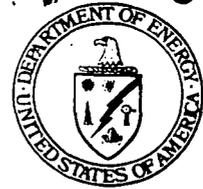




## Department of Energy

Ohio Field Office  
 Fernald Area Office  
 P. O. Box 538705  
 Cincinnati, Ohio 45253-8705  
 (513) 648-3155



APR 03 1997

DOE-0775-97

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

Mr. Tom Schneider, Project Manager  
 Ohio Environmental Protection Agency  
 401 East 5th Street  
 Dayton, Ohio 45402-2911

Dear Mr. Saric and Mr. Schneider:

### PROPOSAL TO USE ON-SITE LABORATORY TO PERFORM CHEMICAL AND RADIOLOGICAL ANALYSES IN SUPPORT OF SOIL CERTIFICATION EFFORTS

Reference: Facsimile, Saric to R.J. Janke, information packet concerning the, "FEMP On-site Laboratory Capability" (subject paraphrased), dated March 12, 1997.

The Department of Energy, Fernald Environmental Management Project (DOE-FEMP) has reviewed the referenced facsimile concerning the capability of the on-site laboratory to perform chemical and radiological analyses, in accordance with the Site-Wide Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Quality Assurance Project Plan (SCQ) requirements, for Analytical Support Levels (ASL) B, C, and D. The purpose of this letter is to (1) provide the requested documentation to show that the on-site laboratory has consistently demonstrated that it is capable of performing chemical and radiological analyses at ASLs B, C, and D in accordance with the requirements stipulated in the SCQ and (2) propose the use of FEMP laboratory to support soil certification efforts in Area 1, Phase I (A1PI) activities as needed, as well as in future area-specific remediation efforts.

The use of the FEMP laboratory in A1PI certification activities will primarily be limited to any re-certification efforts that may be needed in the event of initial certification failure. Through our weekly conference calls and regular A1PI/Soil Issues meetings updates, the U.S. Environmental Protection Agency (U.S. EPA) will be kept abreast of all current developments concerning A1PI certification results and any potential certification unit failures. As you are aware, certification analyses for A1PI are currently being performed

entirely at off-site laboratories; therefore, it is not expected that substantial numbers of analyses will need to be performed on-site. However, given the time-critical nature of the A1PI activities, the use of the FEMP laboratory for re-certification analyses, if needed, provides the FEMP additional flexibility. In terms of future area-specific certification analyses, specific details as to the planned use of on-site laboratory capabilities as opposed to off-site, contract laboratories will be provided in the area-specific Integrated Remedial Design Packages. Through your review of the enclosed documentation, we are confident that you will find that the FEMP laboratory has adequately demonstrated the capability of generating data necessary to support the Operable Unit 5 (OU5) soil certification needs.

#### Approved Laboratory List

As mentioned in the facsimile, the U.S. EPA received a letter from DOE, dated June 21, 1994, which shows that the on-site lab was approved for chemical and radiological analyses at levels B, C, and D. Enclosure 2 to this letter provides the current SCQ approved laboratory list which indicates that the on-site lab is approved for chemical and radiological analyses at levels B, C, and D. Please note that the on-site laboratory has consistently maintained this level of approval since the submittal of the June 1994 letter.

#### Annual Audit of On-site Laboratory

The referenced facsimile mentioned the fact that "there should be audit reports from 1995, 1996, and possibly 1997 confirming the lab was audited and is operating acceptably for conducting radiological and chemical analysis at levels B, C, and D." Enclosure 3 to this letter provides copies of the final audit reports for the 1995 and 1996 audits of the on-site laboratory, along with a copy of the draft report for the recently completed 1997 audit. With the exception of the 1997 audit, all issues raised in these audits were adequately addressed by the on-site laboratory. Once the 1997 audit report is finalized, the on-site laboratory will appropriately address all issues in accordance with the schedule defined by the report. As indicated by these reports the on-site laboratory is operating acceptably for conducting radiological and chemical analysis at levels B, C, and D.

#### Status of Changes Requested During EPA Audit

The referenced facsimile indicated that, "On January 9, 1995, EPA received a letter from DOE detailing how DOE has addressed EPA's previous comments on the on-site lab." The facsimile requested that DOE ". . . make sure these changes were indeed made . . . ." The FEMP has reviewed the U.S. EPA's previous comments on the on-site laboratory and has verified that these issues were appropriately addressed. The Fluor-Daniel Fernald (FDF) Quality Assurance organization also rechecked these issues during subsequent annual audits to ensure continued compliance on the U.S. EPA's findings and observations from the U.S. EPA 1994 audit.

### Additional On-site Laboratory Performance Evaluation Programs

In addition to complying with the SCQ requirements, the on-site laboratory has been and is currently a very successful participant in several external Performance Evaluations Programs (PEP) which further demonstrate operational proficiency over and above the requirements of the SCQ. These PEPs include:

- The FDF Inter-laboratory Data Comparability (IDC) program for metals, inorganics, organics and radiological analyses (participant since its inception);
- The DOE Environmental Measurements Laboratory (EML) Program Evaluation Plan from the Hazardous Analytical Substance List (HASL) for radiological analyses (participant since 1989);
- The DOE Mixed Analyte Performance Evaluation Program (MAPEP) from Idaho Falls for both metals and radiological analyses (participant since initiation in 1995);
- The U.S. EPA Environmental Monitoring Systems Laboratory (EMSL) program from Las Vegas for radiological analyses (participant since 1990);
- Laboratory performance Evaluation Study (Discharge Monitoring Report Quality assurance Program (DMR QA));
- Analytical Products Group Proficiency Environmental Testing (APG-PET) for water testing.
- American Industrial Hygiene Association (AIHA) Bulk Asbestos Proficiency Testing Program;
- The National Institute for Standards and Testing (NIST) Bulk Asbestos Identification Program as part of the NIST accreditation program.

PEPs most relevant to the Soils Certification Project include the FDF IDC Program for metals, inorganics, organics and radiological analyses; the DOE EML PEP from the HASL for radiological analyses; the DOE MAPEP from Idaho Falls for both metals and radiological analyses; and the U.S. EPA EMSL program from Las Vegas for radiological analyses. The on-site lab has consistently placed first or second in the IDC program and has also demonstrated high performance capability in the other PEPs.

In conclusion, the on-site laboratory has demonstrated through the 1994 U.S. EPA audit, the annual SCQ and RM-0012 (per 10 CFR Part 830.120) audits by the FDF Quality Assurance (QA) organization, and the excellent performance in numerous external PEPs, that it is capable of performing radiochemical and chemical analyses at the ASLs B, C, and D.

If you have any questions regarding this matter, please contact me at (513) 648-3139, or Robert Janke at (513) 648-3124.

Sincerely,



Johnny Reising  
Fernald Remedial Action  
Project Manager

FEMP:R.J. Janke

Enclosures: As stated

cc w/encs:

N. Hallein, EM-42/CLOV  
G. Jablonowski, USEPA-V, 5HRE-8J  
R. Beaumier, TPSS/DERR, OEPA-Columbus  
M. Rochotte, OEPA-Columbus  
T. Schneider, OEPA-Dayton (total of 3 copies of enc.)  
F. Bell, ATSDR  
D. S. Ward, GeoTrans  
R. Vandegrift, ODOH  
S. McLellan, PRC  
D. Carr, FDF/9  
R. Friske, FDF/52-3  
T. Hagen, FDF/65-2  
J. Harmon, FDF/90  
A. Hunt, FDF/52-5  
A. Meyer, FDF/35  
C. Sutton, FDF/35  
AR Coordinator/78

cc w/o encs:

A. Tanner, DOE-FEMP  
C. Little, FDF/2  
EDC, FDF/52-7

bcc w/encs:

M. Davis, ANL

R. Johnson, ANL

K. Picel, ANL

I. Fisenne, DOE-EML

K. Miller, DOE-EML

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**ENCLOSURE 1**

**FACSIMILE, INFORMATION PACKET  
CONCERNING FEMP ON-SITE LABORATORY  
FROM J. SARIC TO R.J. JANKE, DATED  
MARCH 12, 1997**

DATE: MARCH 12, 1997

TO: ROB JANKE

FROM: JIM SARIC

PAGES: 16

Rob:

Enclosed are several letters regarding lab audits and the SCQ. I reviewed the various revisions of the SCQ and they only showed the on-site lab to be approved for radionuclides and TAL analysis at levels B and E. However, the June 21, 1994, letter shows the on-site lab approved for chemical and radiological analysis at levels B,C, and D. The audit date was January 1994 and the required audit frequency was annual.

On October 27, 1994, EPA auditors audited the on-site lab and looked at FERMCO's lab auditing procedure. Several comments were made on the lab. EPA felt the lab was operating adequately and that the audit procedure was also acceptable, however the audit procedure required follow-up and timelines for a lab to meet required changes.

On January 19, 1995, EPA received a letter from DOE detailing how DOE has addressed EPA's previous comments on the on-site lab.

DOE should check to make sure these changes were indeed made and there should be audit reports from 1995, 1996, and possibly 1997 confirming the lab was audited and is operating acceptably for conducting radiological and chemical analysis at levels B,C, and D.

The enclosed pages should help you find the audit reports. Once found you should send them to me to confirm that the on-site lab is acceptable. On a related note, the SCQ folks should be making sure this audit process is occurring as specified in the June 21, 1994, letter. If any new labs have been added another letter is required.

Sincerely,



Jim Saric

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Department of Energy  
Fernald Environmental Management Project  
P. O. Box 538705  
Cincinnati, Ohio 45253-8705  
(513) 648-3155

JAN 19 1995

DOE-0451-95

RECEIVED

JAN 20 1995

Mr. James A. Saric  
United States Environmental Protection Agency  
Region V  
77 West Jackson Boulevard  
Chicago, Illinois 60604-3590

OFFICE OF RCRA  
WASTE MANAGEMENT DIVISION  
EPA, REGION V

Dear Mr. Saric:

RESPONSE TO OCTOBER 27, 1994 FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION LABORATORY QUALITY AUDIT

The Department of Energy, Fernald Area Office has reviewed your audit findings, and has instructed our contractor, Fernald Environmental Restoration Management Corporation (FERMCO), to make your suggested corrections in response to your findings and concerns. The documentation to verify correction of the issues is included in the enclosed letter from FERMCO.

It was our pleasure to have your staff visit the site and provide input to improve our Laboratory Quality Assurance Program. For more information or comments, please contact Howard Etkind at (513) 648-3158.

Sincerely,

*Alan Griffiths*  
for Jack R. Craig  
Director

FN:Etkind

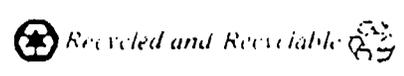
Enclosure: As Stated

cc w/enc:

Patrick J. Churilla, US EPA V  
Brian Freeman, US EPA V

cc w/o enc:

C. Sutton, FERMCO/35



800008



Environmental Management Corporation

P.O. Box 398704 Cincinnati, Ohio 45239-8704 (513) 738-6200

U. S. Department of Energy  
Fernald Environmental Management Project  
Letter No. C:OP:95-0061

Mr. Walter J. Quaider  
Acting Associate Director  
Office of Safety Assessment  
Department of Energy  
Fernald Area Office  
P. O. Box 538705  
Cincinnati, Ohio 45253-8705

Dear Mr. Quaider:

CONTRACT DE-AC24-920H21972, ENVIRONMENTAL PROTECTION AGENCY LABORATORY AUDIT

Reference: Letter number DOE-0355-95, Walter J. Quaider to Don Ofte,  
"Environmental Protection Agency Laboratory Audit," dated January 3,  
1995

In their October 27, 1994 audit of the Fernald on-site laboratory, the USEPA requested that certain steps be taken to improve the laboratory's performance. FERMCO has implemented, or is in the act of implementing, corrective actions relative to the USEPA audit findings. These corrective actions are described below.

**FINDING #1** Several SOPs previously noted as being out of date have not been updated. In particular, 9031 - Data Management and Reporting, 9103 - Mercury by Cold Vapor AA and 9012 - TCLP have not been updated.

**RESPONSE:** The Analytical Laboratory Services Department procedure program requires all laboratory procedures and methods to be reviewed every two years to ensure technical accuracy and compliance with current requirements. All three documents noted in the findings (9031, 9103, 9012) have been reviewed per this requirement and are currently in the process of revision in accordance with 257-D-0001, "Analytical Laboratory Services Department Document Processing and Implementation." Listed below is the current status of each document:

1. 9031, "Management and Reporting of Analytical Laboratory Results" - The author is performing the initial review of the

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Mr. Walter J. Quaider  
 Letter No. C:OP:95-0061  
 Page 2

document to ensure that all technical changes are incorporated.

2. 9103, "SW846:7470, 7471/Cold Vapor Technique for the determination of Mercury in Liquid, Solid, and Sediment Samples using the Leeman PS200 Automated Mercury Analyzer" - The document is currently being reviewed by laboratory personnel prior to being transmitted for formal review.
3. 9012, "Toxicity Characteristics Leaching Procedure (TCLP) for Metallic Analytes" - The document has completed formal review and is in the review comment resolution stage.

**FINDING #2** Blank spaces are still abundant on printed forms and laboratory logbooks. For evidentiary purposes, all unused spaces should be Z'd out, initialed and dated or marked N/A.

**RESPONSE:** The Analytical Laboratory Services (ALS) Department has a procedure (SOP 9007) entitled "Log Keeping Procedure." This procedure clearly addresses the treatment of blank spaces. To remind chemists not to leave blank spaces in log books, an instruction list for filling out log books will be taped in the front cover of each log book by the end of January, 1995.

**OBSERVATION #1** Weights used to check balances were not recently calibrated. The balance in the sample receiving area did not have a check weight present.

**RESPONSE:** As of October 27, 1994 all balance check weights were themselves checked in order to assess their quality and condition as required by ALS Departmental Procedure 257-D-0008 entitled "Instrument and Equipment Repair, Calibration, and Preventative Maintenance."

Each weight was weighed on a balance whose calibration was certified, and the measured value was compared to the known value (i.e., the mass stamped on the weight). In the vast majority of cases, the measured value was exactly equal to the known mass with an accuracy of three decimal places. Only two weights showed any variation from the mass stamped on each weight. In all cases, this variation was no greater than one milligram from the nominal value, which equated to a deviation of 0.1% or less. Based on this testing it is our conclusion that all the balance check weights are suitable for use.

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Mr. Walter J. Quaid  
 Letter No. C:OP:95-0061  
 Page 3

Since this testing was done, the ALS Department has purchased a set of certified weights ranging from 1 mg to 100g to be used to check balance weights to further enhance the ALS Balance Certification Program.

The scale in the sample receiving area is not used to generate any type of analytical data. Rather, it is used to record gross weights (including containers) for sample shipping purposes. This balance has no check weight because high accuracy is not needed. Nonetheless, this scale is part of the ALS Department Calibration Program and is regularly calibrated by the Fernald Scale Shop.

**OBSERVATION #2**

Labels on sample containers in the sample receiving area were observed to have information scratched out. It is unknown whether this occurred in the field or in the laboratory. No information should be obliterated. Changes should be made with a single line through the old information and initialed and dated.

**RESPONSE:**

A letter was sent on January 6, 1995 (M:ENV(ALS):95-0026) to all managers of laboratory personnel and field sampling personnel apprising them of the above USEPA observation. This letter gave the following instructions to laboratory and field sampling personnel:

**The FERMCO driver for this requirement is the Quality Assurance Program Description RM-0012, Rev. 2.**

4.2.7. "Quality Assurance Records shall not be erased or obliterated when revised. Instead, a single line should be drawn through errors or items to be deleted. The person making a revision shall initial and date the revision."

Please advise the samplers or laboratory technicians in your respective organizations to have a heightened awareness regarding this issue. As part of the sample receipt process in the Sample Processing Laboratory (SPL), the technicians will also scrutinize the sample labels and associated documentation for scratched out information.

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Mr. Walter J. Quaider  
 Letter No. C:OP:95-0061  
 Page 4

Finally, the Manager of the ALS Department has asked FERMCO's Quality Assurance Department to schedule a surveillance to address the successfulness of the above instructions. This surveillance is scheduled for the 2nd quarter of FY95.

OBSERVATION #3 The Graphite Furnace Maintenance Logbook numbered 94-035 contained entries with dates earlier than the beginning date on the cover of the logbook. For evidentiary purposes this inconsistency needs to be avoided.

RESPONSE: The Graphite Furnace Maintenance Log Number 94-035 has been corrected to display the correct dates the logbook entries cover.

ALS Department Procedure (SOP 9007) entitled "Log Keeping Procedure," will be modified to specify accurately dating the front cover and the inclusion of date checking as part of a Supervisor's logbook inspection responsibility.

OBSERVATION #4 There is no evidence of supervisory or quality assurance inspection of logbooks. We recommend that logbooks be periodically examined by management for consistency and completeness.

RESPONSE: Logbooks are regularly inspected by Analytical Laboratory Supervisors in accordance with SOP 9007 ("Log Keeping Requirements"). The logbooks in question reside in the Sample Processing Laboratory, which is responsible for sample receipt, distribution, and shipping.

The Supervisor of this laboratory began a weekly routine of checking all logbooks: sample transfer logbooks and refrigerator logbooks. The supervisor signs the bottom of each logbook page verifying that all fields have been entered correctly.

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Mr. Walter J. Quaid  
Letter No. C:OP:95-0061  
Page 5

If you have any questions concerning this document, please contact Chris Sutton,  
Analytical Laboratory Services Department Manager, at 738-9450.

Sincerely,

Don Ofte  
President

DO:CS:eab

c: L. E. Parsons, DOE Contract Specialist  
R. D. George  
File Record Storage Copy 102.1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF

DEC 05 1994

MEMORANDUM

SQC-14J

SUBJECT: Review of FEMP QA Audit Program

FROM: Patrick J. Churilla, Chemist,  
Contract Analytical Services Section

*Patrick J. Churilla*

TO: James Saric, Remedial Project Manager,  
Waste Management Division

In response to your request for a review of FEMP's QA audit program, I examined previous FEMP Laboratory Audit Checklists and audit SOPs and visited the FERMCO laboratory to evaluate the effectiveness of the auditing process. In general, the FEMP QA Audit Program is working very well. Below are my specific findings:

1. The audit checklist used by FEMP is very thorough, covering the analytical processes, quality assurance, project management and documentation.

2. The FEMP Audit Program SOPs are clearly written and internally consistent. However, two areas could have better documentation:

a) The process for developing audit checklists should be more clearly described. It is not clear how particular questions are added to the checklist.

b) A mechanism for setting time limits for laboratory compliance should be added to the audit SOP. Several findings of our audit were the same as those from the FERMCO audit conducted on January 25-28, 1994 and concerned the updating of lab SOPs. These are documented in our audit report.

3. The on-site laboratory audit revealed an efficiently running laboratory with only a few evidentiary issues that need to be addressed. Technical performance was very good.

In conclusion, my opinion is that the auditing process developed by FEMP is adequately evaluating the performance of the laboratories being used in the Fernald clean-up project. However, it does not sufficiently track the implementation of its audit recommendations. We recommend that future audits include timeframes for laboratory

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Printed on Recycled Paper

compliance. These timeframes provide the lab with a helpful reminder to implement necessary quality controls.

If you have any questions please call Brian Freeman at (312)-353-2720 or Patrick Churilla at (312)-353-5210.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

672

IN REPLY TO THE ATTENTION OF

DEC 05 1994

MEMORANDUM

90-147

SUBJECT: Review of FERMCO Laboratories

FROM: Patrick J. Churilla, Chemist,  
Contract Analytical Services Section

Brian Freeman, Chemist, *B. Freeman*  
Contract Analytical Services Section

TO: James Saric, Remedial Project Manager,  
Waste Management Division

As requested, An on-site audit of the FERMCO laboratory was conducted on Oct. 27, 1994 to evaluate the lab's analytical and custodial procedures, determine the adequacy of the current auditing program and determine if past recommendations had been implemented.

1. Several findings of our audit were the same as those from the FERMCO audit conducted on January 25-28, 1994. This indicates that the audit resolution process needs to be improved. These repeat findings are as follows:

a) Several SOPs previously noted as being out of date have not been updated. In particular, 9031 - Data Management and Reporting, 9103 - Mercury by Cold Vapor AA and 9012 - ICP have not been updated.

b) Blank spaces are still abundant on printed forms and laboratory logbooks. For evidentiary purposes all unused spaces should be Z'd out, initialed and dated or marked N/A.

2. Two previous findings which were corrected were:

a) Previously unavailable instrument detection limits were present.

b) ICP logbooks which lacked method information now have the particular method being used recorded.

3. In addition to the above findings we observed the following practices which should be addressed:

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a) Weights used to check balances were not recently calibrated. The balance in the sample receiving area did not have a check weight present.

b) Labels on sample containers in the sample receiving area were observed to have information scratched out. It is unknown whether this occurred in the field or in the laboratory. No information should be obliterated. Changes should be made with a single line through the old information and initialed and dated.

c) The Graphite Furnace Maintenance Logbook numbered 94-035 contained entries with dates earlier than the beginning date on the cover of the logbook. For evidentiary purposes this inconsistency needs to be avoided.

d) There is no evidence of supervisory or quality assurance inspection of logbooks. We recommend that logbooks be periodically examined by management for consistency and completeness.

In summary, our opinion is that the laboratory is currently operating acceptably with only minor changes required to maintain the high evidentiary requirements of the Fernald clean-up project. The only analytical finding that we have is to more frequently check the weights used in measuring the samples.

If you have any questions please call Brian Freeman at (312)-353-2720 or Patrick Churilla at (312)-353-6175.

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ATTENDANCE ROSTER  
EPA AUDIT KICK-OFF MEETING

10/27/94

NAME	COMPANY/AFFILIATION
Howard L. Kind	DOE 645 1151 1151 1151
REINHARD FRISKE	ENV. QA / QC LAB
Amy Meyer	FERMCO / ALS
Hickie Hines	FERMCO / ALS - # 9166 FX-9287
David Madsen	FERMCO / QA
William Kelley	FERMCO / ALS
PATRICK CHURILLA	USEPA - REGION 5
BRUN P. FREEMAN	USEPA - REGION 5
ALEX R. DUARTE	FERMCO / ALS / SMO
CHRIS SUTTON	FERMCO / ALS
RAY DANAHY	FERMCO / ALS / REA
Chris Sutter	FERMCO / ALS / R

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ATTENDANCE ROSTER  
EPA AUDIT CLOSE-OUT MEETING

10/27/94 2:00 pm

NAME	COMPANY/AFFILIATION
Chris Sotta	FERMCO/ALS Dept.
Ray Danahy	FERMCO / ALS DEPT.
<i>[Handwritten signature]</i>	FERMCO/ALS # 9166
David Madsen	FERMCO/QA
Amy Meyer	FERMCO/ALS
BRIAN P. FREEMAN	USEPA RI
PATRICK CHURILLA	USEPA - REGION V
William D Kelley	FERMCO/ALS
Howard Etkind	USEPA RI

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

672

JUN 21 1994  
 DOE-1948-94

① Audit Procedure  
 ② Audit Report  
 ③ SCQ  
 ④ Laboratory Request Form  
 ⑤ will this report apply  
 c/o Dennis Wejowski  
 6-1970

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

Mr. Tom Schneider, Project Manager  
 Ohio Environmental Protection Agency  
 401 East Fifth Street  
 Dayton, Ohio 45402-2911

Dear Mr. Saric and Mr. Schneider:

**NOTIFICATION OF FERNALD ENVIRONMENTAL MANAGEMENT PROJECT APPROVED LABORATORY LIST**

In accordance with the Fernald Environmental Management Project (FEMP) Sitewide Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Quality Assurance Project Plan (SCQ), the enclosed FEMP approved laboratory list is submitted for your acceptance. The laboratories indicated on the attached list have been audited in accordance with the requirements of the SCQ and have been approved by the FEMP for sample analysis of activities covered by the SCQ.

It is requested that written acceptance of the attached laboratory list be provided to the Department of Energy, Fernald Field Office (DOE-FN) in the form of an acceptance letter. After acceptance of the approved laboratory list, when laboratories are added or deleted from the list, DOE will notify EPA and the list will be modified accordingly. All laboratories added to the list will be submitted to the EPA for acceptance in accordance with the SCQ requirements.

If you or your staff have any questions, please contact John H. Trygier at (513) 648-3154.

Sincerely,

*Jack R. Craig*  
 Jack R. Craig  
 Fernald Remedial Action  
 Project Manager

FN:Trygier

Enclosure: As Stated



000020

cc w/enc:

K. A. Chaney, EM-423, TREV  
D. Kozlowski, EM-423, TREV  
A. Alwan, USEPA-V  
G. Schupp, USEPA-V  
J. Kwasniewski, OEPA-Columbus  
W. J. Kehew, DOE-FN  
J. Michaels, PRC  
L. G. Abernathy, FERMCO  
P. F. Clay, FERMCO  
H. W. Richardson, FERMCO  
C. Sutton, FERMCO  
AR Coordinator, FERMCO

120000

*Account*

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**FERNALD ENVIRONMENTAL MANAGEMENT PROJECT APPROVED LABORATORY LIST, JUNE 20, 1994**

Laboratory Name and Location	Analytical Support Level	CLP	Type of Services / Analysis	Period of Performance	Date of Last Audit	Auditing Organization	Audit Results / Status	Audit Frequency	Remarks
AccuLabs 4663 Table Mountain Drive Golden, Colorado 80403-1650	B, C, D	No	Radiological	4/94 - 5/95	5/94	FERMCO	Passed / Approved & Contracted	Annual	
Clemson Technical Center, Inc. 100 Technology Drive Anderson, SC 29625	B, C, D	Yes	Chemical	9/93 - 9/94	10/93	FERMCO	Passed / Approved & Contracted	Annual	
Core Labs 420 W. First Street Casper, WY 82601	B, C, D	No	Radiological	9/94 - 9/95	5/94	SQIG	Passed / Approved & Contracted	Annual	
DataChem Laboratories 960 West Levoe Drive Salt Lake City, UT 84123	B, C, D	Yes	Chemical, Radiological	9/93 - 9/94	10/93	FERMCO	Passed / Approved & Contracted	Annual	Audit Scheduled 7/18/94
EEL 10163 Cincinnati-Dayton Road Cincinnati, OH 45241	B	No	Drinking Water Parameters	1/94 - 1/95	1/94	FERMCO	Passed / Approved & Contracted	To be determined	Ohio EPA SDWA Approved
FERMCO Analytical 7400 Wiley Road Fernald, Ohio 45030	B, C, D	Yes	Chemical, Radiological	1/94 - 1/95	1/94	FERMCO	Passed / Approved	Annual	
<del>TAS - St. Louis</del> 13715 Rider Trail North Earth City, MO 63045	B, C, D	Yes	Chemical	9/93 - 9/94	10/93	FERMCO	Passed / Approved & Contracted	Annual	
Lockheed Analytical Laboratories 975 Kelly Drive Las Vegas, NV 89119-3705	B, C, D	Yes	Chemical Radiological	9/93 - 9/94	9/93	FERMCO	Passed / Approved & Contracted	Annual	Audit Scheduled 6/27/94
Oak Ridge Analytical Services 1345 Oak Ridge Turnpike, #333 Oak Ridge, TN 37830	B, C, D	Yes	Radiological	8/93 - 8/94	11/93	FERMCO	Passed / Contract Terminated	N/A	Laboratory closed due to merger.
Roy F. Weston, Inc. 208 Welsh Pool Creek Lionville, PA 19341	B, C, D	Yes	Chemical	9/93 - 9/94	9/93	FERMCO	Passed / Approved & Contracted	Annual	
TMA/Eberline 7021 Pan American Freeway Albuquerque, NM 87109	B, C, D	No	Radiological	4/94 - 5/95	5/94	FEMRCO	Passed / Approved & Contracted	Annual	
Twin City Testing 1908 Innerbelt Business Center St. Louis, MO 63114-5700	B, C, D	Yes	Chemical	9/93 - 9/94	9/93	FERMCO	Passed / Approved & Contracted	Annual	

\* Supplier Quality Information Group (SQIG) is a joint committee of DOE sites Quality Assurance personnel which share audit information on various suppliers including contract laboratories.

Report

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**ENCLOSURE 2**

**FERNALD ENVIRONMENTAL MANAGEMENT PROJECT**

**APPROVED LABORATORY LIST**

Lab Name	Service	Contract	CLP	ASL	Period of Performance	Approval Status	Auditing Organization	Date of Last Audit	Date of Next Audit	Responsible FEM Management Organization	FEM Contact
Accutabs Research 4643 Table Mountain Drive Golden, CO 80403-1650 303-277-9514 POC: Bud Summers	Radiological	Rad-BOA	N/A	B,C,D	11/95-11/96	Approved/Contracted	FDF	9/96	9/97	SPO	Keith Tomlinson
		REN	N/A	B,C,D	10/96-10/96	Approved/Contracted	FDF	9/96	9/97	SPO	Keith Tomlinson
Advanced Terra Testing 833 Parfet Street, Unit A Lakewood, CO 80215 POC: Chris Mlanocke	Geotechnical	Geotechnical	N/A	N/A	10/96-9/97	Approved/Contracted through Parsons	FDF	2/96	6/97	Engineering	Steve Garland
CompChem 3306 Chapel Hill/Nelson Pkwy. Research Triangle Park, NC 27709-4998 POC:	Chemical	Chem-BOA	Y	B,C,D	10/96-10/96	Not Approved/ Not Contracted (No Rad License)	FDF	3/96	N/A		
Detech Laboratories 4300 Glendale-Milford Road Cincinnati, OH 45242-3607 613-733-6336 POC:	Asbestos	Asbestos	N/A	B	11/96-11/97	Approved/Contracted	FDF	10/96	9/97	SPO	Jenny Vance
DataChem Laboratories 960 West Levey Drive Salt Lake City, UT 84123 801-266-7700 POC: Jim Johnston	Industrial Hygiene	Industrial Hygiene	N/A	B	11/96-11/97	Approved/Contracted	FDF	6/96	6/97	SPO	Jenny Vance
	Chemical	Chem-BOA	Y	B,C,D	11/96-11/97	Approved/Contracted	FDF	6/96	6/97	SPO	Larry Evans
	Radiological	Rad-BOA	N/A	B,C,D	11/96-11/97	Approved/Contracted	FDF	6/96	6/97	SPO	Keith Tomlinson
Environmental Physics, Inc. PO Box 30712 Charleston, SC 29417 803-766-1170 POC: James Mastmoreland	Radiological	Rad-BOA	N/A	B,C,D	11/95-11/96	Approved/Contracted	FDF	8/96	8/97	SPO	Keith Tomlinson
	Radiological	REN	N/A	B,C,D	11/96-11/97	Approved/Contracted	FDF	8/96	8/97	SPO	Keith Tomlinson
FW Analytical Laboratory Services	Chemical, Radiological	N/A	Y	B,C,D	N/A	Approved	FDF	2/97	2/98	ALS	Amy Mayer
FW WPP	Chemical, Radiological	N/A	N/A	B	N/A	Approved	FDF	10/96	9/97	WTP	Ev Henry
Lockheed Martin 975 Kelley Drive Las Vegas, NV 89119-3706 702-361-3956 POC: Mary Ford	Chemical	Chem-BOA	Y	B,C,D	11/96-11/96	Approved/ Not Contracted	FDF	N/A	N/A		
	Radiological	RSL-TOS	N/A	B,C,D	11/95-11/96	Approved/ Not Contracted	FDF	9/96	N/A		
General Engineering Laboratory 2040 Storage Road Charleston, SC 29417 803-686-8171 POC: Nancy Slater	Chemical	Chem-BOA	Y	B,C,D	11/96-11/97	Approved/Contracted	FDF	8/96	8/97	SPO	Larry Evans
Quality Labs Pineville, KY POC:	Geochemical	Purchase Order	N/A	B	12/94-12/96	Approved/ Not Contracted	FDF	12/94	N/A		
Ray F. Macken 208 Walsh Pool Creek Lionsville, PA 19341 610-701-6100 POC: Mary Stone	Chemical	Chem-BOA	Y	B,C,D	11/96-11/97	Approved/Contracted	FDF	8/96	8/97	SPO	Larry Evans
Ranta 1908 Innersbelt Business Center St. Louis, MO 63114-5700 314-426-0880 POC: Paul Smith	Chemical	RCRA/CECCLA	Y	B,C,D	10/96-10/96	Approved/ Contract Expired	FDF	7/96	N/A		
	Chemical	Chem-BOA	Y	B,C,D	11/96-11/97	Approved/Contracted	FDF	7/96	7/97	SPO	Larry Evans

Fernald Environmental Management Project Approved Laboratory List

Lab Name	Service	Contract	CLP	ARL	Period of Performance	Approval Status	Auditing Organization	Date of Last Audit	Date of Next Audit	Responsible FDF Management Organization	FDF Contact
Pace 5390 McIntyre Street Golden, CO 80403 POC:	Chemical	Chem-BOA	Y	B,C,D	11/95-11/96	Approved/ Not Contracted	FDF	N/A	N/A		
Thomas Blitch 7021 Pan American Highway NE Albuquerque, NM 87109 505-345-3461 POC: Ernie Sanchez	Radiological	Rad-BOA	N/A	B,C,D	11/95-11/96	Approved/Contracted	FDF	10/96	11/97	SPO	Kath Tomlinson
Geosyntec Consultants Geomechanics and Environmental Laboratory (GEL) 5775 Peachtree Dunwoody Road, Ste. 100 Atlanta, GA 30342 POC: Robert N. Swan, Jr.	Geotechnical	Geotechnical	N/A	BE	8/95-11/97	Approved/Contracted	FDF	3/97	3/98	Soils Remediation Project	Steve Garland
Geosyntec Consultants Geomechanics and Environmental Laboratory (GEL) 5775 Peachtree Dunwoody Road, Ste. 100 Atlanta, GA 30342 POC: Rader S. Rod, Ph.D., P.E.	Geotechnical	Geotechnical	N/A	BE	8/95-11/97	Approved/Contracted	FDF	3/97	3/98	Soils Remediation Project	Steve Garland
Geosyntec Consultants Materials Testing Laboratory (MTL) Boca Raton, FL POC: Richard Charron	Geotechnical	Geotechnical	N/A	BE	8/95-11/97	Approved/Contracted	FDF	3/97	3/98	Soils Remediation Project	Steve Garland
QuintCurve 13716 Rider Trail North Earth City, MO 63045 314-298-0566 POC: Diane Mueller or Robert White	Chemical	Chem-BOA	Y	B,C,D	11/96-11/97	Approved/Contracted	FDF	8/96	8/97	SPO	Larry Evans
IEA, Inc. 3000 Weston Parkway Cary, NC 27513 919-677-0090 POC: Lisa G. Hill	Radiological	Rad-BOA	N/A	B,C,D	11/96-11/97	Partial Approval/ Contracted	FDF	N/A	TBD	SPO	Kath Tomlinson

Key to Acronyms:

- Chem-BOA = Chemical Analysis Laboratory Services - Basic Ordering Agreement
- DOE = Department of Energy
- EPA = Environmental Protection Agency
- FDF = Fluor Daniel Fernald
- IM = Industrial Hygiene
- NA = Not Applicable
- NPDES = National Pollutant Discharge Elimination System
- OEPA = Ohio Environmental Protection Agency
- Rad-BOA = Radioanalytical Laboratory Services - Basic Ordering Agreement
- RCRA/CERCLA = Resource Conservation and Recovery Act/Comprehensive Environmental Response, Compensation and Liability Act Subcontract
- REM = Radiological Environmental Monitoring
- SPO = Sampling Projects Operations
- TBD = To Be Determined (when use is needed)

0026

APPROVED:   
A.R. Duarte, Lead  
Sampling Projects Operations

APPROVED:   
William D. Kelley, QA Engineer  
Remediation Data Quality

**ENCLOSURE 3**

**ANNUAL AUDIT REPORTS FOR  
ON-SITE LABORATORY (1995-1997)**



**INTEROFFICE MEMORANDUM**

**To:** Roy Cohen, MS52-2  
Chris Sutton MS35

**Date:** March 14, 1995

---

**Location:** Various

**Reference:**

**From:** Stephen J. Reutcke

**FERMCO #:** M:PQA:(PA):95-0063

**Location:** MS81-3

**Client:** DOE DE-AC24-92OR21972

**Extension:** 648-6165

**Subject:** **Audit Report I95-10,  
Analytical Laboratory  
Services (ALS) & Data  
Validation Activities**

- c: File Record Storage Copy 106.4.4.5
- V. Daino, DOE/FN, MS45
  - D. J. Eddy, MS81-1
  - M. A. Forrest, MS81
  - S. L. Hinnefeld, MS31
  - S. K. Kaster, DOE/FN, MS45
  - R. E. Kline, MS81-1
  - L. A. Manning (Halliburton NUS)
  - D. W. Hoover, MS43
  - D. S. Madsen, MS35
  - G. P. Ruesink, MS52-2
  - E. B. Spencer, MS73
  - J. F. Weissenberg, MS 81
  - DR File 94-176
  - Audit File I95-10

This letter transmits the subject audit report I95-10 for the audit conducted during the period from February 28, through March 2, 1995. The results of the audit were discussed in detail with ALS and DVA Management at the audit close-out meeting held on March 2, 1995 in laboratory conference room 189.

The audit activities and subsequent "findings" and "observations" impact three different areas of responsibility at FERMCO (ALS, DVA, and S&H). Therefore, the "findings" and "observations" are listed on three attachments, one for each responsible area. Management needs to evaluate all "findings" and "observations" associated within their respective areas of responsibility.

ALS, DVA, and S&H Management are requested to provide responses for the individual "findings" and "observations", as listed in the respective attachments. Responses need to be structured to provide information as directed in the "Audit Response Requirements" section in the attached audit report (Page 3), within the time specified.



**INTEROFFICE MEMORANDUM**

FERMCO No. M:POA:(PA):95-0063  
March 14, 1995  
Page 2

The Audit Team want to again thank you and your staff for their cooperation and contributions during completion of the audit and follow-up activities.

*Stephen J. Reytcke 3/20/95*  
Stephen J. Reytcke, Manager  
Performance Assurance

SJR: DWH: amp  
Attachment

QUALITY ASSURANCE INTERNAL AUDIT I95-10  
FERMCO ANALYTICAL LABORATORY SERVICES (ALS)  
AND  
DATA VALIDATION ACTIVITIES (DVA)

DATE OF AUDIT: February 28, 1995 through March 2, 1995  
DATE OF REPORT: March 7, 1995  
AUDIT LOCATION: FERMCO Work Activity Areas

AUDIT TEAM MEMBERS & ASSIGNMENTS: D. W. Hoover (LA), QA Program & Mgmt. Systems  
M. A. Forrest (A), S&H, CHP, & Waste Mgmt.  
G. P. Ruesink (A), Organic & Inorganic Laboratories and Data Validation Activities  
L. A. Manning (A), Radiochemical Laboratory  
E. B. Spencer (A), Sample & Data Management  
LA=Lead Auditor.....A=Auditor

PURPOSE OF AUDIT: To assess the effectiveness of FERMCO's Quality and Management Systems for providing Analytical Laboratory Services (ALS) and conducting Data Validation Activities (DVAs) associated with providing analytical data and data packages, as required to support on-going projects at the FEMP. The state of implementation for the stated program requirements was an integral part of the audit activities. Since the majority of analytical data being produced is subject to legal scrutiny, FERMCO is required to conduct evaluations to assure that analytical processes and data reports produced are scientifically valid and legally defensible.

AUDIT SCOPE: Analyses required to support the on-going projects at the FEMP are subject to all four different Analytical Support Levels (ASL) B, C, D, and E, as defined in the FERMCO SCQ (Document FD-1000). ASLs are specified on FERMCO's analytical requests for analysis/chain-of-custody documents for each set of samples submitted.

Verify that FERMCO ALS and DV Departments have developed program control documents, as required, to effectively implement the requirements specified in FERMCO's Quality Assurance Plan (Document RM-0012) and FERMCO's Sitewide CERCLA Quality Assurance Project Plan (SCQ, Document FD-1000). Verify that activities are performed in accordance with the requirements identified.

In addition, status of corrective action implementation, associated with FERMCO audits I94-04 and I94-06 were evaluated.

AUDIT CONCLUSIONS: FERMCO ALS and DV Departments have developed and implemented Management Systems, as required, to effectively support analytical data at ASL B for organic, inorganic, and radiochemical analyses. ASLs are defined in FERMCO's SCQ (Document FD-1000, Section 2, Item 2.3.3). Previous FERMCO QA Audits I94-04 and I94-06 are closed. In addition, DR-94-176 IS CLOSED, based on evaluation information detailed in Attachment 1, Audit Observation AO-95-0024.

QA AUDIT I95-10  
FERMCO ALS & DV ACTIVITIES

**CONDUCT OF AUDIT:** An Audit Plan was prepared and issued to the ALS and DV Departments on February 1, 1995. Auditors, ALS, and DV representatives participated in the opening meeting held at 9:00 AM, February 28, 1995 in Analytical Lab Room 189. Since the original auditor assignments included two people from the Halliburton NUS Laboratory in Pittsburgh, a brief "auditors only" meeting was held following the opening meeting. This meeting was used to distribute auditor checklists and to reassign auditor areas of responsibility necessitated by a change of schedule for two of the originally assigned auditors (Dave Yesso and Melvin Boyd).

Interviews/discussions were conducted with various ALS and DV Department personnel and managers. Program Plans, Procedures, and Record Files were reviewed and various operations/activities were observed, including but not limited to: Health & Safety Practices, Chemical Hygiene Plan implementation, QA & Management Systems, Sample Processing activities, Organic-Inorganic-Radiochemical Laboratory operations, and Laboratory Data Management, Data Validation, and Waste Management activities. Copies of program control documents were provided to the audit team for evaluation on a very timely basis, when requested by audit team members.

Forty-eight people from the various departments or groups, as identified below, attended meetings or were interviewed during conduct of audit activities. (Indicates Attendance at \*Opening/\*\*Closing Meetings).

- ALS Management & Facilities Administration (11) - Chris Sutton\*/\*\*, Michele Miller\*/\*\*, Nelson Weichold, Kathie Fisher, Debbie Reichard, Ellen Hansmann, Lisa Leick, Denise Arico, Wanda Burke, Angela Dees, and May Blanton.
- Sample Processing/Data Management (10) - Alex Duarte\*/\*\*, Donna Baker\*/\*\*, Mike Rolfes\*/\*\*, Jenny Vance\*/\*\*, Gordon Bell, Mark Cornell, Paul McSwigen, Doug Stark, Joel Wright, and Deanna Smith.
- Radiological & Isotopic Analyses (9) - Ray Danahy\*/\*\*, Harold Humphrey\*/\*\*, Carl Bishop\*/\*\*, Bob Hellman\*/\*\*, Al Bacon, Virgil Lacy, Tim Dall, Mark Stewart, and Larry Herrick.
- Organic/Inorganic Analyses (8) - Amy Meyer\*/\*\*, John Gillespie, John Reilman, Barry Beegle, Ervin O'Bryan, Angela Brown, Alan Davis, and Debbie Brennan.
- Data Validation (8) - Dan Benedikt\*/\*\*, Sharon Blake, Jim Cross, Jim Chambers, Roy Cohen, Rao Paturi, Marcia Wiltz, and Holly Bradley.
- QA/QC (2) Steve Reutcke\*/\*\* and Bill Kelley \*/\*\*. Bill Kelley was interviewed during the audit concerning PE sample programs.

QA AUDIT I95-10  
FERMCO ALS & DV ACTIVITIES

DUCT OF  
AUDIT:

Cont'd  
The audit close-out meeting was conducted at 3:00 PM, 03/02/95 in ALS Room 189. A draft copy of the "findings" and "observations" identified during audit activities were provided to Laboratory Management after the close-out meeting.

AUDIT  
RESPONSE

The audit activities and subsequent "findings" and "observations" impact three different areas of  
REQUIREMENTS: responsibility at FERMCO (ALS, DVA, and S&H).  
Therefore, the "findings" and "observations" are listed on three attachments, one for each responsible area. Management needs to evaluate all "findings" and "observations" associated within their respective areas of responsibility.

Corrective action responses for each individual "finding" listed in the attachments need to include actions taken to identify: 1.) a root cause; 2.) all completed work affecting the "finding" and an evaluation to assure that similar problems do not exist in other work areas; 3.) corrective actions that have been, or will be taken, to correct the problem and prevent recurrence; 4.) the person assigned responsibility for implementing corrective actions; and 5.) a schedule date when corrective actions will be completed.

"Observations" listed in the attachments need to be evaluated by the appropriate management personnel. A response is required for each individual "observation" as shown above or, as a minimum, provide a description of the evaluation process and a conclusion statement.

AUDIT DETAILS:

The following audit evaluation details are structured so that they directly correlate to the criteria and requirements, as outlined in FERMCO's QAPD, Document RM-0012.

1. PROGRAM

The ALS and DV Departments are organized in a manner that effectively supports FERMCO's quality program requirements. Policy statements, endorsed by FERMCO and ALS Management, are prominent in all three Quality Assurance Program documents associated with providing analytical processes and data validation. They are: 1) FERMCO Site Document RM-0012, "Everybody's Quality Assurance Program Description", 2) FERMCO Site Document FD-1000, "Sitewide CERCLA Quality Assurance Project Plan (SCQ)", and 3) CIO AC94-0109, "Analytical Laboratory Services Quality Assurance Management Plan. The ALS QAMP, Item 1.2 and 1.3, deals with generation of scientifically valid and legally defensible data, produced with a high degree of ethical principles.

QA AUDIT I95-10  
FERMCO ALS & DV ACTIVITIES

PROGRAM - Cont'd

Program Control Documents (including Quality Assurance Plans and Procedure Documents) show a strong commitment to quality and ethical conduct throughout laboratory operations and data validation. The Satellite Accumulation Area was neat and orderly and requirements for maintenance of the SAA were effectively implemented.

The Radiation Safety Program was developed and is implemented by the Radiation Safety Department within the Safety and Health Division. The program implemented is consistent with the requirements, as identified in the SCQ (Section 1, Item 1.2)

ALS's Chemical Hygiene Plan (CHP) was reviewed and judged as meeting the basic requirements specified in OSHA 29 CFR 1910.1450. The CHP was reviewed and updated by ALS's Chemical Hygiene committee in January, 1995. CHP requirements, in general, appear to be effectively implemented. Considerable improvement was noted in CHP implementation since the last audit.

Four Audit Observations (AO-95-0001 through AO-95-0004), associated with "QA Program & Management Systems", are identified and detailed in Attachment 1 and 3.

2. PERSONNEL TRAINING AND QUALIFICATION

ALS's required quality levels for work are detailed in job descriptions showing minimum education and training requirements for each position. Program controls have been implemented to assure analyst proficiency in performing specific methods and/or procedures is documented and methods training is traceable to work being performed. Technical or analytical operations managers are responsible for implementing, approving, and verifying that employees are adequately trained. Safety training records are documented in subject matter files and were found to meet the basic requirements, as specified in OSHA 29 CFR 1910.1450 and OSHA 29 CFR 1910.120.

One Audit Finding (AF-95-0001) and one Audit Observation (AO-95-0005), associated with "Personnel Training and Qualification", are identified and detailed in Attachments 1 and 2.

3. QUALITY IMPROVEMENT

ALS and DV programs include provisions that make every employee responsible for quality improvement. Provisions for identifying areas for improvement are included in self-appraisals (QC or PE samples), internal self-assessments, internal QA audits, and external audits. Responsibilities are assigned for establishing and implementing processes to detect, control, correct, and prevent quality problems and to promote quality improvement. Considerable improvement was noted for this Criteria since the last audit.

QA AUDIT I95-10  
FERMCO ALS & DV ACTIVITIES

QUALITY IMPROVEMENT - Cont'd

Four Audit Observation (AO-95-0006 through AO-95-0009), associated with "Quality Improvement", are identified and detailed in Attachment 1.

4. DOCUMENTS AND RECORDS

ALS and DV Program Documents provide systematic methods for controlling preparation, issuance, use, and revision of program control documents. Individual responsibilities are assigned to confirm that correct issues of documents are distributed to controlled copy holders.

In general, records that furnish documentary evidence of quality are specified, prepared, maintained, and protected against damage, deterioration, or loss.

Employees are encouraged to report all work related injuries and the appropriate document files are maintained by the Health & Safety Division.

Five Audit Findings (AF-95-0002 through AF-95-0006) and seven Audit Observations (AO-95-0010 through AO-95-0016), associated with "Documents and Records", are identified and detailed in Attachments 1 and 2.

5. WORK PROCESSES

In general, ALS and DV have prepared and implemented program control documents, as required, to assure that work is performed under controlled conditions using technical standards, instructions, procedures or other appropriate means of detail commensurate with the complexity and risk of the work. Maintenance and calibration programs for analytical instrumentation are documented and were found to be in compliance with program requirements, with the exceptions noted.

The Sample Processing Laboratory (SPL) is to be especially commended for their ability to organize, distribute, and track sample and sample analyses reports for up to 600 samples/week sent to the various on-site and off-site laboratories.

Three Audit Findings (AF-95-0007 through AF-95-0009) and two Audit Observations (AO-95-0017 and AO-95-0018), associated with "Work Processes", are identified and detailed in Attachments 1 and 2.

6. DESIGN

The FERMCO ALS laboratory design provides for separation of relatively "dirty" operations (e.g. sample receiving, sample

QA AUDIT I95-10  
FERMCO ALS & DV ACTIVITIES

DESIGN - Cont'd

preparation, and glassware washing) from "clean" analysis operations. Fume hoods, purified water, instrument air and gases, computer equipment, and an abundance of bench space is available at analyst work stations.

Program controls used to assure that data collection systems, computer programs, and software control/security is the subject of a special audit. Audit I95-03, scheduled to be conducted in mid-March-1995 will evaluate these processes.

Two Audit Observations (AO-95-0019 and AO-95-0020), associated with "Design", are identified and detailed in Attachment 1.

7. PROCUREMENT

FERMCO ALS have developed and implemented program controls, as required, to effectively control purchased materials and services. Program controls include assignment of responsibility for post-purchasing control of materials, equipment, and services.

8. INSPECTION AND ACCEPTANCE TESTING

In general, FERMCO ALS have developed and implemented program controls, as required, for performing inspections and tests to assure that analytical systems are effectively functioning. Acceptance tests and performance criteria are required during instrument calibration processes. Laboratory instrument/equipment calibration and maintenance activity are documented in log books maintained for each instrument.

Analytical data generated in the laboratory is assessed before it is reported to ensure that the data satisfies customer requirements. Data assessed include accuracy (bias), precision, completeness, representiveness, and comparability.

Three Audit Findings (AF-95-0010 through AF-95-0012) and three Audit Observations (AO-95-0021 and AO-95-0023), associated with "Inspection and Acceptance Testing", are identified and detailed in Attachment 1.

9. MANAGEMENT ASSESSMENT

ALS and DV employees are encouraged to continuously assess and improve analytical processes/procedures, with proper authorization. A relatively new self-assessment program was implemented with the first assessment conducted in August, 1994. Laboratory group managers are responsible for resolving items identified during the assessment program.

QA AUDIT I95-10  
FERMCO ALS & DV ACTIVITIES

9. MANAGEMENT ASSESSMENT - Cont'd

Performance evaluation and quality control sample results are provided to and reviewed by the ALS manager and other responsible laboratory managers.

One Audit Finding (AF-95-0013), associated with "Management Assessment", is identified and detailed in Attachment 1.

10. INDEPENDENT ASSESSMENT

The FERMCO Quality Assurance (QA) Division schedules and conducts internal audits and surveillances, on an on-going basis. Although somewhat infrequent, ALS have been subjected to audits from external sources (DOE, USEPA, etc.). Items identified during the internal QA or external audit/surveillance processes are tracked to closure by both QA and ALS management.

One Audit Observation (AO-95-0024), associated with "Independent Assessment", is identified that resulted in the closure of an open deviation report (DR-176) as detailed in Attachment 1.

*Donald Hoover*

Donald Hoover, Lead Auditor  
FERMCO QA Consultant

*Signature available in audit file.*

Mary Ann Forrest, Auditor  
FERMCO QA, Project Management

*Signature available in audit file.*

Lisa Manning, Auditor  
Halliburton NUS Labs

*Grace Ruesink*

Grace Ruesink, Auditor  
FERMCO QA, Quality Systems

*EB Spencer*

Bonnie Spencer, Auditor  
FERMCO QA, Quality Certification

**ATTACHMENT 1**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT FINDINGS**  
**ANALYTICAL-LABORATORY SERVICES (ALS) "AREA OF RESPONSIBILITY"**

● ● ●

AF-95-0002 Program Control Documents (Administrative and Methods SOPS) are not being issued in a timely manner. A list showing program control documents (new issues and changes) that are currently "in process" for change/issue was provided by ALS, Department Quality & Procedure Development. A cursory review of the listing shows that 13 requests (3 new issues and 10 changes) submitted during CY-1993 have not, as yet, been issued. The issue/change process needs to be more responsive to assure that activities are in compliance with program requirements. Net

**Requirement:** The FERMCO QAPD, Document RM-0012 (Item 4.2.3), specifies that: "Timeliness guidelines shall be implemented for distribution of new or revised controlled documents."

● ● ●

AF-95-0003 There is no chain-of-custody record that documents the transfer of digestates from the radiological sample preparation area to the isotopic analysis area. Transfer of custody records of digestate samples needs to be routinely documented. Q-1

**Requirement:** FERMCO SCQ, Document FD-1000 (Item 7.2.1.1.8), specifies that: "Each laboratory must follow its established system for assure that sample custody is documented for all movements of both the sample and its extracts/digestates."

● ● ●

AF-95-0004 Logbook #95-007 for Sample Preparation is not bound nor are the pages consecutively numbered. Also, sign off sheets within the log were incomplete. 7

**Requirement:** The ALS QAMP, Document CIO AC94-0109, Item 13.3.1. specifies that: "All logbooks are controlled documents and shall be bound, assigned a control number and have sequentially numbered pages."

● ● ●

AF-95-0005 Thorium purifications are being performed from a draft revision to ALS SOP 256-S-2003. R-

**Requirement:** The FERMCO SCQ, Document FD-1000 (Item 4.4.3), includes requirements for providing and revision of controlled documents. The FERMCO QAPD, Document RM-0012 (Item 4.2.3) specifies that: "FERMCO shall ensure controlled documents are distributed to and used by personnel performing work."

● ● ●

AF-95-0006 Error correction has shown some improvement during the past year, however write-overs, obliterations, and undated corrections were present in most logs maintained in the radiochemistry lab. Notes in Logbook 4378 were not initialed and dated. 7

ATTACHMENT 1  
 FERMCO INTERNAL AUDIT I95-10 - AUDIT FINDINGS  
ANALYTICAL LABORATORY SERVICES (ALS) "AREA OF RESPONSIBILITY"

F-95-0006 Cont'd

**Requirement:** The FERMCO SCQ (Document FD-1000), Item 4.4.2.1, second paragraph, states: "corrections [to records] shall be made by drawing a single line through the incorrect information on hard copies, making the correct entry, and initialing and dating the revised entry."

● ● ●

AF-95-0007 ALS SOP 256-S-3015 (Radiometric Rapid Screening Method For Determination Of Alpha And Beta Activity In Various Matrices) does not include a correction for self absorption and sets the maximum solid on the planchet at 50 mg. However, the analyst uses 100 mg as a maximum. The self absorption correction factor for alpha radiation, which is not applied to the rapid screen results, increases from 1.5 at 50 mg solids to 2.5 at 100 mg solids. The 50 mg maximum needs to be enforced or a correction for self absorption needs to be included in the procedure and applied during screening.

**Requirement:** ALS SOP 256-S-3015, Items 7.9 and 7.10, outlines the procedural steps involving the different sample sizes.

● ● ●

AF-95-0008 Temperature recordings for ambient temperatures in the counting room have varied from 63 to 90 degrees F over the past several months. The counting equipment is sensitive to temperature swings.

**Requirement:** The FERMCO QAPD, Document RM-0012 (Items 5.1 & 5.2) specifies that controls include: "controls which influence critical parameters of facility operations.....shall be accomplished under controlled conditions."

● ● ●

AF-95-0010 Samples are normally received in the SPL with a pH strip attached to the sample container when preservation is required. The pH strip is often lost or damaged in transit. The pH of radiochemistry, VOA and metals samples are not verified and documented at the analyst level.

**Requirement:** ALS CIO AC94-0109, item 9.3.1 states: ".....the analyst shall inspect and verify the material type and condition and confirm need for and identification of analysis." of samples upon receipt" and the FERMCO SCQ, Document FD-1000 (Item 12.4.3.1) specifies that laboratories shall have: ".....a routine that ensures compliance with preservation requirements."

● ● ●

**ATTACHMENT 1**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT FINDINGS**  
**ANALYTICAL LABORATORY SERVICES (ALS) "AREA OF RESPONSIBILITY"**

AF-95-0011      Reagents, standards (stock and intermediate), tracer spike materials, and QC sample materials are not being prepared and/or preparation is not adequately identified or documented for traceability purposes, as identified below:

- a. Reagents and standards in the thorium purification laboratory are not assigned unique identification numbers.
- b. Standard 209-93-84 showed an expiration date of 09/27/94, but the standard is still being used in the thorium purification laboratory.
- c. Stock and intermediate radiochemical standard solutions are used, indefinitely, until exhausted. Evaporative losses can occur that would render the standard inaccurate. Expiration dates need to be identified with the option to re-verify or dispose of the solution when expired. Criteria applied to re-verification of old versus new radiochemical working standards needs to be included in SOP documents for reference and consistency purposes.
- d. Reagent and standards logbooks are not reviewed on a quarterly basis by supervisory personnel.
- e. NIST traceability is not documented in the logbook for tracer spike and QC sample materials used in thorium purification. At the minimum, the solution ID number and mass or volume used needs to be documented.

**Requirement:** ALS SOP 257-D-0015, Items 8.5.3.2, 8.6, 8.2.11, 8.5.10, and 8.5.2, respectively. In addition, the FERMCO SCQ, Document FD-1000 (Appendix B, Form D-10, Item 5.1.4) shows: "A NIST or NIST-traceable, or equivalent agency standard material is used as an internal tracer for each sample analysis".

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AF-95-0012      The ALS preventive maintenance and calibration programs are not adequate. A more pro-active approach needs to be taken by developing a system that prompts and monitors the preventive maintenance and calibration activities on a routine basis. A number of non-compliance issues were identified during the audit and include:

- a. The calibration tag on a large scale 15-X268-SCH was noted to be out-of-date and the equipment was not tagged as being out-of-service. Documentation was located that showed that the scale was calibrated, as required by Scale Maintenance SOP 52-S-1000, but the calibration tag was not replaced.
- b. GPC-1 was out-of-service and out-of-calibration, but was not tagged as such. After being noticed during the audit, the unit was tagged, thus closing this item.
- c. The calibration frequency written on the gamma spectrometer calibration stickers were not in agreement with the calibration program requirements. The sticker for unit 4 was corrected as a result of this audit; the others were not corrected.

**ATTACHMENT 1**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT FINDINGS AND AUDIT OBSERVATIONS**  
**ANALYTICAL LABORATORY SERVICES (ALS) "AREA OF RESPONSIBILITY"**

AF-95-0012      Cont'd.

- d. Monthly preventive maintenance activities for the alpha spectrometers were not recorded in the maintenance log.
- e. Thermometers and thermocouples in the radiochemistry lab were not calibrated.
- f. Run logs are not maintained to document calibration activities for the metals laboratory. Run logs need to be maintained to demonstrate that calibrations have been performed and that corrective actions are systematically documented.
- g. A preventive maintenance schedule and/or program is not documented for isotopic, methanol, or TOX/TOC analysis. A programmatic system needs to be developed and implemented to address these activities.

**Requirement:** The FERMCO SCQ, Document FD-1000 (Items 8.4.1 and 13.2), FERMCO QAPD, Document RM-0012 (Item 5.2), and ALS CIO AC94-0109 (Items 5.2 and 6.0) establishes requirements for preventive maintenance and calibration programs and ALS SOP 257-D-008 address tag-out of instruments/equipment.

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AF-95-0013      Self Assessments are performed in accordance with CIO AC94-0109, Item 13.4. DRs and CARs resulting from QA audits, NCs for the sample/analysis processes, and items noted on safety inspection reports are tracked to closure by AFA but they do not track "deviations" identified during self assessments. Cg

**Requirement:** CIO AC94-0109, Item 13.5.1 specifies that: "AFA shall track assessment/audit findings and assure resolution in accordance with Site Procedures, as applicable".

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**FERMCO INTERNAL AUDIT I95-10 - AUDIT OBSERVATIONS**

AO-95-0001      Staffing & Resources... FERMCO is currently undergoing a "Voluntary - Reduction In Force" (V-RIF) action. The full impact of the V-RIF process will not be realized until after April, 1995, but it will, without doubt, have a negative impact on ALS activities. The full extent of activities that will be affected by the V-RIF cannot be evaluated at this time. Reference FERMCO QAPD, Document RM-0012 (Management Policy). Cg

AO-95-0002      The roof leaks in many of the laboratory areas. In addition to being a safety concern (wet-slippery floors), the leaks could present a sample contamination problem. Housekeeping practices need to be improved in the following areas, as identified during audit activities: a.) Rooms C35 and C43 were especially dirty and were noted to have paint flaking from ceilings and walls; b.) Hoods were cluttered in Room 169; c.) Aisle was partially blocked in Cg

**ATTACHMENT 1**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT OBSERVATIONS**

AO-95-0002      Cont'd

Room 207; d.) A cart was blocking the control panel in Room 169, violating the 36" clearance OSHA Safety requirement; and e.) Radiological survey bulletin boards, located throughout the laboratory, did not have survey information posted and are not being used for their intended purpose. Reference FERMCO QAPD, Document RM-0012 (Item 1.3.3 and 1.4.14).

AO-95-0003      Requirements identified in ALS's Chemical Hygiene Plan (CHP), in most areas, were in compliance with 29 CFR 1910.1450. Emergency equipment was available in work areas and personnel were aware of the location of the equipment and requirements of the CHP. The following "observations" were noted. Reference FERMCO QAPD, Document RM-0012 (Item 1.3.3).

- a. Three hoods have been tagged out for approximately one year (1-206, 1-220, and 1-204).
- b. Hood 209C in Room 209 is alarming.
- c. Three items were noted in Room C43 (high level uranium processing area): 1.) there is a safety show but no water; 2.) there is no safety eyewash station; and 3.) there is no heat.
- d. The elevator at northwest end of the new north addition to the building is not operable. The elevator is needed for movement of heavy materials/equipment.
- e. The distilled water system in Room 206 is not working.
- f. Deionized water is not readily available in all laboratories.
- g. Conductivity meters are not calibrated nor used in Radioanalytical Laboratories.
- h. The emergency number label is not posted on the phone in Room 207.

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AO-95-0005      Unacceptable interlaboratory comparison study and QC/performance sample results are not formally investigated. Laboratory management are notified of the outliers, as reported, but they are not tracked to closure. Reference FERMCO QAPD, Document RM-0012, (Item 2.2.6).

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AO-95-0006      The "Continuous Improvement" concept needs to be "promoted" in Sections 8 & 9 of CIO AC94-0109, Analytical Laboratory Services Quality Assurance Management Plan. "Continuous Improvement is not specifically mentioned in the identified areas of the CIO. Document RM-0012, FERMCO's Quality Assurance Program, Pages 14-18, shows a "strong" commitment to "continuous improvement" activities/processes. From information obtained during audit interviews, apparently the CIO is being re-structured into a format comparable to RM-0012. This should provide assurance that requirements of RM-0012 are addressed in the ALS document. Reference FERMCO QAPD, Document RM-0012 (Item 3.0).

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**ATTACHMENT 1**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT OBSERVATIONS**

AO-95-0007      The ALS QAMP, Document AC94-0109, Item 8.4.4.1, first and last sentences, as presented, contradict each other. The first sentence should relate that: a) trip blanks consist of deionized distilled water prepared by QA/QC in the analytical laboratory; and b) trip blanks prepared by sample teams are prepared elsewhere. C

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AO-95-0008      Efficiency and background checks for the gas proportional counters are not translated into control chart formats for evaluation. Reference FERMCO QAPD, Document RM-0012 (Item 3.2.2). R

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AO-95-0009      Two "observations" associated with water purity within the laboratory areas were identified. Reference ALS QAMP, Document CIO AC94-0109 (Item 4.1.2) and FERMCO QAPD, Document RM-0012 (Item 3.2.3).

- a. The quality of reagent water in the radiochemistry lab is monitored on an after-the-fact basis through method blanks. R
- b. The water source in the TOC/TOX laboratory is not checked for conductivity. Since the TOC/TOX laboratory analyzes for constituents that cannot be monitored by conductivity, monitoring is not necessary for their operations. The problem is that other groups periodically obtain supposedly pure water from the TOC/TOX laboratory. N

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AO-95-0010      Refrigerator logs in the GC/MS VOA area were incomplete. Column headings were not identified and recent entries were either incomplete or missing. Logbook functions need to be clearly identified and column headings for documenting logbook entries need to be consistently identified. In addition, to ensure proper operation of refrigerators, daily monitoring must be performed on a routine basis. Reference FERMCO QAPD, Document RM-0012, Item 4.2.6. A

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AO-95-0011      ALS program control documents do not identify "who" is responsible for maintenance of working or historical files nor do they specify retention requirements. Reference ALS QAMP, Document CIO AC94-0109 (Items 3.7.2 and 10.2.1), identify documents created and controlled by ALS and Item 3.7.2 specifies that the records are maintained in accordance with DOE Order 1324.2A. DOE

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AO-95-0012      Supervisory review and approval of sample preparation and analysis logbooks in the radiochemistry laboratory are performed and documented on an infrequent basis (monthly to quarterly). Several instances of "no review" were noted in the organics and metals areas. This is not good laboratory practice. Reference FERMCO QAPD, Document RM-0012 (Item 4.2.6). R

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**ATTACHMENT 1**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT OBSERVATIONS**

AO-95-0013      The Satellite Accumulation Area (SAA) work station contained an out-dated copy (Revision 2) of SSOP-0035. The latest revision (Revision 3) was issued on October 18, 1994. ALS needs to make sure responsibilities are assigned and that work stations are routinely monitored to assure that the most current issues of SOPs are readily available at the user level. Reference FERMCO QAPD, Document RM-0012 (Item 4.2.3). N

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AO-95-0014      Procedures that describe Sample Management work activities associated with the FACTS system appear to be unnecessarily fragmented. Procedures appear to need review and compilation/reorganization. Reference FERMCO QAPD, Document RM-0012 (Item 4.2.1). A

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AO-95-0017      Corrective actions are not routinely noted in VOA run logs. Corrective actions need to be documented to identify reasoning for reanalysis, etc. Reference ALS QAMP, Document AC94-0109 (Item 9.6.1). H

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AO-95-0018      Only the last five digits of the FACTS sample identification number are recorded in the alpha spectrometry run log book. This practice does not provide for unique sample traceability in the identified log book. Reference FERMCO QAPD, Document RM-0012 (Item 5.4.9). O

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AO-95-0019      Three "observations" were identified associated with spreadsheets and worksheets prepared by analysts in the Thermal Mass Spectrometry Laboratory. Reference FERMCO QAPD, Document RM-0012 (Item 6.2.6, 6.2.7, and 5.3.9, respectively).

- a. Spreadsheets for CCV, LCS, duplicates, and unit conversions have not been verified to ensure that the calculations being performed are correct. A systematic check of spreadsheets needs to be performed on a routine basis to ensure that conversions being made are accurate. P
- b. Data entered on spreadsheets is not cross-checked. Cross checks need to be performed to ensure that data has been entered correctly.
- c. Analyst identification is not documented on worksheets used for tray loading. Preparatory sheets need to document analyst identification for traceability purposes.

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AO-95-0020      The three "observations" listed below were identified during this audit but will be more thoroughly evaluated during Audit I95-03 (Computer Software Validation, FACTS and SWIFT) scheduled to be conducted in mid-March, 1995.

- a. Analytical data packages received from sub-contractor laboratories and software are not virus checked prior to use. Dm

ATTACHMENT 1  
FERMCO INTERNAL AUDIT I95-10 - AUDIT OBSERVATIONS

AO-95-0020 Cont'd

- b. Software is canned, but customized for FEMP use. No evidence was produced that documents FERMCO validation and verification activities.
- c. The FACTS computer system cannot always keep up with the demand. The Sample Processing Laboratory (SPL) loses valuable time when FACTS cannot be accessed.

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AO-95-0021 Although analytical and top-loading balances are routinely checked with Class C checkweights, acceptance ranges for the checkweighing process have not been established. In order to effectively document balance calibration activities, acceptance ranges need to be formally established. Reference FERMCO QAPD, Document RM-0012, Item 3.2.3).

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AO-95-0022 VOA holding blanks are not being routinely analyzed. The holding blanks need to be routinely analyzed to ensure that samples are not being contaminated during storage. Reference FERMCO QAPD, Document RM-0012 (Item 3.2.3).

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AO-95-0023 Methanol used for VOA analysis is not checked to verify purity prior to use. The purity needs to be checked in order to eliminate propagation of sample contamination due to use of contaminated solvents. Reference FERMCO QAPD, Document RM-0012 (Item 3.2.3)

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AO-95-0024 Deviation Report, DR 94-176, is closed. Audit/surveillance/CTR interfaces with sub-contractor Analytical Laboratories are performed semi-annually. Audit/surveillance personnel contact CTRs and are aware of problems currently being experienced and are considered to be a "designated representative" for the identified CTR when off-site laboratories are evaluated.

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**ATTACHMENT 2**  
**FERMCO INTERNAL AUDIT I95-10 - AUDIT FINDINGS AND AUDIT OBSERVATIONS**  
**DATA VALIDATION ACTIVITIES (DVA) "AREA OF RESPONSIBILITY"**

**AUDIT FINDINGS**

AF-95-0001      There is no documented program for qualifying data validators. A program needs to be developed that demonstrates that data validators are qualified and the qualification activities need to be documented.

**Requirement:**      FERMCO QAPD, Document RM-0012, Item 2.3.2 assigns responsibility to FERMCO Division Managers to: "Identify and document those work functions requiring special skills and implement training procedures to ensure the adequacy of personnel proficiency for work to be performed...".

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AF-95-0009      There is no organization/group currently assigned or available to perform field data validation activities. The Quality Control Group, assigned this responsibility in SSOP-1004, no longer exists. This responsibility needs to be organizationally reassigned to provide complete validation of sampling activities.

**Requirement:**      FERMCO SCQ, Document FD-1000, Appendix B, Form D.5

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**AUDIT OBSERVATIONS**

AO-95-0015      The requirements listed are specified in the FERMCO SCQ (Document FD-1000) for Data Validation, but are not currently in compliance. SCQ Document Change Requests are being prepared by the FERMCO SCQ Coordinator to delete these items as requirements.

- a.      SCQ, Item D.2.2.1  
         Validators do not validate all chemical and radiological data.
- b.      SCQ, Item D.2.5.2  
         Original data packages are not used for validation activities.
- c.      SCQ, Item D.4.1.4  
         Data validators do not use black ink or initial and date each page/calculation reviewed.

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AO-95-0016      Data Validation project logbooks used for the transfer of validation records do not have the purpose of the logbook identified, nor are column headings clearly and consistently identified. Additionally, the routine review that is performed by validators is not documented. Proper logbook data entry and review practices need to be adopted to ensure that logbook entries are complete. Reference FERMCO QAPD, Document RM-0012 (Item 4.2.6).

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ATTACHMENT 3  
FERMCO INTERNAL AUDIT I95-10 - AUDIT OBSERVATIONS  
SAFETY & HEALTH (S&H) "AREA OF RESPONSIBILITY"

AO-95-0004      The I95-10 audit team identified the following listed "observations" during audit activities in the analytical laboratory areas that do not fall within the realm of ALS or DVA responsibility. Reference FERMCO QAPD, Document RM-0012 (Item 1.3.3).

- a.) An air monitor unit was set-up in Room 129 and was noted to be in violation of the requirement for a 36" clearance for electrical panels.
- b.) IH does not check the velocity of the fume hoods on a regular basis.
- c.) ALS management is not provided copies of injury reports or accident statistics on a regular basis. The number of injuries and illnesses attributed to chemical exposures is considered negligible (per Walt Mengel and Roger Grant). There were no fires related to chemicals (per Chris Sutton).
- d.) Maintenance of OSHA logs and incident reports are not the responsibility of ALS or DV management. Information pertinent to laboratory operations is not being disseminated to laboratory management.

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QA AUDIT 195-10  
FERMCO ALS & DV ACTIVITIES

9. MANAGEMENT ASSESSMENT - Cont'd

Performance evaluation and quality control sample results are provided to and reviewed by the ALS manager and other responsible laboratory managers.

One Audit Finding (AF-95-0013), associated with "Management Assessment", is identified and detailed in Attachment 1.

10. INDEPENDENT ASSESSMENT

The FERMCO Quality Assurance (QA) Division schedules and conducts internal audits and surveillances, on an on-going basis. Although somewhat infrequent, ALS have been subjected to audits from external sources (DOE, USEPA, etc.). Items identified during the internal QA or external audit/surveillance processes are tracked to closure by both QA and ALS management.

One Audit Observation (AO-95-0024), associated with "Independent Assessment", is identified that resulted in the closure of an open deviation report (DR-176) as detailed in Attachment 1.

Donald Hoover, Lead Auditor  
FERMCO QA Consultant

Paul M. ... Auditor  
FERMCO QA, Project Management

  
Lisa Manning, Auditor  
Halliburton NUS Labs

Grace Ruesink, Auditor  
FERMCO QA, Quality Systems

Bonnie Spencer, Auditor  
FERMCO QA, Quality Certification

QA AUDIT 195-10  
FERMCO ALS & DV ACTIVITIES

9. MANAGEMENT ASSESSMENT - Cont'd

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*Donald Hoover*  
FERMCO QA Consultant Auditor

*Mary Ann Forrest*  
FERMCO QA, Portage, Auditor

Lisa Manning, Auditor  
Halliburton NUS Labs

*Grace Ruesink*  
Grace Ruesink, Auditor  
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FERMCO QA, Quality Certification





**INTEROFFICE MEMORANDUM**

FERMCO No. M:ETS(ALS):96-0153  
 May 10, 1996  
 Page 2

- 2) In the Summary it was also stated that QA has "Reservations ... about ALS maintaining needed frequency of production of ASL D radiochemical and/or ASL B Metal data packages.". In June, 1995 ALS generated two ASL D data packages for radium analyses. These packages met the requirements of ASL D packages as required from off-site radiochemical laboratories, as defined in the FERMCO Radioanalytical Basic Ordering Agreement. These packages were successfully validated by the Data Quality Section. Regarding ASL B chemical data packages, these packages are generated routinely, especially for Waste Programs management projects. The on-site lab is quite capable of generating ASL B chemical data packages as required by our clients.
  
- 3) Under the "Audit Conduct" section of the report, it states that, "Review of the IDC Program revealed that out of four labs submitting data for all analytes, e.g., metals, volatiles, semivolatiles, radiochemical, minerals, etc., ALS ranked number 3 for quality of data.". Upon closer inspection of these IDC reports, ALS actually ranked either number 1 or number 2 for all analyses, based on accuracy of results. Specifically:

<u>Period Covered</u>	<u>Analytes</u>	<u>Rank</u>
1995 (annual)	Chemical	3 (annual) <sup>1</sup>
1995 (annual)	RAD	2 (annual) <sup>2</sup>
1996, first qtr.	Chemical	1
1996, first qtr.	RAD	1
April, 1996	Chemical	1
April, 1996	RAD	2

<sup>1</sup> without "lates"; rank with lates was 1  
<sup>2</sup> without "lates"; rank with lates was 3

From these data, it appears that the on-site lab consistently ranks higher than most of the subcontract laboratories we do business with. The ALS lab produces high quality data.

If you have any questions, please do not hesitate to call me at 648-5441, or Roy Cohen at 648-3924. Roy will be the first point of contact for any additional communications or actions pertaining to audit 196-09.

CS:RJC:eab  
 Attachments

000049

**FERMCO AUDIT 196-09**  
**FINDINGS AND RESPONSES**

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**FINDING 1** A systematic breakdown in document control was evident. That was indicated by work instructions and procedures not being as detailed as required to safely perform work, and by not reflecting actual work being performed.

- a. There did not appear to be an obvious way to tell when procedures were in review or had been reviewed unless a revision had been made.
- b. The review cycle of 3-5 years is far too long, as evidenced by procedures not reflecting actual work processes.
- c. Specific requirements for procedures were issued as memos. Procedures did not indicate a modification or a clarification had been issued. Two specific examples are the recently issued balance and pipet calibration requirements.
- d. Neither calibration acceptance nor corrective action requirements for pipet calibration were present with the GFAA log.
- e. Logbook for the Leeman Plasma Spec 2.5 ICP was not available.
- f. Logbooks supporting chemical analysis controls were in loose leaf notebooks that were not sequentially numbered and/or controlled. (LLEM, ICP/MS)
- g. Instructions for filling out the Maintenance and Calibration logbook were not identified within the SOP.

Requirement: The FERMCO QAPD, Document RM-0014, item 4.2.1 specifies that "A system shall be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design."

**RESPONSE** Overall, ALS believes that the document system is functional. In the past several months, we have made a great effort to exercise more control over documents, and have set up a system that will ensure compliance to all quality assurance requirements. The findings and observations made during the audit will aid ALS in improving the system.

- a. During the review process, a yellow page is inserted in the Procedure at each appropriate procedure station to note that a review is in progress. An example is attached.
- b. Procedures are reviewed every three years per the new ALS procedure 257-D-0025, section 3.14. However, when the document owner/PTR needs to revise a procedure to reflect work processes, then they **MUST** revise the procedure when the process no longer matches the procedure. Attached please find the periodic review form.
- c. The memos issued by Janet Angert covering balance and pipet calibration requirements (example attached) will be made a part of the permanent ALS procedure by August 30, 1996.
- d. The memo summarizing the calibration requirements is now permanently attached to the front of the GFAA calibration logbook.
- e. At the time of the audit, the logbook for the Plasma-Spec ICP was being stored in the drawer beneath the instrument because the bench space was being used for items necessary to bring the instrument on line. (The instrument was not yet in use at the

time of the audit.) The logbook has been updated to reflect all recent maintenance performed on the instrument as it is being brought on-line, and will be kept by the instrument.

f. Prior to the audit, ALS recognized this need for bound notebooks, and a request had been forwarded to the print shop to obtain bound notebooks with pre-numbered pages. These bound notebooks have been obtained, and have been in use since April 1, 1996 for all chemical analyses records.

g. The Preventative Maintenance and calibration requirements for all inorganic/organic instrumentation have been incorporated into the Standard Operating procedures as CIOs (AC96-0017, AC96-0038 for example) a result of the 1995 QA audit. The CIO documents will be incorporated into the Nitrate/Nitrite (procedure 256-S-06012) and Volatile Organics by Gas Chromatography/Mass Spectrometry (procedure 256-S-0130) methods at the time of the next revision. The procedure for Metals by ICP (256-S-5044) has these requirements included already.

**FINDING 2** Work related instructions and/or specific procedures were not available and/ or controlled for:

- a. review/ revision of procedures (memo)
- b. use of the auto loader in the kPA procedure
- c. chain of custody (intra-laboratory)
- d. uranium and thorium interelement corrections
- e. check of distilled/ demineralized water

**Requirement:** The FERMCO QAPD, Document RM-0012, item 5.2.2 specifies that "Work shall be performed to established technical standards and administrative controls. Work shall be planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of detail commensurate with the complexity and importance of the work."

#### RESPONSE

a. A procedure is being finalized (257-D-0025; ALS Document Program procedure) that covers how procedures are created, reviewed, and revised. Sections 8.1 (substantive revisions), 8.2 (non-substantive revisions), and 8.5 (periodic reviews) in particular cover review and revision of existing procedures. This procedure will be issued by June 3, 1996.

b. Changes in the LLEM kPA procedure, 3062, are being made. They include the use of the autoloader. The procedure will be finalized by June 15, 1996

c. **Previous audits**, including the one by the USEPA on October 27, 1994, have been satisfied that the ALS Department's on-site laboratory has sufficient internal chain of custody controls to allow for data defensibility and traceability. Nonetheless, these controls are detailed in several procedures. To simplify and consolidate the on-site internal COC elements, these elements will be consolidated in a single procedure by June 28, 1996. This procedure will be implemented by July 31, 1996.

d. The Inorganic/organic analysis (IOA) group has several procedures pertaining to metals analyses when U and Th are present, AC96-008 for example. An SOP will be developed to link all these procedures together by June 28, 1996. This one procedure

will aid the analysts in predetermining which sample preparation and instrumental correction methods will be used to deal with U and Th in the samples by addressing how to compensate for potential U and Th interferences. This procedure will ensure that data generated from the analysis of FEMP samples is valid and usable.

e. Acceptance limits for the conductivity of the DI water in room 213 of Building 53 were established on March 27, 1996. The requirements state that the DI water must exhibit a resistance of at least 2 megaohm/cm to be acceptable. This is documented in FMPC notebook #4081 in the referenced room. The IOA group utilizes procedure 256-5022 for the conductivity check, which requires that the conductivity of the distilled/deionized water be consistent with requirements for ASTM Type II water (maximum resistivity of 1.0 megaohm/cm).

**FINDING 3** Work instructions and procedures are not as detailed as required to safely perform work, and do not reflect actual work being performed, e.g.,

- a. Method 3062, 8/30/89
  - Procedure does not reflect operation of equipment currently in use
- b. 256-S-0006, Rev 0
  - Westinghouse stores items are referenced
  - Procedure needs to provide for a positive test for organic material
  - Dangers related to heating perchloric acid to dryness if organics are present are seriously understated
  - Steps relating to boiling and heat lamp evaporation need to stress low and slow to prevent sample splattering
  - "Selected Gamma Emitters by Increasing Energy" is outdated
  - Figure 1 Work Record is outdated
- c. SOP 9031, Rev. 0, 8/14/91
  - Procedure only generally relates to current practices

Requirement: The FERMCO QAPD, Document RM-0012, item 5.2.2 specifies that "Work shall be performed to established technical standards and administrative controls. Work shall be planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of detail commensurate with the complexity and importance of the work.

**RESPONSE** a. Method 3062 is currently under review/revision (see finding 2, above), and will be finalized by June 15, 1996.

b. Method 256-0006 for alpha/beta was cancelled on 12/14/95. It has been replaced with procedure 256-S-3021, which addresses these issues.

c. Procedure 9031 was cancelled on 3/14/96. A Change in Operation (CIO) is in progress, AC96-0028. The CIO will result in a procedure which specifically addresses how analytical laboratory results are managed (generated, reviewed, and approved) and reported by lab personnel.

**FINDING 4** Electronic Spreadsheets currently in use have not been routinely verified in order to ensure that they are calculating correctly. (Low level Lab)

**Requirement:** The FERMCO QAPD, Document RM-0012, item 8.3.1 specifies that "A test control program shall be established as required and implemented for acceptance testing to demonstrate that items will perform as intended."

**RESPONSE** The new Lotus Spreadsheets for the Berthold instrument has been validated, and documented in the instrument logbook. The validation consisted of hand-calculating results using the same raw data points that were entered into the Lotus spreadsheet. A copy of this hand-calculation was placed in the instrument logbook.

This spreadsheet validation will be performed before any spreadsheet is used to calculate and report results for actual samples, per the procedure contained in the ALS Quality Assurance Management Plan, section 5.13. Routine verification of the spreadsheet algorithm will occur with each analytical batch via the analysis of a Laboratory Control Sample (LCS), which must produce a result that falls within the 99 % confidence interval established for the LCS. In the event of a change in the software (the introduction of a different algorithm), the new algorithm must be validated per the QAMP, section 5.13 (a hand calculation using the exact equation or formula encoded into the software that results in the same result obtained by the software, taking into account significant figures).

**FINDING 5** Calibration standards do not have a greater accuracy than the standards being calibrated, calibrations had expired on standards, e.g.,

- a. Weights used to check balances were not in the same range as the working range of the weights being measured, (Low Level Lab), and certifications of the standard weight sets in the laboratory were expired. One set of weights was out for calibration
- b. The laboratories do not have acceptable standards to certify the daily overcheck weights accompanying the laboratory balances.

**Requirement:** The FERMCO QAPD, Document RM-0012, item 8.5.5 specifies "Measuring and test equipment is to be calibrated against standards having an accuracy that will ensure that the equipment being calibrated will be within required tolerances. If nationally recognized standards exist, calibration standards are to be traceable to them....calibration standards are to have a greater accuracy than the standards being calibrated."

**RESPONSE a.** A memo will be issued by May 30, 1996 which will give analysts specific guidance on the checking of balances using weights that are in the same range as the materials being weighed. This memo will become part of a procedure by December, 1996. This upcoming procedure will also present requirements on the accuracy of the weights being used- based on the manufacturer's specifications. A memo issued by Janet Angert (memo M:ETS (ALS):96-0093) provided direction for the required accuracy of weights used for the daily check of analytical balances. For example, if the analyst is using a 5-gram weight as the daily check, the weight must read 5.0000 grams  $\pm$  0.0004 grams.

b. At this time, a primary set of weights is being certified; they were sent out in March, 1996. All secondary weights will be checked against the primary set once this set is certified and returned to the FEMP; this secondary weight certification is

expected to be completed by August, 1996. This procedure mentioned above will also require analysts to use the secondary weights for the balance checks rather than the primary weights. 672

In addition, training on proper balance operation, including the proper use of weights, will be conducted by Janet Angert for all ALS staff by August, 1996.

**FINDING 6** Controls were not in place for the test and examination services provided to support site restoration and environmental monitoring, e.g.,

a. Samples requiring preservation for kPA analysis were not being recorded. (256-S-1004, Sections 6.1 and 6.1-1), e.g.,

b. Lot numbers of acids used for sample prep are not being documented. (Low level lab)

c. Outdated standards were stored with active standards in storage cabinets. (SOP 257-D-0015)

d. Reagents found in the EPM Lab did not have expiration labels; expiration labels did not have the received and/or opened date entered on the label. (SOP 257-D-0015)

e. Several undated working standards were observed for GFAA.

**Requirement:** The FERMCO QAPD, Document RM-0012, item 8:6.1 specifies "Establish chemical analysis controls for the test and examination services provided to support site restoration, environmental monitoring, and health programs."

**RESPONSE** a. All lab analysts will again be instructed to check the pH (via pH paper) of all samples prior to analysis that do not have a pH strip on the container. If this strip is not present, it will be documented in the batch preparation logbook, with the result of the pH measurement obtained at that time. A memo was issued by Department Management (memo M:ETS(ALS):95-0414; "Audit Corrective Action- Verification of pH of Samples) that instructed chemists to take corrective action regarding preservation of samples and actions to take regarding the presence of absence of pH readings. Non-conformance memoranda will be issued for samples not properly preserved per ALS Procedure AC96-0021, and section 3.5 in the Quality Assurance Management Plan (QAMP).

b. We do not believe that it is necessary to record lot numbers of the nitric acid used for U in air analyses because it has been our experience that the quality of the nitric acid has remained acceptable over a period of several years. If a high blank were to occur, then a new bottle of acid would be used, and the previous bottle would no longer be used.

c. Effective immediately, outdated standards will not be stored with active standards.

d. Effective immediately, expiration dates will be placed on all reagents as they are prepared.

**e. Effective immediately, new standards that are used for GFAA analyses will be dated as they are received, then opened. All standards currently in use will be dated by May 31, 1996.**

**Items c., d., and e. are covered in ALS Procedure 257-D-0015 (Preparation of Reagents and Standards), and also in the Chemical Hygiene Manual, document RM-3001, section 4.5, "Rules for Storage of Chemicals". Laboratory analysts will receive a reminder in the form of a memorandum which will be issued by May 30, 1996.**

**Observation 1:** Current procedures were not available in rooms where work processes are being performed, e.g.,

- sample prep
- sample log-in
- glassware cleaning
- standards prep
- analytical methods (visual inspection)

**Requirement:** The FERMCO QAPD, Document RM-0012, item 4.2.1 specifies "A system shall be implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design."

**RESPONSE** Sixteen procedure stations exist throughout the lab (see attached list of procedure stations). These stations are located throughout the laboratory, and are readily available to all ALS employees in both the controlled and administrative areas of the building. Each procedure station contains all documents (procedures, CIOs, etc...) necessary to conduct daily operations in the laboratory. Each staff member has the list of the procedure stations. Procedure stations offer advantages over placing individual procedures by the different instruments.

- The documents are protected from contamination from samples or reagents,
- documents are more easily updated, being in a more centralized location,
- no one will inadvertently move a document to another location that other analysts do not know about.

**Observation 2:** The work card is legal, however, transferring data by hand adds a possibility of transcription error when an automated data system is available

**Requirement:** The FERMCO QAPD, Document RM-0012, item 4.2.1 specifies "A system shall be implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design."

**RESPONSE** After the analyst enters the results on the workcards, a second analyst reviews the entries against the raw data to ensure that no transcription errors have occurred. This second analyst approves the results, and verifies approval by their signature. This approval step is found in procedure AC96-0028. Lab equipment software is not yet configured to permit downloading of final results directly onto workcards.

**Observation 3:** Preventative Maintenance (PM) schedules are not available in all the PM documentation. PM has not been noted for the Berthold instrument (Low Level Lab).

**Requirement:** The FERMCO SCQ, Document FD-0001, section 13.2 specifies that "Maintenance activities shall be documented in logs."

**RESPONSE:** CLOSED during audit. LLEM Preventative Maintenance Schedules were placed in logbooks for the Berthold Counter, the Tennelec LB 5100 counters, and the kPA uranium analyzers in the LLEM lab.

**Observation 4:** Randomly chosen standards were expired, could not be traced to NIST, or solutions for calibration were not traceable; acceptance limits for conductivity had not been established.

**Requirement:** The FERMCO QAPD, Document RM-0012 section 8.6.1, specifies "Establish chemical analysis controls for the test and examination services provided to support site restoration, environmental monitoring, and health programs."

**RESPONSE:** CLOSED during audit. A U in water standard (#213-95-0222) had expired. It was replaced by a new standard. (NOTE: The old standard was checked against the new standard, and found to be acceptable, but it has been taken out of use.)

**Observation 5:** Several undated GFAA working standards were discovered in the inorganics laboratory. Dating of standards is required by the SCQ. Note that this is different from using expired standards

**Requirement:** The FERMCO SCQ, Document FD-0001, section 12.4.3.1 specifies that "use of current labeled and dated standards" shall be examined during an audit.

**RESPONSE** Effective immediately, new standards that are used for GFAA analyses will be dated as they are received, then dated again when opened. All standards currently in use will be dated by May 31, 1996. This requirement will be documented in a memorandum by May 31, 1996, per the Chemical Hygiene Plan, section 4.5.

**Observation 6:** Although monthly pipet calibrations are required (per FERMCO memo that has not yet been made a part of the procedure), lapses of multiple months were noted in the logbook.

**Requirement:** The FERMCO SCQ, Document FD-0001, section 12.4.3.1 specifies that "procedures and records for equipment calibration, maintenance, and evaluation" shall be examined during an audit.

**RESPONSE** The analysts have been reminded to enter all periodic (monthly) pipet calibration data into the appropriate logbooks. This requirement will be part of the new procedure (see Finding # 1, item (c)). In addition, a formal memorandum will be issued to analysts by May 31, 1996.

**Observation 7:** The FERMCO laboratory has no acceptance requirements for calibrating thermometers.

**Requirement:** The FERMCO QAPD, Document RM-0012 section 8.5.1, specifies "A program shall be established and implemented to control the calibration, maintenance, accountability, and use of equipment used for acceptance of items during inspection and testing."

**RESPONSE** Thermometer calibration, including determination of acceptance limits, will be completed, documented and formalized as a procedure by June 15, 1996.

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**Observation 8:** Eye wash stations in rooms 148 and 190 had inconsistent pressure: high pressure in one station (by the wall-148), low pressure on one side (near the sink-148).

**Requirement:** Although no document specifically addresses this issue, consistent pressure is expected.

**RESPONSE** A work order has been written to RSO for repairs on the eyewash fixtures in rooms 148 and 190.

**Observation 9:** Hood in room 168 had a cracked front, FH 158A EF-1.

**Requirement:** no specific reference in QAPD or SCQ

**RESPONSE:** A work order was written to RSO on 8/15/95 (work order # CM009814-00-00) for repair of the glass sash on the fume hood in room 168. Due to higher priorities, this work order has not been completed as of May 10, 1996. A memo will be sent to Mike Hundley by May 17, 1996 requesting timely completion of the repair.

**Observation 10:** A fire extinguisher was not evident in the SAA.

**Requirement:** Each work area should contain a fire extinguisher.

**RESPONSE:** CLOSED during audit: A fire extinguisher was placed in the SAA by Tim Weigel of Facilities Services.

**Observation 11:** Personnel records indicated both chemical hygiene and rad worker training were overdue for personnel identified to ALS management.

**Requirement:** The FERMCO QAPD, Document RM-0012, Criterion 2 deals with the proper and timely training of all FEMP personnel.

**RESPONSE:** CLOSED during audit. It was indicated that Ervin O'Bryan needed to take Rad Worker I training. However, the ETS training coordinator, Debbie Reichard, indicated that Ervin had received this training on March 9, 1995, and is not due for refresher training until March 9, 1997. Four individuals were noted as needing Chemical Hygiene refresher training: Ray Danahy, Ervin O'Bryan, Mark Harper, and Amy Meyer. All four individuals have received the Update to the Chemical Hygiene Manual, and will read this update, sign the required form on the last page of the Update, and send it back to Debbie Reichard by May 10, 1996.

**Observation 12:** Spare parts lists for the analytical instruments were not provided.

Requirement: The FERMCO QAPD, Document RM-0012, and the FERMCO SCQ, Document FD-0001 both specify that there shall be a "...listing of spare parts necessary to minimize downtime...".

**RESPONSE** The need for spare parts lists to be maintained by ALS itself is ameliorated by the service contracts we have on every major piece of instrumentation; GFAA, ICP, ICP/MS, GC/MS, and Plasma-spec ICP, autoanalyzers, radiochemical counting instrumentation, and so on. Because ALS maintains these service contracts, the manufacturer's technical service representatives possess the spare parts listings, and, in many instances, are better able to determine which parts are needed in the event of an instrument malfunction than the operator. ALS believes that carrying these service agreements fulfills the requirements of RM-0012 and the SCQ.

ANALYTICAL LABORATORY SERVICES DEPARTMENT  
DOCUMENT PROGRAM

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DOCUMENT REQUEST (DR)

Page 1 of 2  
A3

★ IDENTIFY REVIEW REQUIREMENTS ON PAGE 2 OF THE DR. THE CHOICES ARE EITHER OPTION 1, 2, OR 3, OR 2 AND 3. OWNER SIGNATURE INDICATES REVIEW REQUIREMENTS HAVE BEEN IDENTIFIED ON PAGE 2 OF THE DR.

This Block Is For OQPD Use Only.

REQUEST DATE: \_\_\_\_\_  
REQUEST NUMBER: \_\_\_\_\_  
ISSUE/REVISION/CANCELLATION DATE: \_\_\_\_\_  
WRITER: \_\_\_\_\_

NOTE: Request will not be processed without PTR and Owner signatures, and a Charge Number.

PTR: \_\_\_\_\_ EXT: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_  
OWNER: \_\_\_\_\_ EXT: \_\_\_\_\_ ★ SIGNATURE: \_\_\_\_\_  
PTR ORG: \_\_\_\_\_ AUTHORIZING ORG: \_\_\_\_\_ CHARGE NO.: \_\_\_\_\_

(CURRENT DOCUMENT INFORMATION OR NEW DOCUMENT TITLE)

DOCUMENT NUMBER: \_\_\_\_\_ ISSUE DATE: \_\_\_\_\_  
REVISION NUMBER: \_\_\_\_\_ REVISION DATE: \_\_\_\_\_  
DOCUMENT TITLE: \_\_\_\_\_

REASON FOR REQUEST: \_\_\_\_\_  
SUPERSEDES (DOCUMENT NO.): \_\_\_\_\_  
DRIVER(S): \_\_\_\_\_

DOCUMENT REQUEST TYPE

NEW  
 REVISION  
 CANCELLATION  
 PERIODIC REVIEW  
 CIO INCORPORATION

DOCUMENT TYPE

DEPARTMENT  
 SECTION  
 SOP  
 CIO  
 REQUIREMENTS DOCUMENT  
 METHOD  
 PLAN  
 OTHER \_\_\_\_\_

KEY WORDS: \_\_\_\_\_

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NOTE: AFTER IDENTIFYING REVIEW REQUIREMENTS, PLACE AN "X" THROUGH NON-APPLICABLE OPTIONS.

DOCUMENT REVIEW REQUIREMENTS TABLE

DOCUMENT TYPE	REVIEW ONLY OR REVIEW / APPROVAL						
	ETS	ESH	EC	QA	EQ & SA	ALS MGR	DOC OWNER
METHOD	R	A	R	A	R	A	A
SOP	R	A	R	A	R	A	A
CIO	---	---	---	---	---	---	A
PLAN	As applicable and determined by the Document Owner					A	A
REQUIREMENTS						A	A
GUIDANCE						A	A

A = REVIEW/APPROVAL  
R = REVIEW ONLY

(OPTION 1)  Transmit Document for Review or Review/Approval as listed in the Document Review Requirements Table.

(OPTION 2)  Delete the following individuals/organizations from the Document Review Requirements Table as indicated on lines below.

\_\_\_\_\_

\_\_\_\_\_

(OPTION 3)  \*Add the following individuals/organizations for Review as indicated on lines below.

\_\_\_\_\_

\_\_\_\_\_

\*Indicate "R" or "A" for each addition.



**INTEROFFICE MEMORANDUM**

<b>To:</b>	Distribution	<b>Date:</b>	March 18, 1996
<b>Location:</b>	Fernald	<b>Reference:</b>	N/A
<b>From:</b>	Janet Angert, MS35 <i>ja</i>	<b>FERMCO #:</b>	M:ETS(ALS):96-0093
<b>Location:</b>	Fernald	<b>Client:</b>	DOE DE-AC24-92OR21972
<b>Extension:</b>	648-5361	<b>Subject:</b>	<b>LIMITS FOR THE DAILY CHECK OF ANALYTICAL BALANCES</b>

**DISTRIBUTION:**

- |   |                              |
|---|------------------------------|
| Carl Bishop, MS35, Fernald              | Bill Kelley, MS35, Fernald   |
| Barb Campbell, MS35, Fernald            | Amy Meyer, MS35, Fernald     |
| Ray Danahy, MS35, Fernald               | Ervin O'Bryan, MS35, Fernald |
| Mike Feller, MS35, Fernald              | Chris Sutton, MS35, Fernald  |
| Harold Humphrey, MS35, Fernald          | Dawn Webber, MS35, Fernald   |
| c: File Record Storage Copy 106.4.14.11 |                              |
| Angeia Dees, MS35, Fernald              | Mike Rolfes, MS1, Fernald    |
| Alex Duarte, MS35, Fernald              | Mike Soldano, MS31, Fernald  |
| Kathy Hudson, MS60, Fernald             | Doug Stark, MS35, Fernald    |
| John Roberts, MS35, Fernald             |                              |

Analytical balances are routinely used in the Analytical Laboratory Services Department (ALS) and the Quality Control (QC) laboratories. A list of the balances currently located in these areas is attached. The direction provided in this memo is intended for the balances used in ALS and QC laboratories. However, it may be applied to any analytical balance.

Each day that a balance is used, the calibration is verified and documented in a logbook. The maximum allowable difference between the expected value and the reading displayed by the balance is  $\pm 4$  in the last readable position. For example, if a 5 gram weight is placed on a balance that is readable to the nearest 0.1 mg, the allowable readings would be between 4.9996 and 5.0004 g.

For some balances, these limits are not tight enough. More restrictive limits may be set by the manager/supervisor responsible for the laboratory. However, NO manager/supervisor may set less restrictive limits.



## INTEROFFICE MEMORANDUM

FERMCO No. M:ETS(ALS):96-0093

March 18, 1996

Page 2

The ALS and QC laboratory managers/supervisors are responsible for the following activities:

- A. Notify all analysts that limits have been established for the daily calibration check of analytical balances.
- B. Post the limits for each balance and the procedure described below in the front of each logbook used to document the daily calibration checks.
- C. Ensure that all analysts are aware of the information provided below.

If the daily calibration check is not within the permitted limits, the following procedure must be used:

1. Ensure that the balance is level and the pan is clean.
2. Following the directions provided in the Operator's Manual, start the balance through its internal calibration program. (Not all balances have this ability.)
3. After the internal calibration is completed, check the calibration again. Document the steps taken and the results of the second calibration check in the logbook.
4. If the result is still outside of the allowed limits, notify the supervisor.
5. If the supervisor cannot solve the problem, tag the balance Out-of-Service and notify the person responsible for preventative maintenance and calibration. At this time, Janet Angert (ext. 5361) is the responsible individual. Document in the logbook that the balance has been taken out of service.
6. The Out-of-Service tag can only be removed after the person responsible for preventative maintenance and calibration is satisfied that the problem has been solved and the balance is functioning properly.
7. If the person responsible for preventative maintenance and calibration cannot solve the problem, if the balance remains out of service for more than two working days, and if

**INTEROFFICE MEMORANDUM**

FERMCO No. M:ETS(ALS):96-0093

March 18, 1996

Page 3

no other balances can reasonably be used for the work, the balance may be put back into limited service under the following circumstances:

- The supervisor/manager responsible for the laboratory determines that the balance problem is not serious enough to negatively impact the data produced.
- The balance will only be used to generate data for a specified method or methods.

Under these circumstances, the Out-of-Service tag will be replaced by a tag that indicates the balance can only be used for the method(s) listed on the tag. The tag will be signed and dated by the responsible supervisor/manager. In addition, the balance will be operated under a Nonconformance until the problem is solved.

8. If the balance is operated under the circumstances described in Item 7, the following information will be documented in the logbook:
  - the fact that the balance has been placed in limited service
  - the date that this occurred
  - the method(s) for which the balance can be used during this time
9. After the balance is working properly again, note the change in status in the logbook.

If you have any questions regarding the information provided in this memo, please contact me at extension 5361 or by cc:Mail.

Thank you for your support in this area.

JLA:eab  
Attachment

**ANALYTICAL BALANCES**  
**Inventory List**  
**ALS and QC Laboratories**

Item No.	Location	Group	Manufacturer	Model No.	Serial No.	Current Comments
1	Lab - 147	IOA	Amer. Sci.	S/P 180	2901149	RWP
2	Lab - 147	IOA	Ohaus	GT 410	1178	
3	Lab - 147	IOA	Sartorius	R 300 S	40110016	
4	Lab - 148	IOA	Sartorius	1801	36040062	
5	Lab - 165	IOA	Mettler	PE 160	E 76612	RWP
6	Lab - 165	IOA	Setra	1000	6620	
7	Lab - 168	IOA	Sartorius	B 610	38030038	
8	Lab - 168	IOA	Mettler	AE 100	K 65413	
9	Lab - 169	IOA	Sartorius	R 200 D	20200916	
10	Lab - 169	IOA	Mettler	AE 240	F 96706	
11	Lab - 169	IOA	Mettler	PM 480	1113250122	New
12	Lab - 175	IOA	Mettler	PC 180	B 66907	
13	Lab - 190	IOA	Setra	2000	166459	RWP
14	Lab - 190	IOA	Sartorius	PC 1801	3505033	RWP
15	Lab - 192	IOA	Sartorius	1402	35090144	
16	Lab - 192	IOA	Sartorius	A 120 S	36100186	
17	Lab - 208	IOA	Mettler	PE 160	E 63076	
18	Lab - C43	IOA	Sartorius	1801	3409264	RWP
19	Lab - 191	QC	Mettler	AE 200	L 54262	
20	Lab - 191	QC	Sartorius	E5500S	3611056	
21	Lab - 191	QC	Mettler	AE 163	B 81656	
22	H&S - 215	R&IA	Mettler	UM 3	K 85764	
23	H&S - 215	R&IA	Sartorius	A 200 S	10605982	
24	H&S - 215	R&IA	Mettler	AE 163	F 19005	
25	H&S - 215	R&IA	Fisher	7215 A	11951	
26	Lab - 157	R&IA	Mettler	AE 100	H 15911	
27	Lab - 184	R&IA	Mettler	PM 4800	P 03687	
28	Lab - 188	R&IA	Fisher	XA200DS	11071	
29	Lab - 203	R&IA	Mettler	AE 240	L 43737	
30	Lab - 204	R&IA	Sartorius	BP 61	50710419	New
31	Lab - 206	R&IA	Accu-Lab	333	2810393	
32	Lab - 206	R&IA	Mettler	PE 3600	E 85856	
33	Lab - 207	R&IA	Mettler	PE 3600	E 85858	
34	Lab - 209	R&IA	Amer. Sci.	DTL4100S	15458	
35	Lab - 209	R&IA	Amer. Sci.	ER120A	2903736	RWP
36	Lab - 214	R&IA	Mettler	AE 50	M 81738	
37	Lab - 220	R&IA	Ohaus	GT 2100	5068	

000065

## MASTER LIST OF ALS PROCEDURE STATIONS

PROCEDURE STATION NO.	OWNER	BUILDING	ROOM NUMBER
LB-1203	Anderson	Lab	203
LB-1207	Wise	Bldg. 53	213
LB-1301	Stark	Lab	W-28
LB-2000	Danahy	Lab	219
LB-2003	Dryden	Lab	213A
LB-2201	Dryden	Lab	157
LB-2301	Dryden	Lab	209
LB-2302	Dryden	Lab	206
LB-2307	Dryden	Lab	189
LB-2309	Dryden	Lab	220
LB-3000	O'Bryan	Lab	193
LB-3203	Feller	Lab	169
LB-3205	Duarte	Lab	C-7
LB-4101	Meyer	Lab	173
LB-5000	Meyer	Lab	E-31
ALS-1000	Meyer	Lab	C-10

**This document 256-S-0117  
has been reviewed  
by the owner and is  
in the process of  
being updated.**

**Process  
initiated 10/95 .  
A95-0139**

**See Procedural Development for  
more information.**

000067



100109H  
672

INTEROFFICE MEMORANDUM

To: All Laboratory Analysts, MS35      Date: July 10, 1995  
ACS Personnel, MS35  
SPL Personnel, MS35

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Location: Fernald      Reference: N/A

From: Chris Sutton, MS35      FERMCO #: M:ETS(ALS):95-0414  
*RGS FOR C.S.*

Location: Fernald      Client: DOE DE-AC24-92OR21972

Extension: 648-5441      Subject: Audit Corrective Action -  
Verification of pH of  
Samples

c: File Record Storage Copy 106.4.14.11  
John Harmon

In our annual QA audit earlier this year, we received a finding pertaining to verification of pH of samples. The finding noted that when pH strips are lost in sample transit, ALS analysts are not verifying and documenting the pH of radiochemistry, VOA, and metals samples. Our laboratory QA manual and the SCQ state that we have to document the pH of potentially improperly preserved samples.

Therefore, effective July 12, 1995, any water samples that do not have a pH strip with them must be noted in the batch preparation log book. The results of pH testing with pH paper must also be noted. If the samples are not properly preserved, a nonconformance form must be issued per our nonconformance procedure AC95-0097.

If you have any questions, please ask your supervisor.

CS:eab

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. NONCONFORMANCE REPORT NUMBER: (This number is assigned by The PQA Nonconformance Administrator.)		F96-0062	
2. TYPE OF NONCONFORMANCE REPORT: Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION <input type="checkbox"/> FINDING <input checked="" type="checkbox"/> DEVIATION <input type="checkbox"/> CORRECTIVE ACTION REPORT <input type="checkbox"/>	
3. DATE DISCOVERED: Enter the date the nonconformance was identified.		3. 3/28/96	
4. RESPONSIBLE ORGANIZATION: Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. Env Tech Serv 4b. ALS	
5. RESPONSIBLE MANAGER: Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. Chris Sutton 5b.	
6. LOCATION: Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. On-site Lab / Low Risk 6b. < HC 3	
7. ASSESSMENT ACTIVITY: Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit 195-19, QEP Number, Walk-through, etc.)		7. Audit I96-09	
8. REQUIREMENTS: (Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
RM-0012, 4.2.1 - A system shall be established and implemented to Control Preparation, review, approval, issuance, use, or revision of documents that establish policies, prescribe work			
9. NONCONFORMANCE: (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
A systematic breakdown in document control was evident. See Audit Report I96-09 for examples. Logbooks were not adequately structured and controlled for documenting chemical analyses and calibration acceptance			
10. PREPARED BY: <u>Mary Ann Barrett</u>		11. Phone: <u>5387</u>	12. Mail Stop: <u>43</u>
13. Date: <u>4/15/96</u>			

### PERFORMANCE QUALITY ASSURANCE EVALUATION

14. QUALITY ASSURANCE PROGRAM REQUIREMENT: (Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 4.2	
15. DIVISION/DEPARTMENT REQUIREMENT: (Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as the Paragraph, etc.)		15. —	
16. NOTIFICATION: (Enter the date the responsible manager was notified of the nonconformance. Enter manager agree a nonconformance exists.)		16. 3/28/96	
17. TRENDING INFORMATION: (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii))		17. 2.0 A i, iii	
18. TAGGING REQUIRED:   YES   <input checked="" type="checkbox"/> NO	19. P/QA REP.: <u>Mary Ann Barrett</u>	20. DATE:	
21. P/QA MANAGEMENT REVIEW: <u>[Signature]</u>	POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO	22. DATE: <u>4/15/96</u>	
23. P/QA DIV. MANAGER: (CAUs Only)	24. DATE:	24. DATE:	
23A. REPORT TO NTS:   YES   <input checked="" type="checkbox"/> NO	23B. PAAA COORDINATOR:	23C. DATE:	
(P/QA Representative obtains the Nonconformance Report Number from the P/QA Nonconformance Administrator and enters the number in Block 1 above)		25. RESPONSIBLE MANAGER RESPOND BY: (Date)	

# NONCONFORMANCE RESOLUTION

Report Number:

(Required for Findings, Deviations and Corrective Action Reports)

Revision **572**

## Responsible Manager's Response

(Must Complete All Blocks 26 through 35)

USE ADDITIONAL SHEETS AS NECESSARY

26. PROPOSED DISPOSITION AND CORRECTIVE ACTION | | Accept-As-Is | | Rework | | Repair | | Reject |  Other

(A disposition of "Accept-As-Is" and "Repair" requires a written Technical Justification attached to this form. The justification for "Accept-As-Is" or "Repair" resulting in Design changes shall include appropriate documentation of Unreviewed Safety Questions (USQ) pre-screening, screening, and if necessary, a safety evaluation using NS-0002. What action will be taken to correct the identified nonconformance?)

*See Audit Response for Finding 1 in memo  
M: M:ETS (ALS): 96-0153 pp 1 and 2*

27. Technical Justification Approval Signature: | | N/A

Date:

28. Disposition Results in Design Change  
| | Yes |  No

29. USQ/DCN Number: |  N/A

30. Proposed Completion Date:

*August 30, 1996*

31. Investigation of Similar Items and/or Processes for Presence of the Identified Nonconformance:

*none*

32. Measures Taken to Prevent Recurrence:

*see audit response -*

33. Root Cause: (Required for CARs Only)

34. Responsible Manager:

*Chris Sutt*

35. Date of Response:

*5/13/96*

(After entering all of the above information, forward the Original of this form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

## Evaluation of Proposed Disposition and Corrective Action

36. Quality Representative:

| | Accept | | Reject

37. Date:

(If the decision is to "Reject" the Responsible Manager's proposed disposition and/or corrective action, the Quality Representative shall contact the Responsible Manager to resolve the issues.)  
(Return the Original of the Form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

## Completion of Disposition and Corrective Actions

38. Responsible Manager:

39. Date Action Completed:

(After completing all the proposed actions, sign and date in the above block and return the Original to the P/QA Nonconformance Administrator.)

## Verification of Actions

40. Verification Action: (Describe when, where and what was done to verify the above actions were completed.)

41. Quality Representative:

42. Date Verified:

43. Quality Manager:

44. Date Closed:

(After completion of all verification actions and closure of this report, return the Original to the P/QA Nonconformance Administrator, MAIL STOP 43.)

**The Original of this Report is Yellow and Must be Sent to Performance Quality Assurance**

050070

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. NONCONFORMANCE REPORT NUMBER: (This number is assigned by The PQA Nonconformance Administrator.)		F96-0063	
2. TYPE OF NONCONFORMANCE REPORT: Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION	11
		FINDING	14
		DEVIATION	11
		CORRECTIVE ACTION REPORT	11
3. DATE DISCOVERED: Enter the date the nonconformance was identified.		3. 3/27/96	
4. RESPONSIBLE ORGANIZATION: Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. Env Tech. Serv	4b. ALS
5. RESPONSIBLE MANAGER: Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. Chris Sutton	5b. —
6. LOCATION: Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. On Site Lab - Low Level	6b. < HC 3
7. ASSESSMENT ACTIVITY: Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit 195-19, QEP Number, Walk-through, etc.)		7. Audit I96-09	
8. REQUIREMENTS: (Identify and Quote the requirement directly from the documents (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity)			
RM-0012, 5.2.2 - Work shall be performed to established technical standards and Administrative Controls.			
9. NONCONFORMANCE: (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
2. Work related instructions and/or specific procedures were not available and/or controlled. See Audit Report I96-09 for examples. Specific example: 2 and 3rd intellectual collection area not being held back by the ICP.			
10. PREPARED BY: <u>Mary Ann Garrett</u>		11. Phone: 5387	12. Mail Stop: 43
		13. Date: 4/15/96	

## PERFORMANCE QUALITY ASSURANCE EVALUATION

14. QUALITY ASSURANCE PROGRAM REQUIREMENT: (Enter the Criterion and paragraph number of the Quality Assurance Program. (RM-0012) requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 5.2	
15. DIVISION/DEPARTMENT REQUIREMENT: (Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as the Paragraph, etc.)		15. —	
16. NOTIFICATION: (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. TRENDING INFORMATION: (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g. 10 F II)		17. 2.0 B ii, ii	
18. TAGGING REQUIRED:   YES   <input checked="" type="checkbox"/> NO	19. P/QA REP.: <u>Mary Ann Garrett</u>		20. DATE: 4/15/96
21. P/QA MANAGEMENT REVIEW: <u>Chris Sutton</u>		POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO	
22. DATE: 4/15/96		24. DATE: —	
23A. REPORT TO NTS:   YES   <input checked="" type="checkbox"/> NO		23B. PAAA COORDINATOR: —	
23C. DATE: —		25. RESPONSIBLE MANAGER RESPOND BY: (Date)	
(P/QA Representative obtains the Nonconformance Report Number from the PQA Nonconformance Administrator and enters the number in Block 1 above)			

# NONCONFORMANCE RESOLUTION

Report Number **672**

(Required for Findings, Deviations and Corrective Action Reports)

Revision: \_\_\_\_\_

## Responsible Manager's Response

(Must Complete All Blocks 26 through 35)

USE ADDITIONAL SHEETS AS NECESSARY

26. PROPOSED DISPOSITION AND CORRECTIVE ACTION	<input type="checkbox"/> Accept-As-Is	<input type="checkbox"/> Rework	<input type="checkbox"/> Repair	<input type="checkbox"/> Reject	<input checked="" type="checkbox"/> Other
--	---------------------------------------	---------------------------------	---------------------------------	---------------------------------	---

(A disposition of "Accept-As-Is" and "Repair" requires a written Technical Justification attached to this form. The justification for "Accept-As-Is" or "Repair" resulting in Design changes shall include appropriate documentation of Unreviewed Safety Question (USQ) pre-screening, screening, and if necessary, a safety evaluation using NS-0002. What action will be taken to correct the identified nonconformance?)

*see Audit Response for Finding 2 in memo.  
M.M. ETS (ALS): 96-0153 pages 2 and 3*

27. Technical Justification Approval Signature: _____	N/A	Date: _____
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28. Disposition Results in Design Change <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	29. USQ/DCN Number: <input checked="" type="checkbox"/> N/A	30. Proposed Completion Date: <i>July 31, 1996</i>
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31. Investigation of Similar Items and/or Processes for Presence of the Identified Nonconformance:  
*none*

32. Measures Taken to Prevent Recurrence:  
*see audit response*

33. Root Cause: (Required for CARs Only)

34. Responsible Manager: <i>[Signature]</i>	35. Date of Response: <i>5/13/96</i>
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(After entering all of the above information, forward the Original of this form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

### Evaluation of Proposed Disposition and Corrective Action

36. Quality Representative: _____	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	37. Date: _____
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(If the decision is to "Reject" the Responsible Manager's proposed disposition and/or corrective action, the Quality Representative shall contact the Responsible Manager to resolve the issues.)  
(Return the Original of the Form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

### Completion of Disposition and Corrective Actions

38. Responsible Manager: _____	39. Date Action Completed: _____
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(After completing all the proposed actions, sign and date in the above block and return the Original to the P/QA Nonconformance Administrator.)

### Verification of Actions

40. Verification Action: (Describe when, where and what was done to verify the above actions were completed)

41. Quality Representative: _____	42. Date Verified: _____
43. Quality Manager: _____	44. Date Closed: _____

(After completion of all verification actions and closure of this report, return the Original to the P/QA Nonconformance Administrator, MAIL STOP 43.)

000072

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. NONCONFORMANCE REPORT NUMBER: (This number is assigned by The PQA Nonconformance Administrator.)		F96-0064	
2. TYPE OF NONCONFORMANCE REPORT: Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION <input type="checkbox"/> FINDING <input checked="" type="checkbox"/> DEVIATION <input type="checkbox"/> CORRECTIVE ACTION REPORT <input type="checkbox"/>	
3. DATE DISCOVERED: Enter the date the nonconformance was identified.		3. 3/27/96	
4. RESPONSIBLE ORGANIZATION: Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. Envr Tech Serv 4b. AUS	
5. RESPONSIBLE MANAGER: Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. Chris Sutton 5b. —	
6. LOCATION: Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. On-Site Lab/Gen Lab 6b. < HC 3	
7. ASSESSMENT ACTIVITY: Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7. Audit I96-09	
8. REQUIREMENTS: (Identify and Quote the requirements directly from the documents (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity)			
Ru-0012, 5.2.2 Work shall be performed to established technical standards and Administrative Control.			
9. NONCONFORMANCE: (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
3. Work instructions are not as detailed as required to safely perform work and do not reflect actual work being performed. See Audit Report I96-09 for examples of work.			
10. PREPARED BY: Mary Ann Forrest		11. Phone: 5387	12. Mail Stop: 43
13. Date: 4/15/96			

## PERFORMANCE QUALITY ASSURANCE EVALUATION

14. QUALITY ASSURANCE PROGRAM REQUIREMENT: (Enter the Criterion and paragraph number of the Quality Assurance Program. (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. Rm-0012, 5.2	
15. DIVISION/DEPARTMENT REQUIREMENT: (Enter the document number and paragraph of the division or department requirements that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as the Paragraph, etc.)		15. —	
16. NOTIFICATION: (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. TRENDING INFORMATION: (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g. 1.0 F ii))		17. 2.0 A iii	
18. TAGGING REQUIRED:   YES   <input checked="" type="checkbox"/> NO	19. P/QA REP: Mary Ann Forrest		20. DATE: 4/15/96
21. P/QA MANAGEMENT REVIEW: <i>[Signature]</i> POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO		22. DATE: 4/15/96	
23. P/QA DIV. MANAGER: (CARs Only)		24. DATE:	
23A. REPORT TO NTS:   YES   <input checked="" type="checkbox"/> NO	23B. PAAA COORDINATOR:		23C. DATE:
(P/QA Representative obtains the Nonconformance Report Number from the PQA Nonconformance Administrator and enters the number in Block 1 above)		25. RESPONSIBLE MANAGER RESPOND BY: (Date)	

# NONCONFORMANCE RESOLUTION

Report Number: **672**  
Revision: \_\_\_\_\_

(Required for Findings, Deviations and Corrective Action Reports)

## Responsible Manager's Response

(Must Complete All Blocks 26 through 35)

USE ADDITIONAL SHEETS AS NECESS.

26. PROPOSED DISPOSITION AND CORRECTIVE ACTION | | Accept-As-Is | | Rework | | Repair | | Reject |  Other

(A disposition of "Accept-As-Is" and "Repair" requires a written Technical Justification attached to this form. The justification for "Accept-As-Is" or "Repair" resulting in Design changes shall include appropriate documentation of Unreviewed Safety Questions (USQ) pre-screening, screening, and if necessary, a safety evaluation using NS-0002. What action will be taken to correct the identified nonconformance?)

see audit response for Finding 3 in memo  
M.M. STS(ALS) 46-0153, page 3

27. Technical Justification Approval Signature:  N/A

Date:

28. Disposition Results in Design Change  
| | Yes |  No

29 USQ/DCN Number: |  N/A

30. Proposed Completion Date:

JUNE 15, 1996

31. Investigation of Similar Items and/or Processes for Presence of the Identified Nonconformance:

none

32. Measures Taken to Prevent Recurrence:

see audit response

33. Root Cause: (Required for CARs Only)

34. Responsible Manager: *Chris Little*

35. Date of Response: 5/13/96

(After entering all of the above information, forward the Original of this form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

## Evaluation of Proposed Disposition and Corrective Action

36. Quality Representative:

| | Accept | | Reject

37. Date:

(If the decision is to "Reject" the Responsible Manager's proposed disposition and/or corrective action, the Quality Representative shall contact the Responsible Manager to resolve the issues.)  
(Return the Original of the Form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

## Completion of Disposition and Corrective Actions

38. Responsible Manager:

39. Date Action Completed:

(After completing all the proposed actions, sign and date in the above block and return the Original to the P/QA Nonconformance Administrator.)

## Verification of Actions

40. Verification Action: (Describe when, where and what was done to verify the above actions were completed.)

41. Quality Representative:

42. Date Verified:

43. Quality Manager:

44. Date Closed:

(After completion of all verification actions and closure of this report, return the Original to the P/QA Nonconformance Administrator, MAIL STOP 43.)

000074

The Original of this Report is Yellow and Must be Sent to Performance Quality Assurance

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. <b>NONCONFORMANCE REPORT NUMBER:</b> (This number is assigned by The PQA Nonconformance Administrator.)		F96-0065	
2. <b>TYPE OF NONCONFORMANCE REPORT:</b> Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION        FINDING          4 DEVIATION         CORRECTIVE ACTION REPORT	
3. <b>DATE DISCOVERED:</b> Enter the date the nonconformance was identified.		3. 3/28/96	
4. <b>RESPONSIBLE ORGANIZATION:</b> Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a.	Envt Tech Serv
5. <b>RESPONSIBLE MANAGER:</b> Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		4b.	ALS
		5a.	Chris Sutton
		5b.	—
6. <b>LOCATION:</b> (Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).)		6a.	Gen. Site Lab/Gen. L
		6b.	< HC 3
7. <b>ASSESSMENT ACTIVITY:</b> Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7.	Audit I96-09
8. <b>REQUIREMENTS:</b> (Identify and Quote the requirements directly from the documents (procedures, specifications, drawing, etc.) that best describes the acceptance criteria for the item or activity)			
RM-0012, 8.3.1 - A test control program shall be established as required and implemented for acceptance testing to demonstrate that items will perform as intended			
9. <b>NONCONFORMANCE:</b> (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets if required.)			
4. Electronic spread sheets currently in use have not been routinely verified, in order to ensure they are calculating correctly (bbb)			
10. <b>PREPARED BY:</b> <i>Mary Ann Forrest</i>		11. Phone: 5387	12. Mail Stop: 43
		13. Date: 4/15/96	

**PERFORMANCE QUALITY ASSURANCE EVALUATION**

14. <b>QUALITY ASSURANCE PROGRAM REQUIREMENT:</b> ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 8.3	
15. <b>DIVISION/DEPARTMENT REQUIREMENT:</b> ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph, etc.)		15. —	
16. <b>NOTIFICATION:</b> (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees nonconformance exists.)		16. 3/28/96	
17. <b>TRENDING INFORMATION:</b> (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., I O F ii))		17. 2.0 B ✓	
18. <b>TAGGING REQUIRED:</b>   YES   <input checked="" type="checkbox"/> NO	19. <b>P/QA REP.:</b> <i>Mary Ann Forrest</i>		20. <b>DATE:</b> 4/15/96
21. <b>P/QA MANAGEMENT REVIEW:</b> <i>Chris Sutton</i>		POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO	
22. <b>DATE:</b> 4/15/96		23. <b>P/QA DIV. MANAGER:</b> (CARs Only)	
24. <b>DATE:</b>		23A. <b>REPORT TO NTS:</b>   YES   <input checked="" type="checkbox"/> NO	
25. <b>RESPONSIBLE MANAGER RESPOND BY:</b> (Date)		23B. <b>PAAA COORDINATOR:</b>	

(P/QA Representative obtains the Nonconformance Report Number from the PQA Nonconformance Administrator and enters the number in Block 1 above)

Responsible Manager's Response

(Must Complete All Blocks 26 through 35)

USE ADDITIONAL SHEETS AS NECESS

26. PROPOSED DISPOSITION AND CORRECTIVE ACTION	<input type="checkbox"/> Accept-As-Is	<input type="checkbox"/> Rework	<input type="checkbox"/> Repair	<input type="checkbox"/> Reject	<input checked="" type="checkbox"/> Other
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(A disposition of "Accept-As-Is" and "Repair" requires a written Technical Justification attached to this form. The justification for "Accept-As-Is" or "Repair" resulting in Design changes shall include any documentation of Unreviewed Safety Questions (USQ) pre-screening, screening, and if necessary, a safety evaluation using NS-0002. What action will be taken to correct the identified nonconformance?)

See audit response for finding 4 in memo  
 M.M. ETS (ALS): 96-015.3 pp 3 and 4

Validation of spreadsheet has been  
 completed, as of May 10, 1996.

27. Technical Justification Approval Signature: <i>[Signature]</i>	Date: _____
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28. Disposition Results in Design Change <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	29. USQ/DCN Number: <i>[N/A]</i>	30. Proposed Completion Date: <i>May 10, 1996</i>
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31. Investigation of Similar Items and/or Processes for Presence of the Identified Nonconformance:

*all spreadsheets will be validated as they are developed, before sample results are reported.*

32. Measures Taken to Prevent Recurrence:

*see audit response*

33. Root Cause: (Required for CARs Only)

\_\_\_\_\_

34. Responsible Manager: <i>[Signature]</i>	35. Date of Response: <i>5/13/96</i>
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(After entering all of the above information, forward the Original of this form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

Evaluation of Proposed Disposition and Corrective Action

36. Quality Representative:	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	37. Date:
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(If the decision is to "Reject" the Responsible Manager's proposed disposition and/or corrective action, the Quality Representative shall contact the Responsible Manager to resolve the issues.) (Return the Original of the Form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

Completion of Disposition and Corrective Actions

38. Responsible Manager:	39. Date Action Completed:
--------------------------	----------------------------

(After completing all the proposed actions, sign and date in the above block and return the Original to the P/QA Nonconformance Administrator.)

Verification of Actions

40. Verification Action: (Describe when, where and what was done to verify the above actions were completed.)

\_\_\_\_\_

41. Quality Representative:	42. Date Verified:
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43. Quality Manager:	44. Date Closed:
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(After completion of all verification actions and closure of this report, return the Original to the P/QA Nonconformance Administrator, MAIL STOP 43.)

000076

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. <b>NONCONFORMANCE REPORT NUMBER:</b> (This number is assigned by The PQA Nonconformance Administrator.)		F96-006	
2. <b>TYPE OF NONCONFORMANCE REPORT:</b> Check <i>OBSERVATION</i> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation. An observation, if resolved, could lead to excellence in operations. Check <i>FINDING</i> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation. Check <i>DEVIATION</i> for hardware items when the condition represents a departure from specified requirements or specifications. Check <i>CORRECTIVE ACTION REPORT</i> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION <input type="checkbox"/> FINDING <input type="checkbox"/> DEVIATION <input type="checkbox"/> CORRECTIVE ACTION REPORT <input type="checkbox"/>	
3. <b>DATE DISCOVERED:</b> Enter the date the nonconformance was identified.		3. 3/28/96	
4. <b>RESPONSIBLE ORGANIZATION:</b> Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. <u>Low Tech Serv</u> 4b. <u>ALS</u>	
5. <b>RESPONSIBLE MANAGER:</b> Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. <u>Chris Sutton</u> 5b. <u>        </u>	
6. <b>LOCATION:</b> Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. <u>On-Site Lab/Howe</u> 6b. <u>&lt; HC 3</u>	
7. <b>ASSESSMENT ACTIVITY:</b> Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit 195-19, QEP Number, Walk-through, etc.)		7. <u>Audit I96-09</u>	
8. <b>REQUIREMENTS:</b> (Identify and Quote the requirement directly from the documents (procedures, specifications, drawing, etc.) that best describes the acceptance criteria for the item or activity)			
RM-0012 8.5.5 Measuring and test equipment is to be calibrated against standards having an accuracy that will ensure that the equipment will be within required tolerances.			
9. <b>NONCONFORMANCE:</b> (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
5. Calibration standards do not have a greater accuracy than the standards being calibrated; Calibration shall expire on standards. See Audit Report I96-09 for examples.			
10. <b>PREPARED BY:</b> <u>Mary Ann Forrest</u>		11. Phone: <u>5387</u>	12. Mail Stop: <u>43</u>
13. Date: <u>4/15/96</u>			

### PERFORMANCE QUALITY ASSURANCE EVALUATION

14. <b>QUALITY ASSURANCE PROGRAM REQUIREMENT:</b> ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. <u>DM-0012, 8.5.:</u>	
15. <b>DIVISION/DEPARTMENT REQUIREMENT:</b> ( Enter the documents number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as the Paragraph, etc.)		15. <u>        </u>	
16. <b>NOTIFICATION:</b> (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. <u>3/28/96</u>	
17. <b>TRENDING INFORMATION:</b> (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g. 10 F ii)		17. <u>3.0 C ii; ii</u>	
18. TAGGING REQUIRED:   YES   NO	19. PQA REP.: <u>Mary Ann Forrest</u>		20. DATE: <u>4/15/96</u>
21. PQA MANAGEMENT REVIEW: <u>        </u>		POTENTIAL PAAA:   YES   NO	
23. PQA DIV. MANAGER: (CARs Only) <u>        </u>		24. DATE: <u>        </u>	
23A. REPORT TO NTS:   YES   NO	23B. PAAA COORDINATOR: <u>        </u>		23C. DATE: <u>        </u>
(PQA Representative obtains the Nonconformance Report number from the PQA Nonconformance Administrator and enters the number in Block 1 above)		25. RESPONSIBLE MANAGER RESPOND BY: (Date)	

# NONCONFORMANCE RESOLUTION

Report Number: **672**

(Required for Findings, Deviations and Corrective Action Reports) Revision: \_\_\_\_\_

## Responsible Manager's Response

(Must Complete All Blocks 26 through 35)

USE ADDITIONAL SHEETS AS NECESS

26. PROPOSED DISPOSITION AND CORRECTIVE ACTION | | Accept-As-Is | | Rework | | Repair | | Reject  Or

(A disposition of "Accept-As-Is" and "Repair" requires a written Technical Justification attached to this form. The justification for "Accept-As-Is" or "Repair" resulting in Design changes shall include appropriate documentation of Unreviewed Safety Questions (USQ) pre-screening, screening, and if necessary, a safety evaluation using NS-0002. What actions will be taken to correct the identified nonconformance?)

*See audit response for Finding 5 in memo  
M.M. STS (ALS): 96-0153 pp 4 and 5*

27. Technical Justification Approval Signature: |  N/A

Date:

28. Disposition Results in Design Change  
| | Yes | | No

29. USQ/DCN Number: |  N/A

30. Proposed Completion Date:

*August 30, 1996*

31. Investigation of Similar Items and/or Processes for Presence of the Identified Nonconformance:

*none*

32. Measures Taken to Prevent Recurrence:

*see audit response*

33. Root Cause: (Required for CARs Only)

34. Responsible Manager: *[Signature]*

35. Date of Response: *5/13/96*

(After entering all of the above information, forward the Original of this form to the PQA Nonconformance Administrator. MAIL STOP 43.)

## Evaluation of Proposed Disposition and Corrective Action

36. Quality Representative:

| | Accept | | Reject

37. Date:

(If the decision is to "Reject" the Responsible Manager a proposed disposition and/or corrective action, the Quality Representative shall contact the Responsible Manager to resolve the issues.)  
(Return the Original of the Form to the PQA Nonconformance Administrator. MAIL STOP 43.)

## Completion of Disposition and Corrective Actions

38. Responsible Managers:

39. Date Action Completed:

(After completing all the proposed actions, sign and date in the above block and return the Original to the PQA Nonconformance Administrator.)

## Verification of Actions

40. Verification Action: (Describe when, where and what was done to verify the above actions were completed.)

41. Quality Representative:

42. Date Verified:

43. Quality Manager:

44. Date Closed:

(After completion of all verification actions and closure of this report, return the Original to the PQA Nonconformance Administrator. MAIL STOP 43.)

The Original of this Report is Yellow and Must be Sent to Performance Quality Assurance

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# NONCONFORMANCE RESOLUTION

Report Number **72**

(Required for Findings, Deviations and Corrective Action Reports)

Revision: \_\_\_\_\_

## Responsible Manager's Response

(Must Complete All Blocks 26 through 35)

USE ADDITIONAL SHEETS AS NECESS

26. PROPOSED DISPOSITION AND CORRECTIVE ACTION	<input type="checkbox"/> Accept-As-Is	<input type="checkbox"/> Rework	<input type="checkbox"/> Repair	<input checked="" type="checkbox"/> Reject	AT OI
--	---------------------------------------	---------------------------------	---------------------------------	--	-------

(A disposition of "Accept-As-Is" and "Repair" requires a written Technical Justification attached to this form. The justification for "Accept-As-Is" or "Repair" resulting in Design changes shall include any documentation of Unreviewed Safety Questions (USQ) pre-screening, screening, and if necessary, a safety evaluation using NS-0002. What action will be taken to correct the identified nonconformance?)

See audit response for Finding #6 in memo  
M.M: ETS (ALS): 96-0153 pp. 5 and 6

27. Technical Justification Approval Signature: <i>[Signature]</i>	Date: _____
--	-------------

28. Disposition Results in Design Change <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	29 USQ/DCN Number: <i>[N/A]</i>	30. Proposed Completion Date: <i>May 30, 1996</i>
---	---------------------------------	--

31. Investigation of Similar Items and/or Processes for Presence of the Identified Nonconformance:

*none*

32. Measures Taken to Prevent Recurrence:

*see audit response*

33. Root Cause: (Required for CARs Only)

\_\_\_\_\_

34. Responsible Manager: <i>[Signature]</i>	35. Date of Response: <i>5/13/96</i>
---	--------------------------------------

(After entering all of the above information, forward the Original of this form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

## Evaluation of Proposed Disposition and Corrective Action

36. Quality Representative:	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	37. Date:
-----------------------------	---	-----------

(If the decision is to "Reject" the Responsible Manager's proposed disposition and/or corrective action, the Quality Representative shall contact the Responsible Manager to resolve the issue.)  
(Return the Original of the Form to the P/QA Nonconformance Administrator, MAIL STOP 43.)

## Completion of Disposition and Corrective Actions

38. Responsible Manager:	39. Date Action Completed:
--------------------------	----------------------------

(After completing all the proposed actions, sign and date in the above block and return the Original to the P/QA Nonconformance Administrator.)

## Verification of Actions

40. Verification Action: (Describe when, where and what was done to verify the above actions were completed)

\_\_\_\_\_

41. Quality Representative:	42. Date Verified:
-----------------------------	--------------------

43. Quality Manager:	44. Date Closed:
----------------------	------------------

(After completion of all verification actions and closure of this report, return the Original to the P/QA Nonconformance Administrator, MAIL STOP 43.)

*[Handwritten mark]*

**The Original of this Report is Yellow and Must be Sent to Performance Quality Assurance**



**FLUOR DANIEL FERNALD  
FERNALD ENVIRONMENTAL MANAGEMENT PROJECT**

**P. O. Box 538704  
Cincinnati, Ohio 45253-8704  
(513-648-3000)**

**D R A F T**

**AUDIT I97-14**

**QUALITY ASSURANCE AUDIT  
OF  
ANALYTICAL LABORATORY SERVICES  
FERNALD, OH**

**February 18 - 21, 1997**

**By**

**William Kelley, Lead Auditor (QA)  
Denise Arico, Auditor  
Tom Cox, Auditor  
Jim Cross, Auditor (QA)  
Dave Madsen, Auditor (QA)  
Chris Olbur, Auditor  
Lydia Boada-Clista, Auditor (DOE)**

**Fluor Daniel Fernald (FDF)**

**QUALITY ASSURANCE INTERNAL AUDIT I97-14  
ANALYTICAL LABORATORY SERVICES  
Fernald, OH**

AUDIT I97-14

Date of Audit: February 18 -21, 1997

Report Date: March 17, 1997

**AUDITOR REVIEW:**

William D. Kelley, Lead Auditor, Project QA Engineer, RDQ \_\_\_\_\_ DATE

**AUDIT APPROVAL**

Wes Jackson, Program Team Leader, \_\_\_\_\_ DATE

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**PURPOSE OF AUDIT:**

To assess the adequacy and effectiveness of the Analytical Laboratory Services Management Systems for administration, safety and operating program. Evaluate the state of implementation for the stated program requirements. Since the majority of analytical data produced under the provisions of the FDF contract is subject of legal scrutiny, FDF is required to conduct evaluations to assure that analytical processes and data reports are produced under a high degree of quality and ethical conduct.

**AUDIT SCOPE:**

Verify that Analytical Laboratory Services activities are performed in accordance with requirements outlined in FDF's Quality Assurance Plan (Document RM-0012), and FDF's Sitewide CERCLA Quality Assurance Project Plan (SCQ, Document FD-1000), Analytical Laboratory Services QA Manual and procedures, FDF Conduct of Operations Program (CONOPS, Document RM-0029), FDF Radiological Requirements (Document RM-0020), and the Laboratory Chemical Hygiene Plan (Document RM-3001). Analyses are required to support the site characterization and remediation programs at the FDF site.

The scope of this audit has been expanded relative to prior years with the combining of the Health and Safety and CONOPS disciplines as well as the QA discipline into one rather than several audits. This is the process resulting from the 1996 re-engineering efforts to achieve greater efficiency and effectiveness.

**AUDIT CONCLUSIONS:**

ALS has developed and implemented Management Systems, as required by the SCQ (Section E.2.1 Approved Laboratory Requirements), to effectively provide analytical services. ALS is considered as an acceptable supplier of analytical services. The FDF audit team recommends that ALS be kept on the list of approved labs (See SCQ, Section E.2.3).

**CONDUCT OF AUDIT:**

An Audit Plan was prepared and sent to ALS on January 22, 1997. The auditors and designated ALS representatives participated in the opening meeting held at 9:00 AM, February 18, 1997 at the Large Lab Conference Room of the Laboratory Building.

Interviews/discussions were conducted with various laboratory personnel and coaches. ALS Program Plans, Procedures, and Record Files were reviewed and laboratory operations, health and safety practices, and waste management activities were observed.

The following people were interviewed during conduct of audit activities (\*Opening, §Closing Meeting Attendees):

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<u>NAME</u>	<u>ALS TITLE</u>
Ray Danahy *,§	Team Leader, Isotopic Lab
Mike Feller *,§	Team Leader, Uranium/Thorium Lab
Amy Meyer *,§	ALS Coach (Acting)
Ervin O'Bryan *,§	Team Leader, Inorganic Lab
Debbie Reichard *,§	ALS QA Officer
Lee Ann Stroud *,§	ALS Sample Coordinator
Dawn Webber	Team member
Chari Stevens	Team member
Larry Evans	Team member
Janet Angert	Team member
Donna Lake	Team member
Pat Stoy	Team member
Ben Russell	Team member
Neal Vacchiano	Team member
Tom Granat	Team member
Carl Bishop	Team member
Jane Wise	Team member
Mark Durrrough	Team member
Joanie Martinez	Team member
Kathy Fisher	Team member
Lisa Leick	Team member
Krista Blades	Team member
Ruthie Bolton	Team member

An audit close out meeting was conducted at 1:00 PM, 2/21/97 in the ALS Conference Room.

#### AUDIT DETAILS:

Twelve findings and eighteen observations were identified by the Audit Team. Evaluation details are structured so that they directly correlate to the criteria and requirements, as outlined in FDF's Quality Assurance Program, Document RM-0012.

#### 1. PROGRAM

The ALS organization provides a framework for operating ALS's management systems in a manner that effectively supports FDF's quality program requirements. All ALS employees are formally committed to adhere to a high standard of ethics. ALS produces monthly and annual Technical Performance Indicator reports to summarize the accuracy and timeliness in reporting Performance Evaluation Programs (PEP) results. These programs consist of: Analytical Products Group (APG), USEPA, DOE-EML, Asbestos, Urine QC, and the Interlaboratory Data Comparability program. ALS maintains a distribution list for all the PEP reports.

ALS's Program Control Documents (including Quality Assurance Plans and Procedure Documents) show that ALS is committed and can effectively provide program controls, as required, for processing low level radioactive samples for radiochemical analyses.

ALS's Safety and Health Operations Manual was found to meet FDF program requirements. Requirements outlined in the respective chemical, radiological safety, and waste management manuals appear to be effectively implemented. 672

There is one finding (Attachment 1) related to Criterion 1. There are no observations (Attachment 2).

## 2. PERSONNEL TRAINING AND QUALIFICATION

In general, program controls have been implemented to assure analyst proficiency in performing specific methods/procedures. During the interviews it was very evident that analysts were well trained by the professional and enthusiastic attitude that was exhibited. ALS's required quality levels for work are detailed in job descriptions showing minimum education and training requirements for each position. Some improvement is needed to resolve the problem with the proper location of personnel files.

Personnel qualification and safety training records were found to meet FDF requirements which are basically those requirements, as specified in OSHA 29 CFR 1910.1450.

There is one finding (Attachment 1) related to Criterion 2. There is one observation (Attachment 2).

## 3. QUALITY IMPROVEMENT

ALS Program Documents include provisions (ALS-QAMP) that make every employee responsible for quality improvement. Provisions for identifying areas for improvement are included in self-appraisals (QC or PE samples), internal audits, and external audits. Responsibilities are assigned for establishing and implementing processes to detect, control, correct, and prevent quality problems and to promote quality improvement.

Control charts were examined and found adequate. The use of computer spreadsheets in the radiological labs for QC information is excellent as is the calibration documentation and information. All analytical groups have initiated and are using to varying degrees control charts for at least most of the SCQ required QC requirements. The Radiological labs incorporate the control charts directly into the data reduction/review/data package generation process. Other groups are not as far along. ALS is commended for the significant strides made to date. There are no findings (Attachment 1) related to Criterion 3. There are no observations (Attachment 2).

## 4. DOCUMENTS AND RECORDS

ALS Program Documents provide systematic methods for controlling preparation, issuance, use, and revision of program control documents. In general, records that furnish documentary evidence of quality are specified, prepared, maintained, and protected against damage, deterioration, or loss. There are some records problems related to the past re-organization and some other isolated incidents that need resolution. There are five findings (Attachment 1) related to Criterion 4. There were four observations

(Attachment 2).

5. WORK PROCESSES

In general, ALS has prepared and implemented program control documents, as required, to assure that work is performed under controlled conditions using technical standards, instructions, procedures or other appropriate means of detail commensurate with the complexity and risk of the work.

The radiological laboratories have made tremendous progress in updating required laboratory procedures and eliminating unnecessary, unused and outdated procedures. The labs are clean and orderly. A review of the procedures indicated that all have been validated and are current. A laboratory administrative system is in place to keep track of requested analyses and a review process used where laboratory supervisors approve laboratory results prior to the transmittal to the customer.

Maintenance and calibration programs for analytical instrumentation are documented and were found to be in compliance with program requirements. There are four findings (Attachment 1) related to Criterion 5. There are nine observations (Attachment 2).

6. DESIGN

In general, ALS has developed program controls to assure that data collection systems, computer programs and software function, as intended. Procedure documents have been prepared and effectively implemented for computer program documentation and for software control/security. There are no findings (Attachment 1) related to Criterion 6. There are no observations (Attachment 2).

7. PROCUREMENT

ALS has developed and implemented program controls, as required, to effectively control purchased materials and services. Program controls include assignment of responsibility for the post-purchasing control of materials, equipment, and services. The lab tracks vendors as to quality of supplies. There are no findings (Attachment 1) related to Criterion 7. There are no observations (Attachment 2).

8. INSPECTION AND ACCEPTANCE TESTING

ALS has developed and implemented program controls, as required, for performing inspections and tests to assure that analytical systems are effectively functioning. Acceptance tests and performance criteria are required during instrument calibration processes. In general, laboratory instrument/equipment calibration and maintenance activity are documented in log books maintained for each instrument. The audit team's examination of external PEP data confirmed the effectiveness of the laboratory's program. There is one finding (Attachment 1) related to Criterion 8. There were three observations (Attachment 2).

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9. MANAGEMENT ASSESSMENT

ALS effectively promotes the concept that "Quality Is Everyone's Job". ALS's QA Officer is responsible for resolving quality issues, as they are identified, with laboratory management. External audits and analytical performance evaluation results are regularly reviewed by the ALS Lab Coach, QA Officer, and Laboratory Team Leaders. There are no findings (Attachment 1) related to Criterion 2. There is one observation (Attachment 2).

10. INDEPENDENT ASSESSMENT

ALS has developed and implemented program requirements for conduct of internal self assessments. Systems and operational audit/inspections are conducted on a scheduled basis and formal reports are issued to Management. Non-conformances are identified and tracked to closure. Regulatory agency and QA audits provide fully independent assessments. There are no findings (Attachment 1) related to Criterion 10. There are no observations (Attachment 2).

**ATTACHMENT 1- FINDINGS**

**Requirement**

RM-0012, 1.2.6 - "Senior management shall retain and exercise the responsibility for the scope and implementation of an effective QA Program."

RM-0012, 1.3.3 - "Managers of FERMCO Organizations shall:

8th bullet . . . Ensure, for all assigned work, that the management controls shall include the establishment of responsibilities and the identification of lines of communication.

RM-0012, 5.2.2 - "Work shall be performed to established technical standards and administrative controls."

**Finding F97-14-1**

The scope of 257-D-0026, "ALS Quality Assurance Management Plan" (issued May 16, 1996) does not match the new organization. Re-engineering with the separation of Sample Management Office functions from ALS was formally approved at least by August 28, 1996 with the approval of the FDF organizational chart by Chuck Little for John Bradburne. ALS issued a CIO AC96-0146 on December 19, 1996 relative to shift turnover for a new Section, 5.3.8. Other procedures that greatly impact ALS were organizationally out of date and seemed to go unreviewed. These include SOP 766-S-3001, "ADM Release Completion Assessment" and SOP 766-S-3004, "Document Tracking and Control within ADM."

**Requirement**

RM-0012, 2.2.2 - "All personnel shall be capable of performing their assigned tasks. Training plans shall be developed for all personnel. The training identified in the plans shall prepare the employee to perform the job, as well as, maintain and promote progressive improvement and employee satisfaction. Qualification requirements (experience, education, and training) shall be documented for each position as required."

SOP 257-D-0026, ALS-QUALITY ASSURANCE MANAGEMENT PLAN, 2.2, ¶ 2 - "Position Descriptions define the levels of education and experience that are mandatory for each position in the ALS Department. Candidates shall meet or exceed the listed requirements. Personnel files are maintained by the ALS QA Officer."

SOP 257-D-0026, ALS-QUALITY ASSURANCE MANAGEMENT PLAN, 2.6 - "Training Coordinator shall be responsible for the following:

- Maintaining training records for ALS Department Personnel.
- Maintaining Analyst Method Certification files.
- Maintaining Profile for Needed Training and Compliance status for ALS Department personnel.
- Schedule required training for ALS Department Personnel."

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ATTACHMENT 1- FINDINGS

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**Finding F97-14-2**

The following are examples of current practices in record keeping that are not in compliance with the above requirements:

- The ALS QA Officer does not maintain personnel files which define the levels of education and experience for each employee within ALS.
- The ALS Training Coordinator is not maintaining Analyst Certification files. The ALS QA Officer is currently performing this function.
- Certification records for Mr. Rao Paturi were discovered in the possession of the Inorganic Laboratory Team Leader.
- The records for analytical balance training are kept in Janet Angert's files and not in anyone's personnel file.
- The files maintained by the QA officer contain only certifications and do not contain the complete training records of each individual.

**Requirement**

RM-0012, 4.2.5 - "A system shall be established for implementation of processes to ensure that records are specified, prepared, legible, reviewed, approved, and maintained to accurately reflect completed work."

SOP 257-D-0026, ALS-QUALITY ASSURANCE MANAGEMENT PLAN, 4.6.1 - "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 preparation date."

**Finding F97-14-3**

The following are examples of incomplete records and inadequate review:

- A "Release Completion Checklist" is being utilized by the Document Control organization to review release files for completion. This checklist contains various criteria of items that may or may not be included in a release file. If an item listed on the checklist does not apply to a particular release being reviewed, the line is left blank. It would appear that information was missing from the release file when in fact it was not applicable (ie, a validation summary is not applicable for all releases).

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## ATTACHMENT 1- FINDINGS

- SOP 766-S-3001, Analytical Data Management Release Completion Assessment, section 9.3, states "Proofread work done by other personnel (Independent Verification). Clarify and correct unclear and incorrect documentation as soon as possible." A concurrence review is not being performed after a release completion is performed.

### Requirement

RM-0012, 4.2.6 - "The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability. . . . Evidentiary records shall have appropriate procedures controlling media type, chain of custody, and confidentiality." (See also SCQ, Sections 7.2.1.1, #8 and E.4.1)

CIO AC97-0007 "Analytical Laboratory Services (ALS) Internal Chain of Custody", Step 5.4: "ALS sample custody will be maintained electronically in the FACTS system." and Step 8.3: "When an analyst begins analysis of a sample, update the ICOC records in FACTS. All the information in Section 8.1.2 must be recorded either in the computer system or on a handwritten transfer logsheet."

### Finding F97-14-4

Analyst are not consistently barcoding their name into the FACTS when beginning the analysis of a sample. If "update" refers to a "placing" function, then "activation" should at least be described in another SOP. None of SOPs 257-D-0024, 766-S-3001, nor 766-S-3004 describe the "activation" step. It seems the simplest solution would be to include it in the "update" statements described in steps 8.3 and 8.1.2 of CIO AC97-0007. If performing step 8.3 as presently stated satisfies the "accountability" and "traceability" described in RM-0012, paragraph 4.2.6, which would link an analyst to the results, then it was apparently not clear to ALS personnel how to query this information from the FACTS.

### Requirement

RM-0012, 4.2.6 - "The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

### Finding F97-14-5

The following are examples of lack of accountability and traceability of records:

- There was no documentation of the training of personnel on this new CIO AC97-0007 (i.e. attendance roster). There was no sign off sheet for the review of the CIO by personnel, either.
- There were no evidentiary records for verification of software calculations for control charts on file. Debbie Reichard maintains control charts (SOP

ATTACHMENT 1- FINDINGS

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7501) for the Uranium and Thorium Analysis and Inorganic labs using LOTUS software. She has verified the program calculations but failed to keep them on file for audit review. The charts are utilized by giving plots to each lab for their real time plotting (last 4 pts) of internal QC. The Radiological lab maintains its own charts.

**Requirement**

RM-0012, 4.2.6 - "The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability. Care shall be taken to ensure that the requirements of NARA, applicable standards and any additional statutory requirements are met.

Evidentiary records shall have appropriate procedures controlling media type, chain of custody, and confidentiality."

**Finding F97-14-6**

The following are incidents of inadequate protection of stored data from fire:

- Original data was being maintained in room E-37 in a cabinet that was not fireproof.
- Original data was being maintained in room E-39 in cardboard boxes. This room was found not to be a fire rated file room.

**Requirement**

SOP 766-S-3004, 8.1 - "Document Control maintains a sign-out process for all original documents. An internal chain of custody will be used to record the person in possession of the documents, and the date the documents were removed/returned to Document Control. The intent is that once a release folder is received Document Control there will be a place-holder for that release file at all times. Even if the entire folder is removed, the internal chain of custody will remain in place for accountability."

**Finding F97-14-7**

An internal chain of custody is not being used as a place holder when a release file or documents from within a release file were removed from Document Control. Check-out sheets were developed and are starting to be used but were being maintained in a 3-ring binder.

**Requirement**

RM-0012, 5.2.2- "Work shall be performed to established technical standards and administrative controls. Work shall be planned, authorized and accomplished under controlled conditions using technical standards, instructions, procedures or other appropriate means of detail commensurate

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**ATTACHMENT 1- FINDINGS**

with the complexity and importance of the work."

**Finding F97-14-8**

There is no checklist or procedure describing what the analyst is to check for when reviewing data. Raw data is peer reviewed using the analytical method descriptions of required QC and limits. SOP 257-D-0024, "Management and Reporting of Analytical Laboratory Results", describes the minimum requirements for data entry but not for lab activities.

**Finding F97-14-9**

The procedure 256-S-3014, "The Radiometric Determination of Total Radioactivity in various Matrices", for the preparation of samples for Gross Alpha/Beta analysis does not provide guidance or instruction to:

- Ensure weight stabilization of sample planchets during initial (tare) and final (gross) weighings of the planchet. When the hot, flamed planchet cools down, it absorbs moisture from the air. This absorption of moisture may cause large weighing errors.
- Identify (numbering or marking) sample planchets between the time the initial (tare) weight is obtained and the final (gross) weight is taken. Multiple steps between weighings offer several opportunities for sample misidentification.

**Requirement**

RM-0012, Section 5.3.2 - "A system for identification and control of items shall be established to ensure their proper use and traceability." RM-0012, Section 4.2.5: "A system shall be established for implementation of processes to ensure that records are....maintained to accurately reflect completed work."

**Finding F97-14-10**

In room 192, an undated set of mercury standard solutions made up presumably from a concentrated purchased standard was discovered. Inspection of the mercury standard preparation log revealed that the preparation of these standards was not recorded. Additionally, there was no appropriate log book for the balance in room 175. While this was corrected during the audit, the new book does not replace any potentially missing data.

**Requirement**

RM-0012, Section 5.5.1 - "A system shall be established for the implementation of a process to control the calibration, maintenance, and use of measuring and test equipment used for

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ATTACHMENT 1- FINDINGS

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monitoring and data collection."

SCQ, Section 14.6 - "Method Detection Limits shall be determined according to procedures specified in Appendix B of 40CFR136.."

**Finding F97-14-11**

~~Both ICP/MS instruments were inspected. No MDL or IDL determinations were performed as required.~~

**Requirement**

RM-0012, Section 8.5.4 - "Documentation showing traceability to standards shall be maintained for each piece of measuring and test equipment." RM-0012, Section 5.5.1: "A system shall be established for the implementation of a process to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection."

**Finding F97-14-12**

The weights in room 165 (the sample preparation room) had not been checked against a set of certified weights.

**ATTACHMENT 2 - OBSERVATIONS**

**Requirement**

RM-0012, 2.2.2 - "All personnel shall be capable of performing their assigned tasks. Training plans shall be developed for all personnel. The training identified in the plans shall prepare the employee to perform the job, as well as, maintain and promote progressive improvement and employee satisfaction. Qualification requirements (experience, education, and training) shall be documented for each position as required."

**Observation O97-14-1**

Two ALS personnel out of compliance for site required training. The personnel were identified to management and scheduled for training.

**Requirement**

RM-0012, 4.2.3 - "A system shall be established to ensure that controlled documents are distributed to and used by personnel performing work."

**Observation O97-14-2**

The main ALS procedure book stand location is not obviously identified in the hall way outside of E-31, or on the second floor location either. The E-31 location is also not obviously identified within the E-31 area.

**Requirement**

RM-0012, 4.2.5 - "A system shall be established for implementation of processes to ensure that records are specified, prepared, legible, reviewed, approved, and maintained to accurately reflect completed work."

**Observation O97-14-3**

No records were available to demonstrate that the OJT Instructors that were used to implement the ALS procedure 257-D-0007, "Training, Qualification, and Certification of ALS Department Scientists, Chemists, and Technicians" had either been trained for this function, per site procedure TR-0003, "Instructor Qualification", or had been granted an exemption/waiver form the training by the Training Department per TR-0001, "Exemption from Initial Training." There was no apparent evidence of impact on the quality of the training.

SOP 257-D-0007 (Issued 08-26-94) is in direct violation of the intent of TR-0003. SOP 257-D-0007" describes a process by which scientists, chemists, and technicians become certified by ALS management to independently perform tasks and analyses." It also describes the requirements for and the process of periodic recertification of ALS personnel to ensure they remain capable and qualified to perform analytical tasks. Paragraphs 3.5 (OJT) & 3.12 (Trainer Definition) do

**ATTACHMENT 2 - OBSERVATIONS**

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not adhere to the training team's definitions found in TR-0003 "Instructor Qualification" Issued 1-11-96: Paragraphs, 9.1 "Departmental Specific Training;" and 9.2 "Formal Training." (NOTE: what ALS has really described within the existing SOP 257-D-0007, is a mentoring program; and that SOP does not constitute a viable training program.)

**Requirement**

RM-0012, 4.2.6 - "The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability. Care shall be taken to ensure that he requirements of NARA, applicable standards and any additional statutory requirements are met.

Evidentiary records shall have appropriate procedures controlling media type, chain of custody, and confidentiality."

SOP 257-D-0026, ALS-QUALITY ASSURANCE MANAGEMENT PLAN, 4.7.2 - "Write release number in log book, log into WISDM."

**Observation O97-14-4**

A log book was not being maintained to track release folders as they were received from the Sample Processing Laboratory (SPL) into Document Control..

**Requirement**

RM-0012, 4.2.12 - "All records management systems shall have schedules for records retention and disposition in accordance with the requirements of NARA and DOE 1324.2; Records Disposition."

SOP 257-D-0026, ALS-QUALITY ASSURANCE MANAGEMENT PLAN, 4.12.1 - "On-site data packages are stored for a period of one year in ALS. Off-site data packages go directly to data storage after validation and are archived according to the SCQ requirements."

**Observation O97-14-5**

SOP 766-S-3004, Document Tracking and Control Within Analytical Data Management, section 8.2, states "...Data will be maintained for 6 months following delivery to the customer...". There is a contradiction in data storage between the ALS-QUALITY ASSURANCE MANAGEMENT PLAN and the SOP.

**Requirement**

RM-0012, 5.2.1 - "Work related instructions, procedures, and other forms of direction shall be developed, verified, validated and approved by technically competent personnel, and shall be

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**ATTACHMENT 2 - OBSERVATIONS**

provided to employees doing the work."

**Observation O97-14-6**

Ben Russell Lab Facilities Services Supervisor does not have a controlled copy of the SS/EW SOP 257-D-0021, mentioned previously.

**Requirement**

RM-0012, 5.2.2 - "Work shall be performed to established technical standards and administrative controls. Work shall be planned, authorized and accomplished under controlled conditions using technical standards, instructions, procedures or other appropriate means of detail commensurate with the complexity and importance of the work."

**Observation O97-14-7**

The closure of outlier results from QC samples in the Performance Evaluation Programs (PEP) has not been proceduralized. The procedure 257-D-0023, "Analytical Laboratory Services Operations Non-conformance" is used to document non-conformances in lab processes such as internal QC outliers and sample problems, but not for the PEPs. Debbie Reichard is in charge of the tracking system for -0023 but the team leaders are responsible for tracking closures on the PEPs.

**Requirement**

MS-1001, FERMCO Site Procedure System, Section 4.2 states that the "Subject Expert (SE)-Prepares procedures in accordance with this procedure."

**Observation O97-14-8**

CIOs, METHs, and SOPs pertaining to the ALS team have listed a PTR, (Procedure Technical Representative). This is not consistent with the current site procedure, MS-1001, on how to write and review a procedure.

**Requirement**

RM-0012, Section 5.2.2 - "Work shall be performed to established technical standards and controls."

SOP 7506, "Logkeeping", section 8.10, requires quarterly review of logbooks by the ALS Team Coach or designee.

**Observation O97-14-9**

Calibration, preparation and balance logbooks were examined. Several were noted

**ATTACHMENT 2 - OBSERVATIONS**

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where the quarterly frequency was not met. Specific examples include balance logbook #4359 in room 168 (not reviewed since 3/25/96), balance log #4116 in room 172 (not reviewed since 8/9/96), and logbook 96-027 in room 192 (lapse of 6 months between 5/96 and 11/96).

**Requirement**

RM-0012, 5.2.2 - "Work shall be performed to established technical standards and administrative controls. Work shall be planned, authorized and accomplished under controlled conditions using technical standards, instructions, procedures or other appropriate means of detail commensurate with the complexity and importance of the work."

RM-3001, Laboratory Chemical Hygiene Plan, 7.1.2.d - " When using in-service hoods, sashes must be pulled down to or below the indicated height for acceptable air flow, as shown by the performance sticker."

**Observation O97-14-10**

Seven lab hood doors were left open above the maximum efficiency for face velocity marking, during the use of these hoods.

RM-3001, Laboratory Chemical Hygiene Manual, Section 5.1, states "Good housekeeping practices shall be followed to ensure an orderly, clean, working environment and to minimize unforeseen events and unwanted consequences."

**Observation O97-14-11**

The following are examples of observed practices that were not in compliance but were resolved during the audit:

- 5 month old samples, open to air, were sitting on a table in the XRF lab
- An eyewash station in Room 156 was blocked with clutter
- Perchloric acid bottles with dispensers were stored under a non-working hood in room 168

**Requirement**

RM-0012, 5.2.4 - "Managers shall review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement."

SOP 257-D-0021, "Inspection of Safety Shower Eyewash Stands in the Laboratory Building" Sections 8.5.4. and 8.6.2.

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## ATTACHMENT 2 - OBSERVATIONS

### Observation O97-14-12

The following are examples of observed practices that were not in compliance:

- In seven different lab rooms where there is a combination safety shower-eye wash stand; there was also found adjacent to and within the shower spray radius, a "formal bagged spill kit". In all seven cases this observation was resolved by simply moving the bagged spill kit far enough away from the safety shower spray radius as to prevent inadvertent damage to the spill kit from an activated safety shower.
- In seven of the lab rooms there was no obvious sign identifying the location of the safety shower-eye wash stand within the lab room.

### Requirement

RM-0012, 5.2.4 - "Managers shall review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement."

~~Ask Chris Olbur- Any SOP requirement, quote and section??~~

### Observation O97-14-13

Laboratory Rooms # 174 & # 175 are not accessible from the main laboratory hallway and are not clearly identified from within the hallway. Access to these two lab rooms is gained through laboratory Room # 147. There are no signs within lab room #147 that indicate the location of 174 /75. lab rooms.

### Requirement

RM-0012, 5.4.1 - "A system shall be implemented for a process to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration. Marking and labeling of items shall be maintained throughout packaging, shipping, handling, and storage."

### Observation O97-14-14

The following are examples of samples (Room 204) not being temporarily held/stored in a designated storage area and the their work analysis status not being specified when analysis is delayed:

- Several solids samples in plastic containers were stacked up on the sample receiving bench near the bar coder for a couple of days.
- The samples on the bench were not ordered or arranged for identification of the status of the analytical work such as received/logged, in process and completed. Samples requiring additional work were grouped together

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with completed and newly received samples

- Samples on two "rad" carts awaiting analysis were "parked" in Laboratory 204, partially blocking the back aisles. One cart of Thorium samples (according to dates on the samples) had been there for some time. The samples on this "rad" cart could contribute to the general lab background and to the background of the adjacent LB-4100 Counter in the "counting/office area" of 204.

**Requirement**

RM-0012, Section 8.3.4 - "Administrative controls and status indicators such as tags and labels are to be used to....prevent inadvertent operation of an item."

**Observation O97-14-15**

The maintenance log for the Plasma-Spec 2.5 ICP (room 163) was inspected, and it was discovered that it was over six months out of date. Laboratory personnel stated that the instrument was out of service. However it was not tagged in any way. Also, a historic Mettler balance in the XRF lab was discovered with no calibration tags. Again laboratory personnel stated that this balance was out of service. However, this balance also was not tagged. Note that these two specific situations were corrected during the audit.

**Requirement**

RM-0012, Section 8.5.3 - "Measuring and test equipment is to be calibrated at specified intervals..." RM-0012, Section 5.2.2 - "Work shall be performed to established technical standards and controls."

CIO AC96-0099 (procedure 257-D-0008, section 8.13.2.1) states that pipette calibration shall be verified at least once each month.

**Observation O97-14-16**

The pipette calibration logs in room 192 were examined. It was noted that the monthly calibration frequency had not been met, as the pipettes had been calibrated six times between 1/16/96 and 2/12/97

**Requirement**

RM-0012, 8.5.4 - "Measuring and test equipment is to be calibrated at specified intervals (or immediately before or after use) on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance."

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**ATTACHMENT 2 - OBSERVATIONS**

**Observation O97-14-17**

Out of service equipment tags on unused equipment need to contain additional information to ensure that:

- The necessary calibrations are performed when the equipment is returned to service if the equipment has exceeded the posted calibration sticker date.

(Note: If one of the detectors in a compound (multiple) detection system is still in service, then the system calibration and maintenance needs to be up to date for the system or the entire system including the detector being used should be placed out of service.)

- Required preventive maintenance (PM) is performed if the equipment has exceeded the posted PM sticker date.

(Note: PM information needs to be qualified. If the PM was performed prior to placing the equipment out of service and the instrument has not been used, then PM may not be necessary but the PM sticker and log book entries need to be updated.)

**Requirement**

RM-0012. 9.2.2 - "Management assessments shall be conducted in accordance with a plan, and should focus on management elements that affect work processes, such as strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support.

**Observation O97-14-18**

**ALS Management Assessment Plan M:SWP(ALS):96-0097 of December 5, 1996 uses the Technical Performance Indicators but again December 12, 1996 combines indicators for areas no longer the responsibility of ALS such as TAT for offsite labs, RIR TAT and Offsite Missed Hold Times.**

ATTACHMENT 3 - DOCUMENTS REVIEWED

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General Documents Reviewed

- RM-0012. "Quality Assurance Program"  
FD-1000. "Sitewide CERCLA Quality Assurance Plan (SCQ)"  
RM-0020. "Radiological Requirements"  
RM-0029. "Conduct of Operations"  
RM-3001. "Laboratory Chemical Hygiene Manual"

Procedures Reviewed

- EW-0002. "Chain of Custody/ Request For Analysis Record For Sample Control"  
256-S-1001. "Determination of Gross Alpha and Gross Beta Activities in Water by Gas Proportional Counting"  
256-S-1010. "Operation and Performance Testing For 10-Channel Low-Level Alpha/Beta Proportional Counter Berthold LB-770".  
256-S-3001. "Operating Procedure For the Tennelec LB4100 Low Background  $\alpha/\beta$  Proportional Counter".  
256-S-3012. "Operation and Performance Testing of Tennelec LB-5100 Automatic Low Background Alpha/Beta Counting System".  
256-S-3014. "The Radiometric Determination of Total Radioactivity in Various Matrices".  
256-S-3015. "Radiometric Rapid Screening Method For Determination of Alpha and Beta Activity in Various Matrices".  
256-S-3023. "Sample Screening at the ALS Sample Processing Laboratory".  
257-D-0007. "Training, Qualification, and Certification of ALS Department Scientists, Chemists, and Technicians"  
257-D-0008. "Instrument and Equipment Repair, Calibration, and Preventative Maintenance Requirements"  
257-D-0015. "Preparation of Reagents and Standards"  
257-D-0021. "Inspection of Safety Shower Eyewash Stations"  
257-D-0023. "ALS Laboratory Operations Non-Conformance"

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**ATTACHMENT 3 - DOCUMENTS REVIEWED**

- 257-D-0024, "Management and Reporting of Analytical Laboratory Results".
- 257-D-0026, "Analytical Laboratory Services, Quality Assurance Management Plan".
- 7501, "ALS Control Chart Maintenance and QA Review Procedure"
- 7503, "Analytical Laboratory Services (ALS) Required Reading Program"
- 7506, "Logkeeping".
- 52-S-0020, "Laboratory Building Nuclear Materials Inventory"
- 52-S-1003, "Removal and Disposition of Non-radioactive Unused Chemicals"
- 766-S-3001, "Analytical Data Management Release Completion Assessment"
- 766-S-3004, "Document Tracking and Control Within Analytical Data Management"
- CIO AC97-0007, "Analytical Laboratory Services (ALS) Internal Chain of Custody"
- CIO AC96-0116, "Preparation of Radioactive Laboratory Liquid Wastes for Disposal"
- CIO AC96-0117, "Preparation of Radioactive Laboratory Solid Wastes for Disposal"
- CIO AC96-0118, "Analytical Laboratory Services (ALS) Project Document Program"
- CIO AC96-0137, "Control of Special Source Materials for the Analytical Laboratory Services Department"
- CIO AC96-0142, "Calibration Verification of Analytical Balances"
- CIO AC96-0143, "Preventative Maintenance for Analytical Balances and Weights"

Reports Reviewed

"Final Report, FEMP Internal Audit I96-09".



## INTEROFFICE MEMORANDUM

<b>To:</b>	Stephen J. Reutcke, MS81-3	<b>Date:</b>	June 15, 1995
<b>Location:</b>	Springdale	<b>Reference:</b>	N/A
<b>From:</b>	Chris Sutton, MS35 <i>CS</i>	<b>FERMCO #:</b>	M:ETS(ALS):95-0382
<b>Location:</b>	Fernald	<b>Client:</b>	DOE DE-AC24-92OR21972
<b>Extension:</b>	648-5441	<b>Subject:</b>	ALS Department Responses to Audit Report I95-10

c: File Record Storage Copy 106.4.14.11  
 Ray Danahy, MS35, Fernald  
 Alex Duarte, MS35, Fernald  
 Mary Ann Forrest, MS81-1, Springdale  
 Reinhard Friske, MS52-2, Fernald  
 John Harmon, MS52-2, Fernald

Harold Humphrey, MS35, Fernald  
 William Kelley, MS35, Fernald  
 Amy Meyer, MS35, Fernald  
 Mike Rolfes, MS35, Fernald  
 Nelson Weichold, MS35, Fernald

Attached are the ALS Department responses to findings and observations resulting from Audit I95-10 of the ALS Department. The attachment includes the wording of the entire finding/observation as given in I95-10, the wording of the associated requirement(s) cited in I95-10, and the ALS Department response.

Corrective actions for many of the findings and observations have already been completed. The remainder of most of the corrective actions will be complete by July 31, 1995. A few items either require no corrective actions or no corrective actions are necessary in the opinion of the ALS Department.

If you have any questions, please do not hesitate to call me at 648-5441. I will be the point of contact for any additional communications or actions pertaining to Audit I95-10.

CS:eab  
 Attachments

**FERMCO AUDIT I95-10**  
**FINDINGS AND RESPONSES**

**AF-95-0002**            Program Control Documents (Administrative and Methods SOPS) are not being issued in a timely manner. A list showing program control documents (new issues and changes) that are currently "in process" for change/issue was provided by ALS, Department Quality & Procedure Development. A cursory review of the listing shows that 13 requests (3 new issues and 10 changes) submitted during CY-1993 have not, as yet, been issued. The issue/change process needs to be more responsible to assure that activities are in compliance with program requirements.

**Requirement:**        The FERMCO QAPD, Document RM-0012 (Item 4.2.3), specifies that: "Timeliness guidelines shall be implemented for distribution of new or revised controlled documents."

**RESPONSE**            Recent changes initiated by the Compliance and Communication Section of the ETS Division to the ALS Department Document Program, 257-D-0014, dated 1/30/95, ensure that the issue/change process is more timely. To ensure documents are issued in a more timely manner, the following actions have been taken: 1) individuals involved in document development and processing are scheduled for training to the program document in July, 1995; 2) the processing of documents has been streamlined by having one signature authorization for a temporary change or a document cancellation, and formats established for document types. Furthermore, review requirements are identified on an individual document basis as part of the initiation of a new document or revision (see Attachment #1); 3) reports are transmitted to document owners on a monthly basis identifying overdue processing actions. **CORRECTIVE ACTION HAS BEEN COMPLETED FOR ITEMS 2,3) AND WILL BE COMPLETE FOR ITEM 1) BY JULY 31, 1995.**

**AF-95-0003**            There is no chain-of-custody record that documents the transfer of digestates from the radiological sample preparation area to the isotopic analysis area. Transfer of custody records of digestate samples needs to be routinely documented.

**Requirement:** FERMCO SCQ, Document FD-1000 (Item 7.2.1.1.8), specifies that: "Each laboratory must follow its established system for assure that sample custody is documented for all movements of both the sample and its extracts/digestates."

**RESPONSE** Transfers of digestates within the Radiologic and Isotopic Group will be documented by a note in the batch preparation log book with an accompanying signature under the note by the party acknowledging receipt of the samples. ALS reserves the right to change this practice to a computerized electronic tracking system (using the barcode system in FACTS) in the future. Such a system would record the person relinquishing the samples as well as the one receiving them. The Manager of the Radiologic and Isotopic Analysis Section will issue a policy memo to employees of that section providing the above information and implementation instructions. **CORRECTIVE ACTION WILL BE COMPLETED BY JULY 15, 1995.**

**AF-95-0004** Logbook #95-007 for Sample Preparation is not bound nor are the pages consecutively numbered. Also, sign off sheets within the log were incomplete.

**Requirement:** The ALS QAMP, Document CIO AC94-0109, Item 13.3.1. specifies that: "All logbooks are controlled documents and shall be bound, assigned a control number and have sequentially numbered pages."

**RESPONSE** Logbook #95-007 consists of General Binding Company (GBC) pages bound by the print shop during printing. The Print Shop considers this to be a bound notebook. The pages were numbered consecutively by EPM lab. The print shop was informed that from now on all customized logs need numbered pages. Sign off sheets within the log are now complete. Logbook assignments in EPM lab are attached (Attachment 2). **CORRECTIVE ACTION HAS BEEN COMPLETED**

**AF-95-0005** Thorium purifications are being performed from a draft revision to ALS SOP 256-S-2003.

**Requirement:** The FERMCO SCQ, Document FD-1000 (Item 4.4.3), includes requirements for providing and revision of controlled documents. The FERMCO QAPD, Document RM-0012 (Item 4.2.3) specifies that: "FERMCO shall ensure controlled documents are distributed to and used by personnel performing work."

**RESPONSE** Revision of ALS Method 256-S-2003, "Isotopic Analyses of Thorium in Various Matrices in Alpha Spectrometry" has been completed. The document is currently undergoing final typing, after which it will be authorized and distributed. Issuance of the document is scheduled for June 15, 1995. **CORRECTING ACTION WILL BE COMPLETED BY JUNE 15, 1995.**

**AF-95-0006** Error correction has shown some improvement during the past year, however, write-overs, obliterations, and undated corrections were present in most logs maintained in the radiochemistry lab. Notes in Logbook 4378 were not initialed and dated.

**Requirement:** The FERMCO SCQ (Document FE-1000), Item 4.4.2.1, second paragraph, states: "corrections [to records] shall be made by drawing a single line through the incorrect information on hard copies, making the correct entry, and initialing and dating the revised entry."

**RESPONSE** All log books have an instruction list taped to the front cover of the log book to remind analysts of the log keeping requirements of ALS SOP CIO 95-0010 entitled "Log Keeping". In addition laboratory analysts were reminded in a group meeting that the proper way to make error corrections is with a single line through the mistake and initials of the person making the correction. Also data cross checkers were asked to pay particular attention to instances of incorrect error correction in lab records and to discuss each instance where this occurs with the person who improperly makes corrections. **CORRECTIVE ACTION HAS BEEN COMPLETED FOR THIS ITEM.**

**AF-95-0007** ALS SOP 256-S-3015 (Radiometric Rapid Screening Method For Determination Of Alpha And Beta Activity In Various Matrices) does not include a correction for self absorption and sets the maximum solid on the planchet at 50 mg. However, the analyst uses 100 mg as a maximum. The self absorption correction factor for alpha radiation, which is not applied to the rapid screen results, increases from 1.5 to 50 mg solids to 2.5 at 100 mg solids. The 50 mg maximum needs to be enforced or a correction for self absorption needs to be included in the procedure and applied during screening.

**Requirement:** ALS SOP 256-S-3015, Items 7.9 and 7.10, outlines the procedural steps involving the different sample sizes.

**RESPONSE** Method 256-S-3015, "Radiometric Rapid Screening Method for Determination of Alpha and Beta Activity in Various Matrices", will be revised in such a manner as to require that the residue weight on each planchet be determined to permit self absorption corrections to be made. Until the new revision is issued, the residue weight will be measured and a self absorption correction will be applied. But this will be considered a deviation from the procedure, and will be so stated in the batch log book. **CORRECTIVE ACTIONS WILL BE COMPLETED BY AUGUST 15, 1995.**

**AF-95-0008** Temperature recordings for ambient temperatures in the counting room have varied from 63 to 90 degrees F over the past several months. The counting equipment is sensitive to temperature swings.

**Requirement:** The FERMO QAPD, Document RM-0012 (Items 5.1 & 5.2) specifies that controls include: "controls which influence critical parameters of facility operations.....shall be accomplished under controlled conditions."

**RESPONSE** The HVAC system in the Laboratory Building has certain design flaws. In particular, these design flaws cause large temperature variations to occur in the Spring and Fall when days are warm and nights are cool. The HVAC system operates under a heating/cooling feedback cycle. That is, both the heating and cooling systems operate simultaneously in a continuous feedback mode in order to hold a set temperature. In the Spring and Fall the chillers are

turned off at night to prevent freezing of the lithium bromide solution. Thus, only the heating system is on and labs get quite hot. In the mornings, the chillers are turned on and labs cool down. In short, there is no feedback system on the chiller to keep the lithium bromide solution warm that will allow the chiller to operate continuously.

In the Laboratory Building Habitability Upgrade Project (for which the Change Proposal was only recently approved) funding was included to rectify the above problem. The project engineer, Jerry Janes, and the HVAC engineer, John McCloy, agree that this is a priority project that can be broken out from the remainder of the HVAC upgrade to the Lab Building. Accordingly, the goal is to design a feedback control system for the chiller and install it by the end of Fiscal Year 1995. If the engineering is possible, **CORRECTIVE ACTION WILL BE COMPLETED BY SEPTEMBER 30, 1995.**

**AF-95-0010** Samples are normally received in the SPL with a pH strip attached to the sample container when preservation is required. The pH strip is often lost or damaged in transit. The pH of radiochemistry, VOA and metals samples are not verified and documented at the analyst level.

Requirement: ALS CIO AC94-0109, item 9.3.1 states: ".....the analyst shall inspect and verify the material type and condition and confirm need for and identification of analysis."of samples upon receipt" and the FERMCO SCQ, Document FD-1000 (Item 12.4.3.1) specifies that laboratories shall have: ".....a routine that ensures compliance with preservation requirements."

**RESPONSE** All lab analysts will be instructed that prior to analysis, they must verify (with pH paper) the pH of any water sample that does not have a pH strip on the container. The fact that a pH strip was not present will be documented in the batch preparation log book along with the result of the pH measurement. Nonconformance memoranda will be issued for samples not properly preserved per ALS SOP AC95-0097. A memorandum to all chemists instructing them about the above corrective action will be issued by the ALS Department Manager. **CORRECTIVE ACTION SHALL BE COMPLETED BY JUNE 30, 1995.**

**AF-95-0011** Reagents, standards (stock and intermediate), tracer spike materials, and QC sample materials are not being prepared and/or preparation is not adequately identified or documented for traceability purposes, and identified below:

- a. Reagents and standards in the thorium purification laboratory are not assigned unique identification numbers.
- b. Standard 209-93-84 showed an expiration date of 09/27/94, but the standard is still being used in the thorium purification laboratory.
- c. Stock and intermediate radiochemical standard solutions are used, indefinitely, until exhausted. Evaporative losses can occur that would render the standard inaccurate. Expiration dates need to be identified with the option to re-verify or dispose of the solution when expired. Criteria applied to re-verification of old versus new radiochemical working standards needs to be included in SOP documents for reference and consistency purposes.
- d. Reagent and standards logbooks are not reviewed on a quarterly basis by supervisory personnel.
- e. NIST traceability is not documented in the logbook for tracer spike and QC sample materials used in thorium purification. At the minimum, the solution ID number and mass or volume used needs to be documented.

**Requirements:** ALS SOP 257-D-0015, Items 8.5.3.2, 8.6, 8.2.11, 8.5.10, and 8.5.2 respectively. In addition, the FERMCO SCQ, Document FD-1000 (Appendix B, Form D-10, Item 5.1.4) shows: "A NIST or NIST-traceable, or equivalent agency standard material is used as an internal tracer for each sample analysis".

**RESPONSE** Practices regarding the preparation and documentation of radioactive standards will be improved in the Radiochemistry Lab in the following manner:

- a: The amount of standard (tracer, spike material or lab control sample) and a unique source ID number will be recorded in batch preparation log books so that traceability to the original NIST standard is possible.
- b,c: All standards including intermediate and working solutions will be assigned

an expiration date. If a standard has reached the expiration date stated on its label, measurements will be made to verify that the concentration of the standard has not changed before the standard is used. A new expiration date will be assigned and the details of this process will be recorded in the Reagent and Standard Preparation Log Book described in ALS SOP 257-D-0015 entitled "Preparation of Reagents and Standards".

d.e. The calculations and documentation associated with the preparation of each radioactive standard or working solution will be entered into a Standard Preparation Logbook. Each entry will be reviewed by a second knowledgeable party as it is generated, rather than on a monthly or quarterly basis. Whenever possible, part of the documentation shall consist of measurements to demonstrate that the measured value agrees with the expected value. **CORRECTIVE ACTIONS WILL BE COMPLETED BY JULY 15, 1995.**

AF-95-0012 The ALS preventive maintenance and calibration programs are not adequate. A more pro-active approach needs to be taken by developing a system that prompts and monitors the preventive maintenance and calibration activities on a routine basis. A number of non-compliance issues were identified during the audit and include:

- a. The calibration tag on a large scale 15-X268-SCH was noted to be out-of-date and the equipment was not tagged as being out-of-service. Documentation was located that showed that the scale was calibrated, as required by Scale Maintenance SOP 52-S-1000, but the calibration tag was not replaced.
- b. GPC-1 was out-of-service and out-of-calibration, but was not tagged as such. After being noticed during the audit, the unit was tagged, thus closing this item.
- c. The calibration frequency written on the gamma spectrometer calibration stickers were not in agreement with the calibration program requirements. The sticker for unit 4 was corrected as a result of this audit; the others were not corrected.
- d. Monthly preventive maintenance activities for the alpha spectrometers were not recorded in the maintenance log.
- e. Thermometers and thermocouples in the radiochemistry lab were not

calibrated.

- f. Run logs are not maintained to document calibration activities for the metals laboratory. Run logs need to be maintained to demonstrate that calibrations have been performed and that corrective actions are systematically documented.
- g. A preventive maintenance schedule and/or program is not documented for isotopic, methanol, or TOX/TOC analysis. A programmatic system needs to be developed and implemented to address these activities.

**Requirement:** The FERMCO SCQ, Document FD-1000 (Items 8.4.1 and 13.2), FERMCO QAPD, Document RM-0012 (Item 5.2), and ALS CIO AC94-0109 (Items 5.2 and 6.0) establishes requirements for preventive maintenance a calibration programs and ALS SOP 257-D-008 address tag-out of instruments/equipment.

**RESPONSE** A Senior Chemist in the ALS Department, Janet Angert, has been asked to oversee the calibration and preventative maintenance program to make it more proactive.

Janet Angert will develop a list (database or spreadsheet) of equipment in the ALS Department that requires preventative maintenance and/or calibration by vendors (usually through service contracts). The list will include the equipment, the frequency of the required work, and the next due date. This list will be developed by June 30, 1995.

Janet Angert will use this list to remind section managers when a piece of equipment is due for scheduled work. After such work is completed, the respective manager (Ray Danahy or Amy Meyer) will notify Janet that it has been completed so that the list can be updated. Use of the list in this manner will begin during July 1995.

Specific items are answered below:

- a. A new calibration sticker (dated 3/2/95) has been put on the scale. It will expire in 9/95. The calibration of this scale is maintained by Scale Maintenance. To ensure that the calibration is performed

and documented on schedule, this scale will be included in the list described above. **CORRECTIVE ACTION FOR THIS ITEM HAS BEEN COMPLETED.**

- b. Closed during audit. **NO CORRECTIVE ACTION NECESSARY.**
- c. The discrepancy arose because each gamma spectrometer must be recalibrated for each new sample counting geometry. Multiple "calibration due" stickers would be required for each detector. A separate table has been prepared and placed near each gamma spectrometer which shows the geometries used on that detector and when the calibration for that geometry is due. **CORRECTIVE ACTION FOR THIS ITEM HAS BEEN COMPLETED.**
- d. Ray Danahy will ensure that all future preventative maintenance activities for the alpha specs are properly documented. There is no longer a logbook designated "Alpha Maintenance Logbook". All work for and on this instrument is now documented in the "Alpha System Logbook". The operator of the alpha spectrometry system has also been reminded of the need to document preventative maintenance activities. **CORRECTIVE ACTION FOR THIS ITEM HAS BEEN COMPLETED.**
- e. Highly accurate temperature measurements are not important to the benchtop chemical or physical processes carried out in the Radiochemistry Lab. These operations would not be adversely effected if there was a systematic error of 5 degrees C. or more. Consequently none of the thermometers used in the Radiochemistry Laboratory are calibrated. The additional expense of purchasing certified thermometers for general purpose use cannot be justified. **NO CORRECTIVE ACTIONS ARE PLANNED IN REGARD TO THIS ITEM.**
- f. Run logs will be used to document calibration activities in the metals laboratory. The following headings shall be used in the run logs: instrument, sequence ID, sample/QC ID, and corrective actions. **CORRECTIVE ACTIONS WILL BE COMPLETED BY JUNE 30, 1995.**
- g. Preventative maintenance schedules have been prepared for all instrumentation in the Radiochemistry Lab. See item (d) above. The Radiochemistry supervisors have been instructed to closely monitor performance of PM for all radiochemistry instrumentation. Additionally, preventative maintenance schedules have been prepared

for TOC/TOX and methanol analyses. All of the above schedules are available upon request. **CORRECTIVE ACTION FOR THIS ITEM HAS BEEN COMPLETED.**

AF-95-0013 Self Assessments are performed in accordance with CIO AC94-0109, Item 13.4. DRs and CARs resulting from QA audits, NCs for the sample/analysis processes, and items noted on safety inspection reports are tracked to closure by AFA but they do not track "deviations" identified during self assessments.

**Requirement:** CIO AC94-0109, Item 13.5.1 specifies that: "AFA shall track assessment/audit findings and assure resolution in accordance with Site Procedures, as applicable".

RESPONSE The ALS Department views its self assessment program as an integral part of the TQM process. In this TQM process a group of ALS Department employees evaluates a topic, an operation, a process, or some other aspect of the ALS Department on a monthly basis. Because the employee assessment is designed to improve the way the department does its job, and not to identify variances from requirements, the ALS Department does not recognize "deviations" as a deliverable. Accordingly, it does not track "deviations".

An outline of the self-assessment process is described by Nelson Weichold in his February 27, 1995, letter to ALS employees (M:ENV:(ALS):95-0148). The relevant portion of this letter follows:

"The report (to ALS Management) should consist of a maximum of three pages consisting of 3 basic sections: Scope, Information Obtained, and Concerns/Recommendations. Concerns/Recommendations will be addressed by the ALS Department Manager."

The April self-assessment team was the first to operate under these guidelines. An example of the ALS Department's response to employees is appended as Attachment 3 (Interoffice Memorandum M:ENV:(ALS):95-0303 from C. Sutton entitled "ALS Management Response to April Quality Assessment Report Pertaining to

Laboratory Safety).

The ALS Quality Assurance Management Plan (Section 13.5.1) will be modified by 6/30/95 to read:

"ALS Management (AFA) shall track assessment/audit findings as applicable and assure their resolution in accordance with appropriate procedures, good laboratory practices, best management practices, or ALS Department policies/guidelines".

Finally, the ALS QAMP will have Section 13.4.3 added to it:

13.4.3 Self Assessment Employees of the ALS Department will conduct periodic self assessments of various aspects of ALS Department operations. Concerns and recommendations shall be reported to ALS Department management.

**CORRECTIVE ACTIONS SHALL BE COMPLETED BY JUNE 30, 1995.**

**FERMCO INTERNAL AUDIT  
OBSERVATIONS AND RESPONSES**

**AO-95-0001** Staffing and Resources...FERMCO is currently undergoing a "Voluntary - Reduction In Force" (V-RIF) action. The full impact of the V-RIF process will not be realized until after April, 1995, but if will, without doubt, have a negative impact on ALS activities. The full extent of activities that will be affected by the V-RIF cannot be evaluated at this time. Reference FERMCO QAPD, Document RM-0012 (Management Policy).

**RESPONSE** The ALS Department concurs with the above observation. Ideally, each FERMCO organization unit should have sufficient staff to comply with all SRIDs and client-imposed requirements and still be able to perform the work necessary to get the job done in a timely fashion. Reduction in staff size makes it difficult to accomplish both aspects well.

Through its self-assessment program and TQM efforts, the ALS Department is striving to streamline work processes in order to accomplish the work with fewer resources. The ALS Department has six major objectives to work toward in FY95 (M:ENV(ALS):94-0940). One of these is stated below:

"to streamline and/or clarify, insofar as possible, ALS Department operations in order to waste less time, reduce frustrations, alleviate unnecessary stress, and become more efficient."

This objective, formulated in November, 1994, fully recognizes the staffing reduction implications alluded to in the above observation and expresses the ALS Department's actions to compensate for staffing losses. **CORRECTIVE ACTION IS A CONTINUING PROCESS.**

**AO-95-0002** The roof leaks in many of the laboratory areas. In addition to being a safety concern (wet-slippery floors), the leaks could present a sample contamination problem. Housekeeping practices need to be improved in the following areas, as identified during audit activities: a) Rooms C35 and C43 were especially dirty and were noted to have paint flaking from ceilings and walls; b) Hoods were cluttered in Room 169; c) Aisle was partially blocked in

Room 207; d) A cart was blocking the control panel in Room 169, violating the 36" clearance OSHA Safety Requirement; and e) Radiological survey bulletin boards, located throughout the laboratory, did not have survey information posted and are not being used for their intended purpose. Reference FERMCO QAPD, Document RM-0012. (Item 1.3.3 and 1.4.14).

**RESPONSE** The roof over the center hallway will be replaced as part of the Laboratory Habitability Upgrade Project. The current schedule calls for completion by the end of October, 1995. The following comments address housekeeping practices.

- a) About 75% of the space in Room C-35 is used as storage space for excess equipment and furniture. No attempts are made to clean this space. The XRF area, which includes about 25% of the space in C-43, has good housekeeping practices.

The analysts responsible for Room C-43 have been instructed to improve housekeeping practices.

- b) Hoods are cluttered when they are actively being used for analyses. When they are not used, they are tidied up.
- c) The aisle in Room 207 is temporarily partially blocked by carts when samples are being transported or when large amounts of glassware are being washed. The laboratory design is such that no counter space is adjacent to sinks; therefore, glassware is placed on carts next to the sinks when it is washed. In interim periods, the carts are stored so they do not block aisles.
- d) The cart was removed and employees were instructed not to have carts block control panels.
- e) Per the building radiation technicians, it is no longer required to post room survey information for non-contaminated rooms. Contamination areas do have survey information posted near the

contaminated area.

HOUSEKEEPING CORRECTIVE ACTIONS HAVE BEEN COMPLETED. ROOF CORRECTIVE ACTION TO BE COMPLETED BY OCTOBER 30, 1995.

A0-95-0003 Requirements identified in ALS's Chemical Hygiene Plan (CHP), in most areas, were in compliance with 29 CFR 1910.1450. Emergency equipment was available in work areas and personnel were aware of the location of the equipment and requirements of the CHP. The following "observations" were noted. Reference FERMCO QAPD, Document RM-0012 (Item 1.3.3).

- a) Three hoods have been tagged out for approximately one year (1-206, 1-220, and 1-204).
- b) Hood 209C in Room 209 is alarming.
- c) Three items were noted in Room C43 (high level uranium processing area): 1) there is a safety shower but no water; 2) there is no safety eyewash station/ and 3) there is no heat.
- d) The elevator at northwest end of the new north addition to the building is not operable. The elevator is needed for movement of heavy materials/equipment.
- e) The distilled water system in Room 206 is not working.
- f) Deionized water is not readily available in all laboratories.
- g) Conductivity meters are not calibrated nor used in Radioanalytical Laboratories.
- h) The emergency number label is not posted on the phone in Room 207.

## RESPONSE

- a,b) We have resubmitted work orders for fume hoods on June 1, 1995, through Cleo Adams. He in turn has given them to the Maintenance Estimating Group with instructions to expedite the process.
- c) A test of the safety shower in C-43 showed that it worked and contained water. There is an eyewash and safety shower at the intersection of the West and Central hallways. These are about 15 feet from the door of C-43. Employees have been instructed to use this safety facility. Heat will be added to the west end of the Lab Building when the lab habitability upgrade is finished. The HVAC portion will be complete in about 18 months if funding holds.
- d) The elevator is now operating.
- e,f) The distilled water system is now operable, and all labs plumbed to receive distilled water have it.
- g) Radiochemical analytical procedures do not specify that distilled water meet given conductivity requirements because the analyses do not depend upon conductivity to yield high quality data. Therefore, conductivity of distilled water is not monitored by the radiochemists.
- h) The phone in Room 207 now has the emergency number label on it.

**CORRECTIVE ACTIONS ARE IN PROCESS (a,b,c) OR HAVE BEEN COMPLETED (d,e,f,h).**

**A0-95-0005 Unacceptable interlaboratory comparison study and QC/performance sample results are not formally investigated. Laboratory management are notified of the outliers, as reported, but they are not tracked to closure. Reference FERMCO QAPD, Document RM-0012, (Item 2.2.6).**

**RESPONSE** Beginning with the next performance evaluation results, either internal or external, that are administered by the Quality Control Laboratory in the Quality Assurance Division; outliers will be handled using the ALS Department Non-conformance Procedure (AC95-0097). The non-conformance process will be initiated by Quality Control Laboratory Staff as per the attached letter from William D. Kelly to Chris Sutton (Attachment 4). **CORRECTIVE ACTION HAS BEEN COMPLETED.**

**A0-95-0006** The "Continuous Improvement" concept needs to be "promoted" in Sections 8 & 9 of CIO AC94-0109, Analytical Laboratory Services Quality Assurance Management Plan. "Continuous Improvement is not specifically mentioned in the identified areas of the CIO. Document RM-0012, FERMCO's Quality Assurance Program, Pages 14 - 18, shows a "strong" commitment to "continuous improvement" activities/processes. From information obtained during audit interviews, apparently the CIO is being re-structured into a format comparable to RM-0012. This should provide assurance that requirements of RM-0012 are addressed in the ALS document. Reference FERMCO QAPD, Document RM-0012 (Item 3.0).

**RESPONSE** In the near future, the ALS Department QAMP will be revised to conform to the format of RM-0012. Meanwhile, the following items have been added to Section Eight of the QAMP:

- 8.1 Total Quality Management The ALS Department will actively utilize the Total Quality Management Process described in Criterion 3 of RM-0012.
- 8.1.1 Employee self-assessments as described in 13.4.3 of the QAMP are an integral aspect of total quality management.
- 8.1.2 The ALS Department will utilize the TQM Department as applicable.
- 8.1.3 Employees will be encouraged to identify problems and suggest solutions in order to improve quality.

**CORRECTIVE ACTIONS WILL BE COMPLETED BY JUNE 30, 1995.**

**AO-95-0007** The ALS QAMP, Document AC94-0109, Item 8.4.4.1, first and last sentences, as presented, contradict each other. The first sentence should relate that: a) trip blanks consist of deionized distilled water prepared by QA/QC in the analytical laboratory; and b) trip blanks prepared by sample teams are prepared elsewhere.

**RESPONSE** Section 8.4.4.1 has been modified to read: "Trip blanks consist of deionized distilled water prepared either by QA/QC in the analytical laboratory building or by sample teams elsewhere." The last sentence of Section 8.4.4.1 has been deleted. **CORRECTIVE ACTION WILL BE COMPLETED BY JUNE 30, 1995.**

**AO-95-0008** Efficiency and background checks for the gas proportional counters are not translated into control chart formats for evaluation. Reference FERMCO QAPD, Document RM-0012 (Item 3.2.2).

**RESPONSE** Spreadsheets have been prepared so that daily efficiencies and backgrounds for both alpha and beta radiation may be stored and plotted for each detector in the proportional counter system. **CORRECTIVE ACTION FOR THIS ITEM HAS BEEN COMPLETED.**

**AO-95-0009** Two "observations" associated with water purity within the laboratory areas were identified. Reference ALS QAMP, Document CIO AC94-0109 (Item 4.1.2) and FERMCO QAPD, Document RM-0012 (Item 3.2.3).

- a. The quality of reagent water in the radiochemistry lab is monitored on an after-the-fact basis through method blanks.
- b. The water source in the TOC/TOX laboratory is not checked for conductivity. Since the TOC/TOX laboratory analyzes for constituents that cannot be monitored by conductivity, monitoring is not necessary for their operations. The problem is that other groups periodically obtain supposedly pure water from the TOC/TOX laboratory.

**RESPONSE**

- a. Using blanks to monitor the quality of water in the Radiochemistry Lab is entirely appropriate. The only way to monitor the "radiochemical quality" of the water is to perform a radiological measurement. The presence of nonradioactive ions in this water will not effect radiochemical measurements in any significant way. **NO CORRECTIVE ACTION IS PLANNED IN REGARD TO THIS ITEM.**
- b. A sign was posted in the TOC/TOX laboratory water system stating that this water is to be used for TOC/TOX analyses only. **THIS CORRECTIVE ACTION HAS BEEN COMPLETED.**

**A0-95-0010** Refrigerator logs in the GC/MS VOA area were incomplete. Column headings were not identified and recent entries were either incomplete or missing. Logbook functions need to be clearly identified and column headings for documenting logbook entries need to be consistently identified. In addition, to ensure proper operation of refrigerators, daily monitoring must be performed on a routine basis. Reference FERMCO QAPD, Document RM-0012, Item 4.2.6.

**RESPONSE** VOA refrigerators and column header requirements were corrected to contain appropriate headers and were reviewed with lab personnel. Back-up personnel were identified to ensure daily monitoring. **THIS CORRECTIVE ACTION HAS BEEN COMPLETED.**

**A0-95-0011** ALS program control documents do not identify "who" is responsible for maintenance of working or historical files nor do they specify retention requirements. Reference ALS QAMP, Document CIO AC 94-0109 (Items 3.7.2 and 10.2.1), identify documents created and controlled by ALS and Item 3.7.2 specifies that the records are maintained in accordance with DOE Order 1324.2A.

**RESPONSE** The Document Control Group in Analytical Data Management (ADM) (a subsection of the Sample Management Office) maintains working and files related to analysis and sample management (excluding raw data for the onsite analytical labs). SOP CIO AC95-0014 "Document Tracking and Control Within Analytical Data Management" defines the procedures used to store, maintain, and

track records held by ADM. This CIO describes the physical layout of files, sign-out procedure for removal of originals, and the database system used to manage document receipt and location.

Historical files are maintained by the Records Management Department of Environmental Technical Services. SOP CIO AC95-0015 "Analytical Data Management Release Completion Assessment" outlines the steps necessary to ensure a given document set is complete before archiving is initiated.

Retention periods for working files are specified on the Project Profiles provided to ADM by Analytical Customer Support for each project. The default retention time is 6 months from project completion. All documents maintained by ADM are stored in accordance with DOE Order 1324.2A. **NO CORRECTIVE ACTION TO BE TAKEN.**

**AO-95-0012** Supervisory review and approval of sample preparation and analysis logbooks in the radiochemistry laboratory are performed and documented on an infrequent basis (monthly to quarterly). Several instances of "no review" were noted in the organics and metals areas. This is not good laboratory practice. Reference FERMCQ QAPD, Document RM-0012 (Item 4.2.6).

**RESPONSE** All radiochemistry raw data, including sample preparation log books, are cross checked by an independent party before analysis results are released. This is done for every batch. The supervisory review of logbooks on a monthly basis is a redundant practice. Radiochemistry management considers this practice to be entirely adequate. In the organics and metals areas, the supervisor or designee reviews logbooks on a monthly to quarterly basis depending upon frequency of analysis or use of logbook. Inorganic/Organic Management considers this practice to be adequate. **NO CORRECTIVE ACTION IS PLANNED IN REGARD TO THIS ITEM.**

**AO-95-0013** The Satellite Accumulation Area (SAA) work station contained an out-dated copy (Revision 2) of SSOP-0035. The latest revision (Revision 3) was issued on October 18, 1994. ALS needs to make sure responsibilities are assigned and that work stations are routinely monitored to assure that the most

current issues of SOPs are readily available at the user level. Reference FERMCQ QAPD, Document RM-0012 (Item 4.2.3).

**RESPONSE** The Analytical Laboratory Services (ALS) Department document program (257-D-0014) describes the distribution of documents. In administration of the program, management identifies required documents to be in the work area. Documents required to perform work are maintained in established procedure record book stations. The record book stations are identified by number and maintained by ALS personnel. The copy of the document in the satellite accumulation was not placed through the record book station system. That document has been removed and ALS personnel assigned to oversee satellite accumulation areas were instructed in a staff meeting to only perform work using documents located in the established record book stations.

**A0-95-0014** Procedures that describe Sample Management work activities associated with the FACTS system appear to be unnecessarily fragmented. Procedures appear to need review and compilation/reorganization. Reference FERMCQ QAPD, Document RM-0012 (Item 4.2.1).

**RESPONSE** Procedure 776-S-4001 "Sample Analysis Planning in the Sample Management Office" is being revised and will address the issues raised in this observation. This procedure will provide an explanation on how the separate procedures in SMO tie together. A Laboratory Information Management Systems guidance document is also in the early stages of creation. This document will bind the data management activities associated with sample management to the activities/responsibilities for maintaining data in FACTS. **CORRECTIVE ACTION TO BE COMPLETED BY JUNE 30, 1995.**

**A0-95-0017** Corrective actions are not routinely noted in VOA run logs. Corrective actions need to be documented to identify reasoning for re-analysis, etc. Reference ALS QAMP, Document AC94-0109 (Item 9.6.1),

**RESPONSE** Corrective actions are being noted now in the VOA runlog. The runlog will be modified to allow more room for corrective actions. **CORRECTIVE ACTION WILL BE COMPLETED BY JULY 1, 1995.**

**A0-95-0018** Only the last five digits of the FACTS sample identification number are recorded in the alpha spectrometry run log book. This practice does not provide for unique sample traceability in the identified log book. Reference FERMCO QAPD, Document RM-0012 (Item 5.4.9).

**RESPONSE** Prior to January 3, 1995, sample identification in the radiochemistry lab counting room consisted of the last 5 digits of the FACTS identification number. Since January 3, 1995, the entire FACTS identification number is used to uniquely identify all samples. **NO CORRECTIVE ACTION IS NECESSARY.**

**A0-95-0019** Three "observations" were identified associated with spreadsheets and worksheets prepared by analysts in the Thermal Mass Spectrometry Laboratory. Reference FERMCO QAPD, Document RM-0012 (Item 6.2.6, 6.2.7, and 5.3.9, respectively).

- a. Spreadsheets for CCV, LCS, duplicates, and unit conversions have not been verified to ensure that the calculations being performed are correct. A systematic check of spreadsheets needs to be performed on a routine basis to ensure that conversions being made are accurate.
- b. Data entered on spreadsheets is not cross-checked. Cross checks need to be performed to ensure that data has been entered correctly.
- c. Analyst identification is not documented on worksheets used for tray loading. Preparatory sheets need to document analyst identification for traceability purposes.

**RESPONSE**

- a. Spreadsheets used in the Mass Spectrometry Lab will be verified by hand calculations to ensure that the calculations are being performed correctly. However, obtaining the correct result on laboratory control samples and other quality control samples is an adequate systematic check of the accuracy of the spreadsheets. If a spreadsheet has become corrupted, it would be evident from the results of these QC samples. This check is done with each batch of

- samples. **CORRECTIVE ACTION WILL BE COMPLETED BY JULY 30, 1995.**
- b. Data entered into spreadsheets will be cross checked to ensure that it has been entered correctly. Spreadsheets will be signed and dated by the cross-checker to signify that the material has been checked and approved. **CORRECTIVE ACTION WILL BE IMPLEMENTED BY JUNE 30, 1995.**
  - c. Mass Spectrometry analysts will be instructed to record who loads trays so that this becomes part of the analysis records. **CORRECTIVE ACTION WILL BE COMPLETED BY JUNE 30, 1995.**

**AO-95-0020** The three "observations" listed below were identified during this audit but will be more thoroughly evaluated during Audit I95-03 (Computer Software Validation, FACTS and SWIFT) scheduled to be conducted in mid-March, 1995.

- a. Analytical data packages received from sub-contractor laboratories and software are not virus checked prior to use.
- b. Software is canned, but customized for FEMP use. No evidence was produced that documents FERMCO validation and verification activities.
- c. The FACTS computer system cannot always keep up with the demand. The Sample Processing Laboratory (SPL) loses valuable time when FACTS cannot be accessed.

**RESPONSE**

- a. All software and electronic data received from subcontractor laboratories are now routinely being virus checked using the Microsoft Antivirus program prior to use. **CORRECTIVE ACTION HAS BEEN COMPLETED.**
- b. Information Resources Management (IRM), the owner of the original validation and verification documentation for FACTS, was not able to locate the documentation, even following the FACTS/SWIFTS audit in March 1995. However, IRM does possess documentation from the consultants that performed the validation and verification activities indicating closure and user acceptance. All FACTS related software now received is verified and validated according to

the nature of the software. Such "V and V" is documented by the ALS ADM Group. **NO CORRECTIVE ACTION TO BE PERFORMED.**

c. Users' perceptions of FACTS being slow and/or unaccessible are somewhat inaccurate. Although it is true that the bottom line is the same (they have trouble getting their work done), the reasons are not always related to FACTS. There are four primary factors that affect FACTS system performance:

1. the VAX, which is the mainframe on which FACTS operates
2. Oracle, which is the database engine for FACTS
3. SQL\*LIMS, which is the software base for FACTS
4. the FEMP local area network

Unfortunately, ALS has no control over the VAX or the network. Downtime or poor performance on either of those platforms is managed by IRM. Note, however, that IRM has been provided with benchmark data which demonstrates that VAX performance has degraded over the past 8 months, while FACTS (SQL\*LIMS and Oracle) performance has remained relatively stable.

That is not to say that FACTS performance cannot be improved. ADM is continually trying to modify either the data in FACTS or the Oracle structures that support it to attempt to gain performance.

In terms of actual downtime, FACTS itself has been down very little, less than 3% over the past year. **CORRECTIVE ACTION FOR THIS ITEM IS ONGOING.**

**A0-95-0021** Although analytical and top-loading balances are routinely checked with Class C checkweights, acceptance ranges for the checkweighing process have not been established. In order to effectively document balance calibration activities, acceptance ranges need to be formally established. Reference FERMCO QAPD, Document RM-0012, Item 3.2.3).

**RESPONSE** Acceptance limits for check weights and the process of weighing check weights will be defined by ALS management in consultation with the senior chemist (Janet Angert) overseeing the department preventative maintenance and calibration program. All analysts will be informed when the acceptance limits are established. These limits shall also be recorded in the logbook used to document the results of the check weight measurements. **CORRECTIVE ACTION WILL BE COMPLETED BY JULY 31, 1995.**

**A0-95-0022** VOA holding blanks are not being routinely analyzed. The holding blanks need to be routinely analyzed to ensure that samples are not being contaminated during storage. Reference FERMCO QAPD, Document RM-0012 (Item 3.2.3).

**RESPONSE** Approximately 80% of VOA samples analyzed have no detectable compounds in them. Trip blanks, which are also stored in the refrigerator, have also consistently had no detectable compounds. Thus, all evidence indicates that no contamination occurs from the refrigerator. Given the low sample load for VOAs (approximately 3 samples every two weeks), refrigerator holding blanks are not justified with each sample. However, refrigerator blanks will be analyzed on a monthly basis as a precaution. **CORRECTIVE ACTION COMPLETED.**

**A0-95-0023** Methanol used for VOA analysis is not checked to verify purity prior to use. The purity needs to be checked in order to eliminate propagation of sample contamination due to use of contaminated solvents. Reference FERMCO QAPD, Document RM-0012 (Item 3.2.3)

**RESPONSE** When a new stock of methanol is used, the VOA analyst will check its purity and verify prior to continued use. This will be done by analyzing the methanol as if it were a sample in order to identify and quantify possible VOA contaminants. **CORRECTIVE ACTION HAS BEEN COMPLETED.**

**A0-95-0024** Deviation Report, DR94-176, is closed. Audit/surveillance/CTR interfaces with sub-contractor analytical laboratories are performed semi-annually. Audit/surveillance personnel contact CTRs and are aware of problems currently being experienced and are considered to be a "designated

representative" for the identified CTR when off-site laboratories are evaluated.

**RESPONSE**        None necessary.

# ATTACHMENT #1

## ANALYTICAL LABORATORY SERVICES DEPARTMENT DOCUMENT PROGRAM

### DOCUMENT REQUEST (DR)

★ IDENTIFY REVIEW REQUIREMENTS ON PAGE 2 OF THE DR. THE CHOICES ARE EITHER OPTION 1, 2, OR 3, OR 2 AND 3. OWNER SIGNATURE INDICATES REVIEW REQUIREMENTS HAVE BEEN IDENTIFIED ON PAGE 2 OF THE DR.

This Block Is For QPD Use Only.	
REQUEST DATE:	_____
REQUEST NUMBER:	_____
ISSUE/REVISION/CANCEL DATE:	_____
WRITER:	_____

NOTE: Request will not be processed without PTR and Owner signatures, and a Charge Number.

PTR: \_\_\_\_\_ EXT: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

OWNER: \_\_\_\_\_ EXT: \_\_\_\_\_ ★ SIGNATURE: \_\_\_\_\_

PTR ORG: \_\_\_\_\_ AUTHORIZING ORG: \_\_\_\_\_ CHARGE NO.: \_\_\_\_\_

(CURRENT DOCUMENT INFORMATION OR NEW DOCUMENT TITLE)

DOCUMENT NUMBER: \_\_\_\_\_ ISSUE DATE: \_\_\_\_\_

REVISION NUMBER: \_\_\_\_\_ REVISION DATE: \_\_\_\_\_

DOCUMENT TITLE: \_\_\_\_\_

REASON FOR REQUEST: \_\_\_\_\_

SUPERSEDES (DOCUMENT NO.): \_\_\_\_\_

DRIVER(S): \_\_\_\_\_

**DOCUMENT REQUEST TYPE**

- NEW
- REVISION
- CANCELLATION
- PERIODIC REVIEW
- CIO INCORPORATION

**DOCUMENT TYPE**

- DEPARTMENT
- SECTION
- SOP
- CIO
- REQUIREMENTS DOCUMENT
- METHOD
- PLAN
- OTHER \_\_\_\_\_

KEY WORDS: \_\_\_\_\_

# Attachment #2

## EPM LOGBOOK

Logbooks  
To be Checked Monthly

	Logbook Number	Used For	Room Number	Cross Checker
1	pH-595	pH	168	H Volk
1	94-031	Fluoride	169	D Brennan
1	94-074/075	Copper	169	MB
1	94-098	UBrPDP	168	Gangert
1	94-099	UBrPDP	185	↓
1	95-012	NO3/NO2/PO4	169	MB
1	94-0002	U-KPA	169	Barry
1	94-0003	Thorium	168	Tod
1	94-0005	Flashpoint	169	H Volk
1	94-0007	TSS	169	Glynn
1	94-0009	G&O	169	Paul / Reggie
1	94-0013	Ammonia	169	D Brennan
2	SPL-0029	Sample transfer	174	T. DePoy
2	4112	Micropipettes	169	H. Volk
2	4116	Sartonus balance R300S	147	D. Brennan
2	4119	#1 pipette cal	168	G. Bowman
2	4124	Balance	185	B. Beegle
2	4223	#3 pipette cal	168	G. Bowman
2	4224	Refrig	185	B. Beegle
2	4225	Refrig	169	H. Volk
2	4359	AE-100 mittler	168	G. Bowman
2	4361	Refrig	169	B. Beegle
2	4362	Balances	169	H. Volk
2	95-006	Mittler balance	174	T. DePoy
2	95-007	Dry & grind % moist	174	T. DePoy
2	95-009	Sample prep/position log XRF	C35	D. Brennan
2	95-010	Cal/main log XRF	C35	D. Brennan
2	95-011	Ohaus GT410 Balance	147	D. Brennan
2	95-013	Oven	147/174	D. Brennan

000130



## INTEROFFICE MEMORANDUM

<b>To:</b> Denise Arico, MS35 Robert Bolin, MS35 John Reilman, MS35 Bill Westerman, MS35	<b>Date:</b> May 15, 1995
<b>Location:</b> Fernald	<b>Reference:</b> N/A
<b>From:</b> Chris Sutton, MS35 <i>CS</i>	<b>FERMCO #:</b> M:ENV:(ALS):95-0303
<b>Location:</b> Fernald	<b>Client:</b> DOE DE-AC24-92OR21972
<b>Extension:</b> 738-9450	<b>Subject:</b> ALS Management Response to April Quality Assessment Report Pertaining to Laboratory Safety

c: File Record Storage Copy 106.4.14.11  
 Ray Danahy Amy Meyer Debbie Reichard  
 Alex Duarte Michele Miller Nelson Weichold

Thank you for your assessment pertaining to laboratory safety. I appreciate your comments and suggestions. Your report has been reviewed by Amy Meyer, Ray Danahy, Nelson Weichold, and myself. Our responses are as follows:

1. By May 31st all unsatisfactory items will be corrected. The Chemical Hygiene Officer (CHO), Robert Bolin, and Facilities Services personnel will help as requested by Section Managers.
2. Each Section Manager will inform the ALS Department Manager and the CHO in writing when the corrections have been implemented.
3. As part of the correction process, the analytical staff will be apprised of the safety requirements.

Additionally we recommend the following:

1. That chemical storage inspections be performed on a quarterly basis. We urge the Chemical Hygiene Committee to make this change to the Chemical Hygiene Plan ASAP.



**INTEROFFICE MEMORANDUM**

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May 15, 1995  
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2. That once per year the chemical storage inspection is included as an ALS monthly self-assessment activity or as part of a more general safety self-assessment.

CS:eab

000132



## INTEROFFICE MEMORANDUM

<b>To:</b>	Chris Sutton. MS35	<b>Date:</b>	May 31. 1995
<b>Location:</b>	Fernald Site	<b>Reference:</b>	N/A
<b>From:</b>	William D. Kelley. MS35 <i>WCK</i>	<b>FERMCO #:</b>	M:PQA:(QCL):95-0162
<b>Location:</b>	Fernald Site	<b>Client:</b>	DOE DE-AC24-92OR21972
<b>Extension:</b>	648-5781	<b>Subject:</b>	FERMCO Internal Audit I95-10 Audit Observations

c: File Record Storage Copy 106.4.4.1  
Reinhard Friske. MS52-2  
Vern Turner. MS10

On attachment 1, page 5 of 8 the observation AO-95-0005 states: "Unacceptable interlaboratory comparison study and QC/performance sample results are not formally investigated". Laboratory Management are notified of the outliers, as reported, but they are not tracked to closure. Reference FERMCO QA PD, Document RM-0012. (Item 2.2.6).

In consultation with Chris Sutton, Manager of ALS, the Quality Control Laboratory (QCL) will use the "ALS Laboratory Operations Non-Conformance" procedure AC95-0097 to initiate required followup by ALS staff.

As on aside, I do not understand the relevance of the RM-0012 Items 2.2.6 to this issue.

WDK:csw



FERNALD ENVIRONMENTAL RESTORATION MANAGEMENT CORPORATION

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

QUALITY ASSURANCE AUDIT NO. I96-09

Environmental Technical Services - Analytical Laboratory

Date of Audit: March 26-29, 1996

Date of Report: April 15, 1996

Audit Location: FERMCO On-Site Laboratory  
Low Level Laboratory

Audit Team Members: Mary Ann Forrest, Lead Auditor  
Grace Ruesink, Auditor  
Harold Swiger, Auditor  
Dayne Thomas, Technical Representative  
Jim Cross, Technical Representative  
Vic Gill, Technical Representative

Purpose and Scope: To investigate activities in conjunction with relevant elements of the FERMCO Quality Assurance Plan, RM-0012, Sitewide CERCLA Quality Assurance Project Plan, and Nevada Test Site Requirements, NVO-325; to assess the capabilities and effectiveness of the implementation by Laboratory personnel.

Executive Summary: Laboratory personnel have developed and implemented basic program requirements and administrative controls necessary to meet established criteria. Their capabilities compare favorably with, and in some cases exceed, analytical services provided by off-site laboratories. They appear capable of producing ASL B/C/D data packages for radiochemical analyses, but incapable of producing the same type ASL chemical data packages. Reservations exist about ALS maintaining needed frequency of production of ASL D radiochemical and/or ASL B Metal data packages. Reservations also exist about ALS producing radiochemical data packages with results which are blank and non-blank corrected.

Audit Conduct: A formal announcement of the intended audit was sent to Laboratory personnel along with an Audit Plan. The auditors held a pre-audit meeting on March 21, 1996 to discuss audit

assignments and address questions by the Team. An opening meeting was held on March 26, 1996, with Laboratory personnel to discuss areas of assessment and counterpart assignments.

Throughout the assessment, various procedures, program plans, and record files were reviewed. Quality, analytical, health and safety, and waste handling checklists were used to evaluate the processes observed.

Review of the Interlaboratory Data Comparability (IDC) Program revealed that out of four labs submitting data for all analytes, e.g., metals, volatiles, semi-volatiles, radiochemicals, minerals, etc., ALS ranked number 3 for quality of data.

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

Jan Angert	Harold Humphrey
Al Bacon	Mike Keller
Donna Baker	Jean Kunze
Barry Beegle	Shelly Kuntz
Carl Bishop	Virgil Lacey
Deborah Brennan	Martin Lake
Barbara Campbell	Amy Meyer
Baohe Chen	Frank Miller
Tim Dall	Paul McSwigan
Ray Danahy	Ervin O'Brien
Mark Durrough	Tim Weigel
Mark Harper	Jane Wise

#### AUDIT DETAILS

##### A. FUNCTIONAL CATEGORY A: MANAGEMENT

##### 1.0 Criterion 1 - Program

Analytical Laboratory Support (ALS) personnel maintain and implement a very organized quality assurance program which is binding on all personnel. A revision to the document is out for review by Managers and should be in effect by April 30, 1996. Issuance of the approved document will close out the last open item from the previous audit.

ALS has just undergone a major reorganization, combining redundant functions and reassigning personnel to suitable positions. One major change in the organization is the addition of a QA Officer who is matrixed from the P/QA Division. All of the required systems are in place and

appear to be working, with noted exceptions. The management team seems to be very well structured, and supportive of facility processes.

A comprehensive Safety and Health Program which encompasses radiation safety, chemical safety, and waste programs is in effect.

Two identified areas do not appear to have adequate personnel to support their processes, however, the problem had been previously addressed by ALS and corrective action is being implemented.

The laboratory is maintained in a well-organized manner. Housekeeping practices have noticeably improved since the last audit.

#### 2.0 Criterion 2 - Personnel Training and Qualification

ALS is supportive of the concept that personnel shall be trained and qualified to perform their assigned work. Resumes of select personnel (15%) were reviewed and the organization chart was scanned to identify change in key personnel since the last audit. A review of analysts' performance evaluations was conducted to ensure certifications were current.

#### 3.0 Criterion 3 - Quality Improvement

The Laboratory personnel QA program implements processes to detect and prevent quality problems and promote continuous quality improvement. A Total Quality Management Project Team, comprised of representatives from all labs, meet on a regular basis to discuss implementation of identified improvements, e.g. methods and procedures. Persons interviewed projected a knowledgeable and positive attitude.

A closed loop corrective action system was assessed and verified to be in effect.

#### 4.0 Criterion 4 - Documents and Records

Review of laboratory systems indicated a programmatic breakdown in document control. However, for the most part, records were maintained and easily retrievable. See Attachment C for a listing of documents reviewed.

Detailed sample, and standards logbooks were maintained by analysts, and preventive maintenance (PM) logbooks were maintained near equipment. However, with minor changes to Chain of Custody, standard prep, and PM logs, laboratory

personnel could make better use of the data for traceability purposes thus improving quality of activities.

See Finding 1, Attachment A.

#### 5.0 Criterion 5 - Work Processes

Custody from sample receipt and login to sample disposition appeared fragmented. Even though there is no evidence of lost samples, the implementation of a "stand-alone" internal Chain of Custody procedure and a "relinquished by" column in the custody log will greatly enhance the process. ✓

*all transfers must be documented*

With exceptions noted, work instructions were prevalent.

ALS recently gained control of their procedures and assigned a Team to conduct review and revision of the procedures, as needed. Currently, the level of detail required to meet FERMCO protocols was not always evident.

See Findings 2 and 3, Attachment A.

#### 6.0 Criterion 6 - Design

The building was designed specifically as an analytical laboratory. The security system appeared adequate to prohibit entrance of unauthorized personnel and to prevent loss of samples. Postings indicated unauthorized personnel must be escorted at all times.

ALS had two electronic information systems, FACTS and WISDM, which currently handle, e.g., sample processing data, personnel information, corrective action data. The software is access controlled. Upon request for modification, a form is generated with user sign off and submitted to the Data Base Administrator.

#### 7.0 Criterion 7 - Procurement

Past history indicated a procurement control system was in place. Criterion 7 was not addressed during the audit.

#### 8.0 Criterion 8 - Inspection and Acceptance Testing

A preventive maintenance program (PM) and calibration program were in place, however, discrepancies existed in both areas. PM schedules were maintained which contain periodic reminders for calibration, but in several instances, the schedules were not in or near the PM logs. PM schedules were inserted in PM logs during the audit to provide notice of PM and calibrations requirements.

Systems that establish chemical analysis controls for the test and examination services provided to support site restoration, and environmental monitoring were inadequate as identified.

See Findings 4, 5, and 6, Attachment A.

9.0 Criterion 9 - Management Assessment

A documented management assessment and self assessment program were perused.

A copy of the latest comprehensive assessment is contained in this audit file.

10.0 Criterion 10 - Independent Assessment

Independent assessments by P/QA are conducted in accordance with the SCQ. Outside organizations, i.e., EPA, Nevada Test Site (NTS) periodically review the assessments conducted by P/QA.



Mary Ann Forrest, Lead Auditor

Grace Ruesink, Auditor

SIGNATURE

Harold Swiger, Auditor

James Cross, Technical Representative

SIGNATURE

Dayne Thomas, Technical Representative

SIGNATURE

Victor Gill, Technical Representative

SIGNATURE

Tom Cox, Technical Representative

APPENDIX A

FINDINGS - I96-09

Requirement: RM-0012, 4.2.1

A system shall be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design.

Finding 1: A systematic breakdown in document control was evident. That was indicated by work instructions and procedures not being as detailed as required to safely perform work, and by not reflecting actual work being performed.

Discussion:

- There did not appear to be an obvious way to tell when procedures were in review or had been reviewed unless a revision had been made.
- The review cycle of 3-5 years is far too long, as evidenced by procedures not reflecting actual work processes.
- Specific requirements for procedures were issued as memos. Procedures did not indicate that a modification or a clarification had been issued. Two specific examples are the recently issued balance and pipet calibration requirements.

Logbooks were not adequately structured nor controlled, e.g.,

- Neither calibration acceptance nor corrective action requirements for pipet calibration were present with the log. (GFAA)
- Logbook for the Leeman Plasma Spec 2.5 ICP was not available.
- Logbooks supporting chemical analysis controls were in loose leaf notebooks that were not sequentially numbered and/or controlled. (Low Level Lab, ICP-MS Lab)
- Instructions for filling out the Maintenance and Calibration Logbook were not identified within the SOP.

Requirement: RM-0012, 5.2.2

Work shall be performed to established technical standards and administrative controls. Work shall

be planned, authorized and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of detail commensurate with the complexity and importance of the work.

Finding 2: Work related instructions and/or specific procedures were not available and/or controlled for:

- review/revision of procedures (memo)
- use of the auto loader in the kPA procedure
- chain of custody (intra-laboratory)
- uranium and thorium interelement corrections
- check of distilled/demineralized water

Discussion: Uranium and thorium interelement corrections are not being performed on the ICP. The instrument has no uranium photodetector, however, the analysts compensate for this, but a procedure describing the compensation was not available. A laboratory's inability to correct for uranium and thorium interferences is viewed as a serious defect affecting quality. Uranium and thorium interelement corrections for the ICP are required of all FERMCO subcontract laboratories due to their demonstrated presence in FERMCO samples".

There is no documented FERMCO intra-laboratory chain of custody procedure as required by SCQ section 7.2.1.1, #8. Off-site laboratories are required to have a dedicated chain of custody procedure addressing specific topics (SCQ E.4.1).

Finding 3: Work instructions and procedures are not as detailed as required to safely perform work, and do not reflect actual work being performed, e.g.,

- Method 3062, 8/30/89
  - Procedure does not reflect operation of equipment currently in use
- 256-S-0006, Rev. 0
  - Westinghouse stores items are referenced
  - Procedure needs to provide for a positive test for organic material
  - Dangers related to heating perchloric acid to dryness if organics are present are seriously understated
  - Steps related to boiling and heat lamp evaporation need to stress low and slow to prevent sample splattering
  - "Selected Gamma Emitters by Increasing

- Energy" is outdated
- Figure 1 Work Record is outdated

- SOP 9031, Rev. 0, 8/14/91
  - Procedure only generally relates to current practices

Discussion: Overall work instructions/procedure program needs to be reviewed for accuracy and completeness.

Requirement: RM-0012, 8.3.1 - A test control program shall be established as required and implemented for acceptance testing to demonstrate that items will perform as intended.

Finding 4: Electronic spreadsheets currently in use have not been routinely verified in order to ensure they are calculating correctly. (Low Level Lab)

Requirement: RM-0012, 8.5.5 - Measuring and test equipment is to be calibrated against standards having an accuracy that will ensure that the equipment being calibrated will be within required tolerances. If nationally recognized standards exist, calibration standards are to be traceable to them. ..calibration standards are to have a greater accuracy than the standards being calibrated.

Finding 5: Calibration standards do not have a greater accuracy than the standards being calibrated, calibrations had expired on standards, e.g.,

- Weights used to check balances were not in the same range as the working range of weights being measured, (Low Level Lab), and certifications of the standard weight sets in the laboratory were expired. One set of weights was out for calibration.
- The laboratories do not have acceptable standards to certify the daily overcheck weights accompanying the laboratory balances.

Requirement: RM-0012 8.6.1 - Establish chemical analysis controls for the test and examination services provided to support site restoration, environmental monitoring, and health programs.

Finding 6: Controls were not in place for the test and examination services provided to support site

restoration and environmental monitoring, e.g.,

- Samples requiring preservation for KPA analysis were not being recorded. (256-S-1004, Sections 6.1 and 6.1.1), e.g., CB, MF
- Lot numbers of acids used for sample prep are not being documented. (Low Level Lab) CB
- Outdated standards were stored with active standards in storage cabinets. (SOP 257-D-0015)
- Reagents found in the EPM Lab did not have expiration labels; expiration labels did not have the received and/or opened date entered on the label. (SOP 257-D-0015) -MF
- Several undated working standards were observed for the GFAA. → EOB

Discussion:

Expiration dates on many standards indicate only the "month" and "Year" on the label. A statement of clarification/policy statement is needed declaring whether this refers to the first day of the month or the last day of the month. This can prevent future personal discretionary interpretations as to whether a standard is in compliance.

APPENDIX C  
DOCUMENT REVIEW

- 3062, 8/30/89 - Determination of Trace Uranium by Kinetic Phosphorescence Analysis
- 9011 Rev.0, 4/17/91 - Quantitative Analysis of Uranium and Thorium in soil Samples by Energy Dispersion X-Ray Fluorescence (EDXRF) Spectroscopy
- 9031 Rev.0, 8/14/91 - Management and Reporting of Analytical Laboratory Results (new document #AC96-0028 replaces SOP 9031)
- 256-S-0123, Rev. 0, 2/28/96 - Calibration and Operation of a Computer Gamma Spectrometry System
- 256-S-2001, Rev. 1, 8/2/95 - Uranium Isotopic Analysis of Various Matrices by Thermal mass Spectrometry
- 256-S-3017, Rev. 0, 9/11/95 - Uranium Isotopic Determination in Water by Alpha Spectrometry \*\*
- 256-S-3018, Rev. 0, 9/18/95 - Uranium Isolation and Purification from Various Matrices for Subsequent Uranium Isotopic Analysis
- 256-S-3022, Rev. 0, 3/27/95 - \*\*\*\*
- 256-S-6008 Rev.0, 11/28/94 - The Determination of Uranium, Manual Volumetric Method
- 256-S-6026 Rev.0, 11/28/94 - The Determination of Uranium, Automated Volumetric Method
- 256-S-6039 Rev.0, 2/22/96 - The Colorimetric (BrPADAP) Determination of Uranium Using An Auto Analyzer
- 257-D-0008 Rev.0, 11/15/94 - Instrument and Equipment Repair, Calibration, and Preventative Maintenance Requirements
- 257-D-0015 Rev.0, 2/2/95 - Preparation of Reagents and Standards
- 766-S-1001, Rev. 0, 12/28/94- Processing Samples Through the Sample Processing Laboratory (AC94-0006)
- 766-S-2001, Rev. 0, 2/28/95 - Dispositioning Samples from the ON-Site Laboratory to the KC-2 Warehouse
- AC95-0175, 12/12/95 - Drying and Grinding Solid Samples in Preparation for Laboratory Analysis
- AC96-0002, 2/16/96 - Sample Preparation and Analysis for Uranium Determination by ICP-MS
- AC96-0028, 3/14/96 - Management and Reporting of Analytical Laboratory Results
- EW-0002, Rev. 0, 9/25/95 - Chain of Custody/Request for Analysis Record for Sample Control
- EW-004, Rev. 4, 3/24/95 - Satellite Accumulation Areas for Hazardous Wastes
- FD-1000, Rev 0.2, 5/4/94 - Sitewide CERCLA QA Project Plan
- MS-1001, Rev. 1, 2/15/96 - FERMCO Site Procedure System \*\*
- MS-1002, Rev. 0, 4/1/95 - Control of Plans and Internal Requirements Documents \*\*\*\*
- RM-0012, Rev. 3, 11/30/94 - FERMCO Quality Assurance Program
- FERMCO (rough draft) "Plutonium Isotopic Determination in Soil by Alpha Spectrometry"

- FERMCO (rough draft "Plutonium Isotopic Determination in Water by Alpha Spectrometry
- Alpha spectrometry lab printouts of quality assurance data and trace yield data
- Environmental Technical Services Division Temporary Document Index

APPENDIX B  
OBSERVATIONS - I96-09

**Requirement:** RM-0012, 4.2.1  
A system shall be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design.

Observation 1: Current procedures were not available in rooms where work processes are performed, e.g.,

- Sample Prep
- Sample Log-in
- Glassware Cleaning
- Standards Prep
- Analytical Methods (Visual Inspection)

**Discussion:** Procedures were available at work stations located near work areas. That is a new concept for lab personnel. During previous audits, uncontrolled or outdated procedures had been found in work areas; the work stations were added in order to maintain better control of documents.

Observation 2: The work card is legal, however, transferring data by hand adds a possibility of transcription error when an automated data system is available.

**Requirement:** SCQ13.2 - Maintenance activities shall be documented in logs.

Observation 3: Preventive maintenance (PM) schedules are not available in all the PM documentation. PM has not been noted for the Berthold instrument (Low Level Lab) PM schedules were available in the laboratory and were placed in the log books. Corrected immediately.

**Requirement:** RM-0012 8.6.1 - Establish chemical analysis controls for the test and examination services provided to support site restoration, environmental monitoring, and health programs.

Observation 4: Randomly chosen standards were expired, could not be fully traced to NIST, or solutions for calibration were not traceable; acceptance limits for conductivity had not been established. All of these items were verified, traced to NIST, as required, therefore, this observation is closed.

Observation 5: Several undated GFAA working standards were discovered in the inorganics laboratory. Dating of standards is required by SCQ section 12.4.3.1. Note that this is different from using expired standards.

Observation 6: Although monthly pipet calibrations are required (per FERMCO memo that has not yet been made a part of the procedure), lapses of multiple months were noted in the logbook.

Observation 7: The FERMCO laboratory has no acceptance requirements for calibrating thermometers as are required by RM-0012, section 8.5.1.

Requirement: SCQ E.2.1.13 - Has laboratory and administrative programs in place which comply with the requirements of OSHA, e.g., MSDS, Chemical Hygiene Plan, Radiation Safety Program, and a Hazardous Waste Management Program

Observation 8: Eye wash stations in Rooms 148 and 190 had inconsistent pressure: high pressure in one station (by the wall - 148), low pressure on one side (near the sink - 148)

Observation 9: Hood in Room 168 had a cracked front, FH 158A EF-1; Work order had been written.

Observation 10: A fire extinguisher was not evident in the SAA. Corrected immediately.

Observation 11: Personnel records indicated both chemical hygiene and rad worker training were overdue for personnel identified to ALS management. Personnel were scheduled for training.

Requirement: RM-0012, 5.3.1, SCQ 13.2 - Listing of spare parts necessary to minimize down time ..

Observation 12: Spare parts lists for the analytical instruments were not provided.

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. <b>NONCONFORMANCE REPORT NUMBER:</b> (This number is assigned by The P/QA Nonconformance Administrator.)		F96-0062	
2. <b>TYPE OF NONCONFORMANCE REPORT:</b> Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation.. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation.. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION	<input type="checkbox"/>
		FINDING	<input checked="" type="checkbox"/>
		DEVIATION	<input type="checkbox"/>
		CORRECTIVE ACTION REPORT	<input type="checkbox"/>
3. <b>DATE DISCOVERED:</b> Enter the date the nonconformance was identified.		3- 3/28/96	
4. <b>RESPONSIBLE ORGANIZATION:</b> Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a.	Envr Dech Serv
		4b.	ALS
5. <b>RESPONSIBLE MANAGER:</b> Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a.	Chris Sutton
		5b.	
6. <b>LOCATION:</b> Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a.	On-Site Lab / Low Level
		6b.	LHC 3
7. <b>ASSESSMENT ACTIVITY:</b> Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7.	Audit I96-09
8. <b>REQUIREMENTS:</b> (Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
RM-0012, 4.2.1 - A system shall be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work.			
9. <b>NONCONFORMANCE:</b> (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
1. A systematic breakdown in document control was evident. See Audit Report I96-09 for examples. Logbooks were not adequately structured nor controlled for documenting chemical analyses and calibration acceptance.			
10. <b>PREPARED BY:</b>	11. <b>Phone:</b>	12. <b>Mail Stop:</b>	13. <b>Date:</b>
Wally Ann Barrett	5387	43	4/15/96
(All Employees Send or Take the Original of this report to the P/QA Representative)			

## PERFORMANCE QUALITY ASSURANCE EVALUATION

14. <b>QUALITY ASSURANCE PROGRAM REQUIREMENT:</b> ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 4.2.1	
15. <b>DIVISION/DEPARTMENT REQUIREMENT:</b> ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph , etc.)		15. —	
16. <b>NOTIFICATION:</b> (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. <b>TRENDING INFORMATION:</b> (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii))		17. 2.0 A i, iii, iv	
18. <b>TAGGING REQUIRED:</b>   YES   <input checked="" type="checkbox"/> NO	19. <b>P/QA REP.:</b> Wally Ann Barrett	20. <b>DATE:</b>	
21. <b>P/QA MANAGEMENT REVIEW:</b> James E. [Signature]	POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO	22. <b>DATE:</b> 4/15/96	
23. <b>P/QA DIV. MANAGER:</b> (CARs Only)		24. <b>DATE:</b>	
23A. <b>REPORT TO NTS:</b>   YES   <input checked="" type="checkbox"/> NO	23B. <b>PAAA COORDINATOR:</b>	23C. <b>DATE:</b>	
(P/QA Representative obtains the Nonconformance Report Number from the P/QA Nonconformance Administrator and enters the number in Block 1 above)		25. <b>RESPONSIBLE MANAGER RESPOND BY:</b> (Date)	

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. NONCONFORMANCE REPORT NUMBER: (This number is assigned by The P/QA Nonconformance Administrator.)		F96-0063	
2. TYPE OF NONCONFORMANCE REPORT: Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation.. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation.. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION	
		FINDING	4
		DEVIATION	
		CORRECTIVE ACTION REPORT	
3. DATE DISCOVERED: Enter the date the nonconformance was identified.		3. 3/27/96	
4. RESPONSIBLE ORGANIZATION: Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. Env Tech Serv	4b. ALS
5. RESPONSIBLE MANAGER: Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. Chris Sutton	5b. —
6. LOCATION: Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. On Site Lab - Low Level	6b. < HC 3
7. ASSESSMENT ACTIVITY: Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7. Audit I96-09	
8. REQUIREMENTS: (Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
RM-0012, 5.2.2 - Work shall be performed to established technical standards and Administrative Controls.			
9. NONCONFORMANCE: (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
2. Work related instructions and/or specific procedures were not available and/or controlled. See Audit Report I96-09 for examples. Specific example: 7 and 14 interlock correction are not being followed by the ICP.			
10. PREPARED BY: Mike Dan Garrett	11. Phone: 5387	12. Mail Stop: 43	13. Date: 4/15/96

### PERFORMANCE QUALITY ASSURANCE EVALUATION

14. QUALITY ASSURANCE PROGRAM REQUIREMENT: ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 5.2.2	
15. DIVISION/DEPARTMENT REQUIREMENT: ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph , etc.)		15. —	
16. NOTIFICATION: (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. TRENDING INFORMATION: (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii))		17. 2.0 B i, ii	
18. TAGGING REQUIRED:     YES   <input checked="" type="checkbox"/> NO	19. P/QA REP.: Mike Dan Garrett	20. DATE: 4/15/96	
21. P/QA MANAGEMENT REVIEW: <i>[Signature]</i> POTENTIAL PAAA:     YES   <input checked="" type="checkbox"/> NO		22. DATE: 4/15/96	
23. P/QA DIV. MANAGER: (CARs Only)		24. DATE:	
23A. REPORT TO NTS:     YES   <input checked="" type="checkbox"/> NO	23B. PAAA COORDINATOR:	23C. DATE:	
(P/QA Representative obtains the Nonconformance Report Number from the P/QA Nonconformance Administrator and enters the number in Block 1 above)		25. RESPONSIBLE MANAGER RESPOND BY: (Date)	

# Nonconformance Report

Revision: 20

(Preparer Completes Blocks 2 through 13)

1. <b>NONCONFORMANCE REPORT NUMBER:</b> (This number is assigned by The P/QA Nonconformance Administrator.)		F96-0064	
2. <b>TYPE OF NONCONFORMANCE REPORT:</b> Check <i>OBSERVATION</i> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation.. An observation, if resolved, could lead to excellence in operations. Check <i>FINDING</i> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation.. Check <i>DEVIATION</i> for hardware items when the condition represents a departure from specified requirements or specifications. Check <i>CORRECTIVE ACTION REPORT</i> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION     FINDING   <input checked="" type="checkbox"/> DEVIATION     CORRECTIVE ACTION REPORT	
3. <b>DATE DISCOVERED:</b> Enter the date the nonconformance was identified.		3. 3/27/96	
4. <b>RESPONSIBLE ORGANIZATION:</b> Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. Env Tech Serv. 4b. ALS	
5. <b>RESPONSIBLE MANAGER:</b> Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. (Chris) Sutton 5b. —	
6. <b>LOCATION:</b> Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. On-Site Lab/Gen Gen 6b. < HC 3	
7. <b>ASSESSMENT ACTIVITY:</b> Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7. Audit I96-09	
8. <b>REQUIREMENTS:</b> (Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
RM-0012, 5.2.2 Work shall be performed to established technical standards and administrative controls.			
9. <b>NONCONFORMANCE:</b> (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
3. Work instructions are not as detailed as required to safely perform work and do not reflect actual work being performed. See Audit Report I96-09 for examples.			
10. <b>PREPARED BY:</b> Mary Ann Forrest		11. <b>Phone:</b> 5387	12. <b>Mail Stop:</b> 43
13. <b>Date:</b> 4/15/96			

**PERFORMANCE QUALITY ASSURANCE EVALUATION**

14. <b>QUALITY ASSURANCE PROGRAM REQUIREMENT:</b> ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 5.2.	
15. <b>DIVISION/DEPARTMENT REQUIREMENT:</b> ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph , etc.)		15. —	
16. <b>NOTIFICATION:</b> (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. <b>TRENDING INFORMATION:</b> (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii)		17. 2.0 A iii	
18. <b>TAGGING REQUIRED:</b>     YES   <input checked="" type="checkbox"/> NO	19. <b>P/QA REP.:</b> Mary Ann Forrest		20. <b>DATE:</b> 4/15/96
21. <b>P/QA MANAGEMENT REVIEW:</b> James C. [Signature]		POTENTIAL PAAA:     YES   <input checked="" type="checkbox"/> NO	
22. <b>DATE:</b> 4/15/96		23. <b>P/QA DIV. MANAGER:</b> (CARs Only)	
23A. <b>REPORT TO NTS:</b>     YES   <input checked="" type="checkbox"/> NO		23B. <b>PAAA COORDINATOR:</b>	
23C. <b>DATE:</b>		25. <b>RESPONSIBLE MANAGER RESPOND BY:</b> (Date)	

FS-F-4370 (Rev. 02/27/96)

(Send this report to the Distribution List provided in paragraph 7.4.14 in QA-0001)

Side 2 of this Form is Not Required for Observations

000150

(Preparer Completes Blocks 2 through 13)

1. <b>NONCONFORMANCE REPORT NUMBER:</b> (This number is assigned by The P/QA Nonconformance Administrator.)		F96-0065	
2. <b>TYPE OF NONCONFORMANCE REPORT:</b> Check <i>OBSERVATION</i> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation.. An observation, if resolved, could lead to excellence in operations. Check <i>FINDING</i> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation.. Check <i>DEVIATION</i> for hardware items when the condition represents a departure from specified requirements or specifications. Check <i>CORRECTIVE ACTION REPORT</i> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION	<input type="checkbox"/>
		FINDING	<input checked="" type="checkbox"/>
		DEVIATION	<input type="checkbox"/>
		CORRECTIVE ACTION REPORT	<input type="checkbox"/>
3. <b>DATE DISCOVERED:</b> Enter the date the nonconformance was identified.		3. 3/28/96	
4. <b>RESPONSIBLE ORGANIZATION:</b> Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a.	Env Tech Div.
		4b.	ALS
5. <b>RESPONSIBLE MANAGER:</b> Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a.	Chris Sutton
		5b.	
6. <b>LOCATION:</b> Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a.	Gen. Site Lab/Gen R
		6b.	< HC 3
7. <b>ASSESSMENT ACTIVITY:</b> Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7. Audit I96-09	
8. <b>REQUIREMENTS:</b> (Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
RM-0012, 8.3.1 - A test Control program shall be established as required and implemented for acceptance testing to demonstrate that items will perform as intended.			
9. <b>NONCONFORMANCE:</b> (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
4. Electronic spread sheets currently in use have not been routinely verified, in order to ensure they are calculating correctly (LHK)			
10. <b>PREPARED BY:</b> Mike Dan Forrest	11. <b>Phone:</b> 5387	12. <b>Mail Stop:</b> 43	13. <b>Date:</b> 4/15/96

### PERFORMANCE QUALITY ASSURANCE EVALUATION

14. <b>QUALITY ASSURANCE PROGRAM REQUIREMENT:</b> ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012, 8.3.	
15. <b>DIVISION/DEPARTMENT REQUIREMENT:</b> ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph , etc.)		15. —	
16. <b>NOTIFICATION:</b> (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. <b>TRENDING INFORMATION:</b> (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii))		17. 2.0 B ✓	
18. <b>TAGGING REQUIRED:</b>   YES   <input checked="" type="checkbox"/> NO	19. <b>P/QA REP.:</b> Mike Dan Forrest	20. <b>DATE:</b> 4/15/96	
21. <b>P/QA MANAGEMENT REVIEW:</b> [Signature]	POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO	22. <b>DATE:</b> 4/15/96	
23. <b>P/QA DIV. MANAGER:</b> (CARs Only)		24. <b>DATE:</b>	
23A. <b>REPORT TO NTS:</b>   YES   <input checked="" type="checkbox"/> NO	23B. <b>PAAA COORDINATOR:</b>	23C. <b>DATE:</b>	
(P/QA Representative obtains the Nonconformance Report Number from the P/QA Nonconformance Administrator and enters the number in Block 1 above)		25. <b>RESPONSIBLE MANAGER RESPOND BY:</b> (Date)	

(Preparer Completes Blocks 2 through 13)

1. <b>NONCONFORMANCE REPORT NUMBER:</b> (This number is assigned by The P/QA Nonconformance Administrator.)		F96-0066	
2. <b>TYPE OF NONCONFORMANCE REPORT:</b> Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation.. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation.. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION <input type="checkbox"/> FINDING <input checked="" type="checkbox"/> DEVIATION <input type="checkbox"/> CORRECTIVE ACTION REPORT <input type="checkbox"/>	
3. <b>DATE DISCOVERED:</b> Enter the date the nonconformance was identified.		3. 3/28/96	
4. <b>RESPONSIBLE ORGANIZATION:</b> Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a. <u>Envt Tech Serv</u>	4b. <u>AWS</u>
5. <b>RESPONSIBLE MANAGER:</b> Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a. <u>Chris Sutton</u>	5b. <u>Chris Sutton</u>
6. <b>LOCATION:</b> Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a. <u>On-Site Lab/Lead Gen</u>	6b. <u>HC 3</u>
7. <b>ASSESSMENT ACTIVITY:</b> Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7. <u>Audit I96-09</u>	
8. <b>REQUIREMENTS:</b> (Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
RM-0012 8.5.5 Measuring and test equipment is to be calibrated against standards having an accuracy that will ensure the the equipment will be within required tolerances.			
9. <b>NONCONFORMANCE:</b> (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
5. Calibration standards do not have a greater accuracy than the standards being calibrated; Calibration had expired on standards. See Audit Report I96-09 for examples.			
10. <b>PREPARED BY:</b> <u>Mary Ann Forrest</u>	11. <b>Phone:</b> <u>5387</u>	12. <b>Mail Stop:</b> <u>43</u>	13. <b>Date:</b> <u>4/15/96</u>

**PERFORMANCE QUALITY ASSURANCE EVALUATION**

14. <b>QUALITY ASSURANCE PROGRAM REQUIREMENT:</b> ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. <u>DM-0012, 8.5.5</u>	
15. <b>DIVISION/DEPARTMENT REQUIREMENT:</b> ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph , etc.)		15. <u>—</u>	
16. <b>NOTIFICATION:</b> (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. <u>3/28/96</u>	
17. <b>TRENDING INFORMATION:</b> (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii)		17. <u>3.0 C, ii</u>	
18. <b>TAGGING REQUIRED:</b>   YES   <input checked="" type="checkbox"/> NO	19. <b>P/QA REP.:</b> <u>Mary Ann Forrest</u>		20. <b>DATE:</b> <u>4/15/96</u>
21. <b>P/QA MANAGEMENT REVIEW:</b> <u>James C</u> POTENTIAL PAAA:   YES   <input checked="" type="checkbox"/> NO		22. <b>DATE:</b>	
23. <b>P/QA DIV. MANAGER:</b> (CARs Only)		24. <b>DATE:</b>	
23A. <b>REPORT TO NTS:</b>   YES   <input checked="" type="checkbox"/> NO	23B. <b>PAAA COORDINATOR:</b>		23C. <b>DATE:</b>
(P/QA Representative obtains the Nonconformance Report Number from the P/QA Nonconformance Administrator and enters the number in Block 1 above)		25. <b>RESPONSIBLE MANAGER RESPOND BY:</b> (Date)	

# Nonconformance Report

(Preparer Completes Blocks 2 through 13)

1. NONCONFORMANCE REPORT NUMBER: (This number is assigned by The P/QA Nonconformance Administrator.)		F96-0067	
2. TYPE OF NONCONFORMANCE REPORT: Check <b>OBSERVATION</b> if the identified condition has little or no impact on the quality of an item, the quality of work, or the reliability of documentation.. An observation, if resolved, could lead to excellence in operations. Check <b>FINDING</b> if the identified condition represents a procedural or program deviation which impacts the quality of work or the reliability of documentation.. Check <b>DEVIATION</b> for hardware items when the condition represents a departure from specified requirements or specifications. Check <b>CORRECTIVE ACTION REPORT</b> if the condition represents trended deviations from specified requirements, a programmatic breakdown, or a Significant Condition Adverse to Quality.		OBSERVATION	<input type="checkbox"/>
		FINDING	<input checked="" type="checkbox"/>
		DEVIATION	<input type="checkbox"/>
		CORRECTIVE ACTION REPORT	<input type="checkbox"/>
3. DATE DISCOVERED: Enter the date the nonconformance was identified.		3. 3/28/96	
4. RESPONSIBLE ORGANIZATION: Enter the Division (4a.) and Department (4b.) of the organization responsible for correcting the nonconformance. (If known)		4a.	Env Sech Serv
		4b.	ALS
5. RESPONSIBLE MANAGER: Enter the Division Manager (5a.) and Department Manager (5b.) of the organization responsible for correcting the nonconformance. (If known)		5a.	(Chris) Sutton
		5b.	
6. LOCATION: Identify the Project/Activity where the nonconformance was observed (6a.) also enter Hazard Category (6b.) (if known).		6a.	On Site Lab/Gen Fund
		6b.	CHC 3
7. ASSESSMENT ACTIVITY: Enter the type and number of the assessment that was being performed when the nonconformance was identified. (e.g. Audit I95-19, QEP Number, Walk-through, etc.)		7.	Audit I96-09
8. REQUIREMENTS: Identify and Quote the requirement directly from the document (procedure, specification, drawing, etc.) that best describes the acceptance criteria for the item or activity.)			
AM-0012, 8.6.1 - Establish Chemical Analysis Controls for the test and examination services provided to support site restoration, environmental monitoring and health programs			
9. NONCONFORMANCE: (Fully describe the nonconformance as it relates to the requirements. (Use supplemental sheets as required.)			
6. Controls were not in place for test and examination services provided to support site restoration, environmental monitoring - See Audit Report I96-09 for examples			
10. PREPARED BY: M. A. Forrest	11. Phone: 5387	12. Mail Stop: 43	13. Date: 4/15/96

### PERFORMANCE QUALITY ASSURANCE EVALUATION

14. QUALITY ASSURANCE PROGRAM REQUIREMENT: ( Enter the Criterion and paragraph number of the Quality Assurance Program, (RM-0012), requirement that best describes the acceptance criteria for the item or process being assessed.)		14. RM-0012 8.6	
15. DIVISION/DEPARTMENT REQUIREMENT: ( Enter the document number and paragraph of the division or department requirement that best describes the acceptance criteria for the item or process being assessed. (Drawing Number, Spec. Number, Procedure Number, as well as, the Paragraph , etc.)		15. —	
16. NOTIFICATION: (Enter the date the responsible manager was notified of the nonconformance. Ensure manager agrees a nonconformance exists.)		16. 3/28/96	
17. TRENDING INFORMATION: (Enter the paragraph number from the Matrix of Nonconformances (Attachment D, QA-0001) that best describes the identified nonconformance. (e.g., 1.0 F ii))		17. 2.0 B V	
18. TAGGING REQUIRED:   YES   NO	19. P/QA REP.: M. A. Forrest	20. DATE: 4/15/96	
21. P/QA MANAGEMENT REVIEW: [Signature]	POTENTIAL PAAA:   YES   NO	22. DATE: 4/15/96	
23. P/QA DIV. MANAGER: (CARs Only)	24. DATE:		
23A. REPORT TO NTS:   YES   NO	23B. PAAA COORDINATOR:	23C. DATE:	
(P/QA Representative obtains the Nonconformance Report Number from the P/QA Nonconformance Administrator and enters the number in Block 1 above)		25. RESPONSIBLE MANAGER RESPOND BY: (Date)	