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**RESULTS OF USEPA REVIEW OF THE USDOE  
LABORATORY AUDIT PROGRAM**

**05/11/93**

**USEPA/DOE-FN  
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LETTER**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
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CHICAGO, IL 60604-3590

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REPLY TO THE ATTENTION OF:

Mr. Jack R. Craig  
United States Department of Energy  
Feed Materials Production Center  
P.O. Box 398705  
Cincinnati, Ohio 45239-8705

HRE-8J

RE: Results of U.S. EPA Review  
of the U.S. DOE Laboratory  
Audit Program

Dear Mr. Craig:

The United States Environmental Protection Agency (U.S. EPA) has completed its review of the United States Department of Energy (U.S. DOE) internal laboratory audit program conducted for the Fernald Environmental Management Project (FEMP).

Although the audit framework appears adequate and the checklists used to conduct the audits are satisfactory, the audit program fails to adequately evaluate the performance of a laboratory. There is not enough detail provided in laboratory evaluation reports to determine if a laboratory is of necessary quality for this project.

U.S. EPA has enclosed specific comments on the internal audit process that must be incorporated into U.S. DOE's internal evaluation program. U.S. DOE must document these changes and submit them to U.S. EPA.

Please contact me at (312) 886-0992, or Robert Holloway at (702) 798-2325 if you have any questions.

Sincerely,

James A. Saric  
Remedial Project Manager

Enclosure

cc: Graham Mitchell, OEPA-SWDO  
Pat Whitfield, U.S. DOE-HDQ  
Nick Kaufmann, FERMCO  
Jim Thiesing, FERMCO  
Paul Clay, FERMCO



4387

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OFFICE OF RCRA  
WASTE MANAGEMENT DIVISION  
EPA REGION 9

MEMORANDUM:

SUBJECT: Review of FEMP QA Audit Program

FROM: Robert Holloway  
Chemist, Radioanalysis Branch  
Nuclear Radiation Assessment DivisionTO: James Saric  
Remedial Project Manager  
Region 5

As you requested, John Akridge and I have reviewed the documents related to the audit program conducted for the Fernald Environmental Management Project (FEMP). Our comments are given below and are restricted to the radiochemical aspects of the audit procedures. Also attached are the documents that we reviewed. The following comments apply to audit E92-12.

1. The general audit framework seems to be adequate and the checklist used for the FEMP audit is a good one.
2. In regard to radiochemistry, the audit report does not have enough detail. There is also very little detail in the handwritten notes that were taken during the audit. The type of information captured during the audit is not what we consider to be the most important information bearing on quality. For example, the notes and report state that the laboratory participates in both the DOE and EPA quality assurance (intercomparison) programs, but does not discuss the performance of the laboratory except to say that follow-up files were adequate on "not acceptable" QA results. Because the isotopes of interest include uranium and thorium isotopes, a complete discussion of the laboratory's past performance on the analysis of these elements should be included. It is impossible to determine from this report whether the laboratory

participated in the cross-checks for uranium and thorium and if so, whether their results were acceptable.

3. Section 5.2.2 in the audit report notes that the training files contain various documents such as resumes, training documents, etc. However, an equally important audit activity would be to compare the resumes and other files against some minimum standard for education and experience. The auditors should give their opinion as to whether or not the staff has appropriate qualifications.
4. The audit team did not identify any minimum QA standards for analytical results nor did they discuss data quality objectives either in terms of their own requirements or the local requirements of the laboratory they were visiting. What do they consider acceptable in terms of accuracy and precision? Does the laboratory meet reasonable standards in that regard?
5. The audit report has no detail in regard to calibration. They do not list equipment used in radiochemistry and do not discuss issues such as calibration frequency, control charts, etc. Most radiochemical laboratories have defects in these areas. (See the audit reports on IT Corporation and Datachem for comparison).
6. The checklist used by the auditors has a section that deals with data review and validation. The auditors marked N/A beside that topic and do not discuss it in the report. Data review is checked as being acceptable in a later part of the checklist. Data review and validation is a topic of considerable importance and should be discussed in the report.
7. The audit report did not discuss the origin and documentation for radioactive standards. We believe that this is an important point that should not be overlooked. Are the standards traceable to NIST, for example? Are the records adequate?

In summary, our opinion is that the audit (E92-12) does not adequately evaluate the performance of the laboratory. There is not enough detail provided in the report to form an opinion as to the quality of the laboratory. The auditors have checked to see if various files and QA elements are in place but have not taken the additional step (in many cases) of comparing those elements against some reasonable standard. The reasonable standard need not be external to the laboratory but can be internal as well. For example, the laboratory should have data quality objectives

for accuracy and precision and an audit should reveal how well the laboratory is doing in meeting their own objectives.

We note that the audit report gives very few, if any, conclusions in regard to data quality. Because the quality of the data is really the only reason for an audit, we believe that an audit report should contain a clear evaluation of the various measures of data quality supported by numerical information where appropriate.

This concludes our review. If you have any questions, please call me at (702) 798-2325 or John Akridge at (702) 798-2673.

Attachments