SCQ requirements for quality control. The audit team reviewed a sanitized (customer's identification removed) CLP data package and logbooks for documentation of LAS's performance of required quality control elements. An interview was conducted with Tuijauna Mitchell-Hall, Jeff Linder, and Ann Racel to assist in performing these evaluations and reviews. The preparation and analysis facilities were also visited during the audit to evaluate general instrumentation and facility adequacy.

INTERLABORATORY PERFORMANCE EVALUATIONS

The audit team evaluated interlaboratory performance evaluation study results to determine LAS's performance in these studies. These included inorganic, organic, and radiochemical analyses. Corrective action documentation for unacceptable results in these studies was reviewed. Sevda Aleckson and Mei Liu were contacted to provide the documentation. The percentage of acceptable analyses was calculated, and the results are listed below.

The most recent interlaboratory performance evaluation studies had over 95% acceptable analyses. This includes organics, inorganics, and radiochemical results. In addition, the laboratory has implemented corrective action response form which requires LAS's quality assurance department concurrence with the response. The performance and corrective action program documents on file have very good analytical accuracy and corrective action responses.

TOXICITY CHARACTERISTIC LEACHING PROCEDURE (TCLP)

The audit team evaluated the TCLP procedure for the quality control elements which are required by the SW 846 method. An interview was

conducted with Ron Callison and Bernice Herbert about their performance of this method. The preparation areas were visited to evaluate equipment and facility design. Records were reviewed for documentation of the quality control elements.

The laboratory must implement a zero headspace extraction procedure before performing these preparations of FERMCO samples. In addition, the extractor rotational frequency verification must be documented and the ambient temperature must be acceptable. LAS has the equipment and knowledgeable personnel required to perform TCLP extractions. The laboratory should be capable of performing TCLP when the above changes have been incorporated.

TOTAL URANIUM (U) BY LASER PHOSPHORIMETRY

The audit team evaluated the capability of LAS's total U by laser phosphorimetry procedure to meet the SCQ requirements for quality control. The audit reviewed a sanitized (customer's identification removed) data package and computer on-line files for documentation of LAS's performance of required quality control elements. An interview was conducted with Russ Stimmel to assist in performing these evaluations and reviews. The preparation and analysis facilities were also visited during the audit to evaluate general instrumentation and facility adequacy.

LAS has knowledgeable personnel performing and controlling this analytical method. The laboratory is well designed and has adequate instrumentation. The procedure includes all required quality control elements and the systems are in place to perform total uranium by laser phosphorimetry to SCQ requirements. The laboratory has a system to track sample holding times and has a system of documentation which will permit validation of the analytical results. LAS is normally using an ICP/MS instrument to analyze uranium, but the laser phosphorimetry system is ready.

GROSS ALPHA AND BETA ACTIVITY

The audit team evaluated the capability of LAS gross alpha and beta activity procedure to meet the SCQ performance requirements. The audit team reviewed a sanitized (customer's identification removed) data package and computer on-line file for documentation of LAS's performance of required quality control elements. An interview was conducted with Russ Stimmel to assist in performing these evaluations and reviews. The preparation and analysis facilities were also visited during the audit to evaluate general instrumentation and facility adequacy.

See Section 1, Findings 1, 3 and Section 2, Concern 2.

6.0 Criterion 6 - Design

LAS is working with a LIMS that was developed without the documentation required by the CLP SOW. The LIMS tracks samples as they are processed through the laboratory. This system is basic and there are calculations involved in the programs. Deliverables are hand calculated.

at this time. LAS is in the initial development planning stage of a new system (ACS) which is an enhancement of the current LIMS software. The ACS is being developed in-house and all Quality Assurance specified by FERMCO applies to this software. The referenced procedures are being implemented for this project. LAS's software and hardware control procedures demonstrate an understanding of the importance of using Quality Assurance techniques to ensure system integrity. LAL-91-SOP-0123, Rev. 0 (Certifying Locally Developed Software) is well written to include adequate software verification, system change controls, test documentation, security, organization, traceability, and quality control.

7.0 Criterion 7 - Procurement

At LAS the Source Selection Board reviews all competitive procurements of \$100,000 or more and major procurements when the competition involves an evaluation and comparison of cost or price and other technical factors. The source selection procedures are designed to (1) maximize competition, (2) minimize the complexity of the solicitation, evaluation, and selection decision, (3) ensure impartial and comprehensive evaluation of all offers, and (4) ensure selection of the source whose offer has the highest degree of quality and whose performance is expected to best meet the solicitation requirements. The Source Selection Board members consist of the Procurement Manager, Quality Assurance representative, technical representative, financial representative, buyer, and other personnel as required. The findings that result from the Board's decision provide permanent procurement file documentation.

LAS maintains a documented receiving inspection system which covers:

- Procured articles, materials, or services indicate evidence of inspections and tests performed by the supplier in accordance with purchase requirements and are accompanied by required certifications (if necessary).
- Chemical analyses and physical tests are conducted according to the approved analytical protocols.

When an article, material, or service procured by LAS does not conform to applicable specifications or other requirements, it is identified as nonconforming, is segregated to the extent practicable, and is held for review action. LAS has established a documented, systematic technique for the identification, documentation, and control of nonconformances.

8.0 Criterion 8 - Inspection and Acceptance Testing

Before an analytical run, the analyst checks schedules and records for maintenance and calibration to ensure that all are current. An initial or continuing calibration check verification is then completed, and the difference between analyzed values and the known standards is calculated. If any calibration check sample exceeds the control limit of the method, adjustments are made and the instrument is recalibrated, as appropriate.

During the course of the analytical run, the analyst incorporates all applicable QC samples in accordance with method-specific SOPs. Following each QC sample analysis, the analyst performs the necessary calculations either manually or by using appropriate software. If any QC sample falls outside method-specific control limits, the problem is investigated and resolved, and corrective action is performed in accordance with the method, the SOP, or the project-specific QA Plan. All information related to the analytical run is documented in the injection and analysis logbooks. All calculations related to QC sample analysis and the types and frequency of QA and QC samples (e.g., audits, blanks, spikes) are described in detail in the method-specific SOPs for inorganic, organic, and radioanalytical analyses.

See Section 1, Finding 2 and Section 2, Concerns 5, 9.

9.0 Criterion 9 - Management Assessment

The quality assurance program includes formal and frequent reports to inform management and technical staff of progress in the on-going implementation of the quality assurance plan. At a minimum, the following LAS parties received regular updates on project quality assurance status: (1) Director, (2) Operations Manager, (3) Program Development staff, (4) Client Services (Project) Manager, (5) section supervisors, and (6) analysts and other technical staff.

10.0 Criterion 10 - Independent Assessment

Technical systems audits and performance evaluation audits are used to determine on-going compliance with the quality assurance program and project plans and to assess the overall quality of data collected during the measurement process. Furthermore, audits help in evaluating sample collection, sample analysis, and data handling procedures. The objectives of these audits are (1) to confirm proper conduct of all sample handling, sample analysis, and data handling and reporting procedures and (2) to minimize the generation of invalid data by detecting potential problems at the earliest stage possible in these processes.

Section 1
FINDINGS

AUDIT E93-11

1. Requirement: TCLP Extractions by SW-846 Method 1311 requires that the rotary extractor operate at 30±RPM during TCLP extractions and that this data be documented.

Additionally this is covered by Lockheed Analytical Services procedure LAL-0048, Rev. 1 - Report Work Sheet, TCLP Worksheet SW-846.

Finding: The rotation frequency was not documented to verify required rotations per minute.

2. Requirement: Quality Assurance Project Plan (SQ) Section 8 - page Calibration Procedures and Frequency says the following

CALIBRATION PROCEDURES AND FREQUENCY

Measuring and test equipment used in the field and the laboratory shall be controlled by formally prescribed calibration requirements. Equipment shall be of the type, range, accuracy, and precision necessary to provide data compatible with the Analytical Support Level (ASL) (Section 2) specified in applicable Data Quality Objectives (DQO) (Appendix C) or Project Specific Plans (PSPs). Calibration of measuring and test equipment shall be performed using documented and approved procedures. When available, accepted procedures published by the American Society for Testing and Materials, the EPA, the National Institutes of Standards and Technology, or manufacturer equipment manuals shall be used. Variance from these procedures shall be justified and documented in PSPs.

Additionally this is covered by LASs procedure LAL-004 Rev. 1 - Report Work Sheet, TCLP Worksheet SW-846.

Finding: The ambient temperature was measured with uncalibrated thermometer that did not have sufficient sensitivity on the graduations (nearest 5 degrees Fahrenheit).

3. Requirement: TCLP Extraction by SW-846 Method requires zero h

space on extractions.

Finding: Contrary to the above LASs procedures LAL-0048, Rev. 1 did not address zero head space extractions.

Section 2
CONCERNS

AUDIT E93-11

1. OSHA Accident Reports lack a controlled follow-up system (i.e., evaluation of root cause for corrective action).
2. An item of concern was the method detection limits. Normally, LAL uses 5 ml of sample for the purge and trap technique. FERMCO specifies SW 846 limits which were established using 25 ml aliquots for ASL B samples. LAL has established MDL's for both 5 and 25 ml Aliquots which meet this criteria, but a 25 ml is not a normal practice.
3. A project specific plan is not written and approved for the FERMCO contract. The plan should include instructions for sample receipt which is specific to the FERMCO contract.
4. LAS has not sent FERMCO a list of individuals authorized to receive samples.
5. An infrared thermometer, model 20554, is calibrated to a NIST traceable standard. Instructions on the use of this instrument were not available to sample receiving personnel.
6. The Chain of Custody Procedure does not document the transfers required by the FERMCO SCQ. Sample extract and digestion are not included in the procedure.
7. A Non-Conformance Memo for FERMCO samples breaking the Chain of Custody has not been specified.
8. The Chain of Custody Procedure is not approved by FERMCO as required by the FERMCO SCQ.
9. Thermometer #1498317C in oven 20100004 was not calibrated at the time of the evaluation. The thermometer was a replacement for one that had broken.

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT**QUALITY ASSURANCE AUDIT NO. E93-17****International Technology (IT) Corporation**

DATE OF AUDIT: October 11-14, 1993
DATE OF REPORT: October 28, 1993
REISSUE DATE: February 23, 1994
AUDIT LOCATION: International Technology (IT) Corporation
St. Louis, MO
AUDIT TEAM MEMBERS: Mary Ann Forrest, Lead Auditor. FERMCO QA
Alfred B. Bacon, FERMCO, Technical Rep.
Jeff Maple, FERMCO, Quality Control
James Paradise, DOE-FN, Observer

PURPOSE AND SCOPE:

Assess the adequacy, effectiveness, and implementation of FERMCO and DOE quality assurance requirements and contractor performance as required by FERMCO contract RFP92616. Investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Program Description, RM-0012, FERMCO contract RFP 92616- RCRA/CERCLA Statement of Work, and the FEMP Sitewide CERCLA Quality Assurance Project Plan (SCQ).

AUDIT SUMMARY:

IT has the necessary licenses, certifications, and controls (e.g., quality program, policy statement, operating procedures) necessary to provide quality data packages to the FEMP in accordance with FERMCO Quality Assurance Program Description and FERMCO contract 92616 Statement of Work except for thorium analysis.

POST AUDIT REVIEW:

A post audit review was conducted in addition to the facility audit to include information pertinent to determining the capability of the laboratory to perform specified analyses. FERMCO Analytical Laboratory Support (ALS) personnel and FERMCO Quality Control (QC) personnel provide information related to the laboratory performance capabilities.

At the time of this audit report, the FERMCO intercomparison program could not provide data for uranium and thorium for IT. A follow up audit at IT will be conducted within the next few months and intercomparison data for uranium and thorium will be evaluated. However, in the DOE Environmental

Measurement Laboratory (EML) program, up to three uranium measurements are made on each of four possible matrices (water, soil, air, and vegetation). The DOE EML intercomparison studies for round 93-09 indicate that for 35 determinations, approximately 91% of the results were within reported EML acceptable range. It is noted that thorium is not included in intercomparison programs sponsored by DOE and EPA due to its limited use at other DOE or commercial sites. Until data for thorium analysis, by IT, can be evaluated, they should not be used for thorium analysis.

AUDIT CONDUCT:

A formal announcement of the intended audit was sent to IT, September 22, 1993. The FERMCO auditors held an opening meeting the afternoon of October 11, 1993, with IT representatives. Following introductions, a tour of the laboratory was conducted by Robert E. White, Project Manager.

Checklists were developed by the audit team for use during the audit to aid in review of the laboratory for compliance with the identified requirements. These checklists are maintained in the FERMCO Quality Assurance audit file.

Findings from Audit E92-11 requiring verification were verified and closed.

Each morning a meeting was held with IT personnel and FERMCO auditors to discuss the previous day activities. Also discussed were contractual issues and SCQ requirements. Questions were posed to the FERMCO Technical Representative by each division of IT and FERMCO is currently in the process of evaluating the questions.

Interviews were conducted with various laboratory personnel and managers: procedures, program plans, and record files were reviewed; laboratory operations, health and safety practices, and waste management activities were observed. Findings and concerns noted during the audit are stated in Sections 1 and 2, of this report, respectively.

The following people were interviewed:

David O. Kornegay	Lab Systems Manager
Robert E. White	Project Manager
R. C. Stites	Business Development
James M. Kleszczewski	Quality Control Coordinator
Bob Cowart	Sample Control Team Leader
Margaret Winter	Director, Total Quality
Erin Corcoran	Metals Group Leader
Don Hesse	Organics Group Leader
Roxanne Patterson	Acting Radiochemistry Group Leader/Wei
	Chemistry Group Leader
Joseph D. Koch	Health & Safety Coordinator
Larry Taake	Laboratory Director
John Hayden	IS Manager

A close-out meeting was held by the auditors, October 14, 1993, with I laboratory and administrative management personnel.

AUDIT OBSERVATIONS:

This section of the audit report is formatted to relate observations made during the audit as related to functional categories and criteria required by the FERMCO Quality Assurance Program Description, RM-0012.

A. FUNCTIONAL CATEGORY A: MANAGEMENT

1.0 Criterion 1 - Program

IT has developed and maintains a written quality assurance (QA) program following the appropriate requirements of NQA-1. Requirements of FD-1000 Site-wide CERCLA Quality Assurance Project Plan (SCQ) including ANSI/ASQC E4-19XX, are specified in the contract and applicable portions are included in IT's QA program. A matrix is included in the FERMCO Quality Assurance Audit file which depicts the correlation between DOE Order 5700.6C, RM-0012, and ANSI/ASQC E4-19XX.

IT's Corporate Quality Assurance Plan is binding on all personnel, a site specific operating procedures describing the St. Louis processes are referenced in the Plan. A policy statement, signed by management personnel is included in the document.

A list of equipment was submitted during the Procurement process prior award of contract. IT has sufficient equipment to perform organic, inorganic, and radiological analyses necessary to support the Statement of Work. However, they are performing only organic and inorganic analyses for data validation.

Employment at IT has remained constant, 50 person equivalents during 1992 compared to 49 person equivalents during 1993. Staffing is adequate

all areas except the Laboratory Information Management System (LIMS) where there was only one qualified staff member.

Housekeeping practices are indicative of a working lab and are acceptable with minor exceptions that were communicated to IT and addressed during the audit.

It is obvious that a lot of time and energy has been expended in order for IT to meet requirements imposed by the SCQ, as noted during the daily meetings.

See Section 1, Finding 1.

2.0 Criterion 2 - Personnel Training and Qualification

IT is supportive of the concept that personnel shall be trained and qualified to perform their assigned work. The audit team recognizes the technical expertise of the staff to be excellent. Resumes were reviewed to ensure analysts met educational and training requirements established by IT. Records indicated that analysts participated in performance evaluation programs, and a system is in place for retraining should it be required. Although some of the training files reviewed were incomplete, analyst qualifications were traceable to methods being performed.

See Section 1, Findings 2 and 3.

3.0 Criterion 3 - Quality Improvement

The IT QA program implements processes to detect and prevent quality problems and promote continuous quality improvement. An effective corrective action system is in place; documents were retrievable and traceable.

Auditors were assured by evidence provided that personnel have assumed ownership of their processes, thus projecting a commitment to quality.

See Section 2, Comment 7.

4.0 Criterion 4 - Documents and Records

A system is in place to control preparation, review, approval, issuance, use, and revision of documents, however, improvements are required as noted in Section 1.

Records containing data used to support CERCLA decision making follow requirements of the FERMCO SCQ and reporting requirements listed in the Statement of Work. Records are maintained for preventive maintenance, calibration, procedures, and other documentation as needed, to meet CERCLA requirements.

IT provides written procedures for specific tasks to the analysts and the instructions are maintained in logbooks. However instructions are not

linked to controlled documents.

Archived quality records are maintained in 1-1/2 hour rated cabinets. This process does not meet NQA-1 requirements. An indexing system is maintained in the LIMS. Records requested for review by the audit team were easily retrievable.

See Section 1, Findings 4, 5, 6, 7, and 8.

B. FUNCTIONAL CATEGORY B : PERFORMANCE

5.0 Criterion 5 - Work Performance

This criterion describes work related instructions, procedures, and other forms of direction including, but not limited to, waste handling, packaging, certification and shipping, and environmental data operations.

The Chemical Hygiene Plan and the Environment Safety & Health manual are being revised. Each laboratory has an effectual labeling process, and safety equipment is installed in or near all work areas.

A preventative maintenance (PM) program for analytical instrumentation is in effect and is operating adequately as indicated in the PM log.

There are standard operating procedures available for pertinent processes, including sample receipt, storage and processing. To ensure chain of custody, laboratory tracking systems are in place. A process for sample receipt (described in Section 7 of the SCQ) was not included in IT's procedure. The process was attached to IT's controlled Chain of Custody procedure during the audit. The IT Project Manager also talked Sample Receipt personnel through the procedure when FERMCO samples were received. This process was observed by the audit team. The FERMCO Technical Representative approved this method of documentation for maintaining custody of samples.

The FERMCO Statement of Work describes mandatory practices for waste management. The sample receipt process and the waste management process described in FERMCO documents ensures that chain of custody is maintained from sample receipt through waste disposal.

Process wastes at IT are analyzed to ensure results meet guideline established in the Statement of Work, and to ensure that radiological levels are within DOT guidelines, prior to shipment to the FEMP. Reanalysis will be performed at the FEMP prior to shipment off site.

Documents, logbooks, and records are prepared by the sample custodian and reviewed by the Sample Receiving Supervisor. Double key entry is performed from the field Chain of Custody into the LIM system.

This criterion also describes the identification and control of items handling, storing, and shipping, and calibration and maintenance

monitoring and data collection equipment.

IT's calibration processes are traceable to NIST and records are maintained indicating standards traceability. The items verified indicated calibrations are up to date. Calibration frequency is described in IT/SL's Quality Assurance Program.

See Section 1, Findings 9, 10, 11, and 12.
Section 2, Concerns 1-6.

6.0 Criterion 6 - Design

This criterion states that data collection processes for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented. Computer programs are to be proven through previous use, or verified through testing or simulation prior to use. A system is in place that defines computer program testing and documentation, and software control and software security. Group Leader have authority to change the process.

IT relies on the manufacturer for software reliability. A self-audit sample data management procedure (IT-1044) is used to verify that data entry is valid. IT relies mainly on manual entries (logbooks) and cannot software application.

The SCQ and Statement of Work requirements relate to performance criteria and QC frequency. Results are confirmed by data review and validation previously stated.

This criterion also provides for discussion of laboratory design. Limit access to the laboratory is maintained by key pads, electronic lock monitored one door entry, sign in log, and alarm system. Intern security is adequate to ensure that sample chain of custody is not compromised.

7.0 Criterion 7 - Procurement

IT has established a program to ensure that purchased items and services meet established requirements and perform as expected.

8.0 Criterion 8 - Inspection and Acceptance Testing

This criterion describes requirements and responsibilities for conducting chemical analyses, and producing analytical data for environmental projects. IT produced an equipment list to identify measurement and test equipment which is calibrated against nationally recognized standards. Laboratory equipment inspections are scheduled and documented.

Quality control standards and data quality objectives that laboratories are required to meet, are described in the SCQ. FERMCO reviewed documents (CLP Forms for Dioxins/Furans Organics) in accordance with SW-

Method 8280, during the pre-award process and found results to be within the acceptable range.

During the audit, FERMCO reviewed data packages at IT for organics in accordance with the 3/90 CLP Statement of Work, and data packages for SW-846 Methods 8240, 8260, 8270, and 8280, ASLs B and C. The "CLP-like" package represented a package that IT is capable of producing for ASLs C and D.

IT passed the DOE EML as stated in "Post Audit Review".

C. FUNCTIONAL CATEGORY C: ASSESSMENT

9.0 Criterion 9 - Management Assessment

This criterion describes a planned and periodic program of management assessments.

A formalized program is not evidenced. However, quality is promoted throughout the laboratory and quarterly reports based on laboratory processes are generated and forwarded to the IT Laboratory Director.

10.0 Criterion 10 - Independent Assessment

IT has implemented a program for the planning and performance of independent assessments. An audit schedule was reviewed. Performance evaluation and blind duplicate samples are processed and a log exists for tracking the samples. The information gleaned from blind duplicates is forwarded to FERMCO to be incorporated into the interlaboratory comparison program.

IT participates in external performance evaluation programs and undergoes audits from the EPA, state, and various auditing organizations. This area was reviewed to ensure independent assessments are being conducted, but evaluation results were not reviewed by the audit team.

Intercomparison studies are discussed in the "Post Audit Review" section

SECTION 1

FINDINGS

Audit E93-17

1. **Requirement:** RM-0012, 1.2.11 - "A graded approach shall be used ensuring that the resources applied are commensurate with the importance of the result to the achievement of site goals."
- Finding:** Inadequate staff exists to appropriately operate the LIMS.
- Comment:** Fire, sabotage, malfunction, illness, etc., could influence operation of the LIMS.
2. **Requirement:** RM-0012, 2.2.7 - "Training programs shall periodically reviewed to determine program and instruction effectiveness, and shall be upgraded when required."
- Finding:** Training records are incomplete.
3. **Requirement:** RM-0012, 2.2.7 - "Training programs shall periodically reviewed to determine program and instruction effectiveness, and shall be upgraded when required."
- Evidence was not produced that individuals review the training files annually (as stated in IT's Training program)
4. **Requirement:** RM-0012, 4.3.5 - "Ensure that correct revisions documents are used for performing work activities."
- Finding:** Documents are not stamped obsolete or superseded.
5. **Requirement:** RM-0012, 4.3.5 - "Ensure that correct revisions documents are used for performing work activities."
- Finding:** Signed receipts issued for superseded/obsolete documents do not indicate the revision number.
6. **Requirement:** RM-0012, 4.3.5 - "Ensure that correct revisions documents are used for performing work activities."
- Finding:** Evidence was not provided that only correct issues documents are maintained in the work areas, i.e. instruction sheets in log books are not tied to controlled documents.

7. **Requirement:** RM-0012, 4.2.6 - "...The maintenance of records shall include provisions for retention, protection,..."
- Finding:** Facilities meeting the requirements of NQA-1 for record storage are not available.
8. **Requirement:** RM-0012, 4.2.6 - "...The maintenance of records shall include provisions for retention, protection,..."
- Finding:** Duplicate records are not available for all processes performed in the laboratory.
9. **Requirement:** RM-0012, 5.2.1 - Work related instructions, procedures...shall be provided to employees doing the work."
- Finding:** A controlled operating procedure for Method 8260 was not available.
10. **Requirement:** RM-0012, 5.2.1 - Work related instructions, procedures...shall be provided to employees doing the work."
- Finding:** Controlled operating procedures for LIMS processes were not available
11. **Requirement:** RM-0012, 5.3.9 - "Develop chain-of-custody procedures for controlling the handling, storage, shipping, and disposal of environmental samples. These procedures for environmental samples shall be taken from the SCQ..."
- Finding:** A controlled procedure for sample receipt was not available upon receipt of samples.
- Comment:** Section 7.2 of the SCQ was in the sample custody area and was followed when FERMCO samples were received. The procedure was reviewed by the Project Manager with sample receiving personnel.
12. **Requirement:** RM-0012, 5.4.10, ITAS Chemical Hygiene Plan Housekeeping
- Finding:** Housekeeping in the sample custody area need improvement as noted
 - cooler shelves do not have lips to prevent falls
 - samples were stacked
 - emergency showers and eye wash station were visibly dirty
- Comment:** The identified areas could result in cross-contamination of samples, broken bottles, personal injury, etc.

SECTION 2

CONCERNS

AUDIT 93-17

1. Documents conflict as to wording on labeling of drums. SL12502, Pg. 10 and CHP 12.4.
2. The TCLP prep log does not contain the lot number of the appropriate extraction fluid. (CORRECTED)
3. Chemicals were stored alphabetically, not by compatibility in the Wet Chemistry Lab (CORRECTED)
4. Spill kits are available in Sample Custody, but are not listed in the Contingency Plan.
5. A log book in the GC Lab was initialed, but not dated. (CORRECTED)
6. The QC Check for MeCl was missing from the appropriate folder. (CORRECTED)
7. A loop was not closed in a corrective action report that had been archived. The oversight was not significant; however, care should be taken to avoid repeat of this error.

FEMP Approved Laboratory List

Issue Date: January 31, 1994
Revision Number: 0

Laboratory Name and Location	Analytical Support Level	Analysis Category	Period of Performance	Date of Last Audit	Approval Status	Remarks
Clemson Technical Center, Inc. Clemson Research Park 100 Technology Drive Anderson, SC 29625	B, C, D	Chemical	9/93 - 9/94	10/13/93 thru 10/17/93	Approved & Contracted	
DataChem Laboratories 960 West Levey Drive Salt Lake City, UT 84123	B, C, D	Chemical Radiological	9/93 - 9/94	10/11/93 thru 10/15/93	Approved & Contracted	
ITAS - St. Louis 13715 Rider Trail North Earth City, MO 63045	B, C, D	Chemical	9/93 - 9/94	10/13/93 thru 10/17/93	Approved & Contracted	
Lockheed Analytical Laboratories 975 Kelly Drive Las Vegas, NV 89119-3705	B, C, D	Chemical	9/93 - 9/94	9/27/93 thru 10/1/93	Approved & Contracted	
Oak Ridge Analytical Services 1345 Oak Ridge Turnpike Suite 333 Oak Ridge, TN 37830	B, C, D	Radiological	8/93 - 8/94	11/1/93 thru 11/4/93	Approved & Contracted	
Roy F. Weston, Inc. 208 Welsh Pool Creek Lionville, PA 19341	B, C, D	Chemical	9/93 - 9/94	9/28/93 thru 10/1/93	Approved & Contracted	
Twin City Testing 1908 Innerbelt Business Center St. Louis, MO 63114-5700	B, C, D	Chemical	9/93 - 9/94	9/13/93 thru 9/17/93	Approved & Contracted	
EEI 10163 Cincinnati-Dayton Road Cincinnati, OH 45241	B	Chemical	1/94 - 1/95	*See Remarks	Ohio EPA Safe Drinking Water Act Approved	Desktop Surveillance 1/27/94 Currently seeking contract
Core Labs 420 W. First Street Casper, WY 82601	B, C, D	Radiological	9/93 - 9/94	5/11/93 thru 5/14/94	Approved & Contracted	
FERMCO Analytical 7400 Willey Road Fernald, OH 45030	B, C, D	Chemical Radiological	1/94 - 1/95	1/24/94 thru 1/28/94	Conditionally Approved	Full approval pending resolution of audit findings.

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