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RESULTS OF LABORATORY AUDITS: IT CORPORATION, OAK RIDGE, TENNESSEE; AND DATACHEM, SALT LAKE CITY, UTAH

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LETTER

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

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IT-LAB / DATACHEM FILE

THE ATTENTION OF: HRE-8J

DATE RECEIVED: 10/5/92

108.14

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

RE: Results of Laboratory Audits: IT Corporation, Oak Ridge, Tennessee; and Datachem, Salt Lake City, Utah

Dear Mr. Craig:

On August 18, 1992, and August 20, 1992, the United States Environmental Protection Agency (U.S. EPA) conducted laboratory audits of the Datachem Laboratory located in Salt Lake City, Utah, and IT Corporation Laboratory located in Oak Ridge, Tennessee, respectively. Both Laboratory audits were conducted to determine the adequacy of the Laboratories for conducting radiochemical analysis to support the United States Department of Energy's Site Wide Quality Assurance Project Plan (QAPjP).

Overall, the laboratories were found to be acceptable for conducting radiochemical analysis in support the Comprehensive Environmental Response Compensation and Liability Act activities at the Fernald Site. However, enclosed are U.S. EPA's comments on the above mentioned laboratories. The laboratories must incorporate the comments, and U.S. DOE must make any necessary changes to the QAPjP.

Also, U.S. EPA is currently investigating and conducting audits of the other laboratories listed in the QAPjP. The results of these audits will be forthcoming. Any comments or corrective actions required, as a result of the audits, may require revisions to the QAPjP.

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
Dennis Carr, WMCO

AUDIT REPORT FOR INTERNATIONAL TECHNOLOGY CORPORATION

On August 20, 1992, an audit team consisting of Robert Holloway and John Akridge performed a laboratory audit of International Technology Corporation IT) at Oak Ridge, Tennessee. Significant results of that audit are given below. Our primary contacts were Dr. Larry Kanipe, Laboratory Director, Dr. L. Lloyd Collins, Manager - Radiological Laboratory, Dr. Charles Russell, Laboratory Manager, and Ms. Leah Rawlins, QC Coordinator. The audit team was given an extensive and informative tour of IT's radiochemistry laboratory. The staff of IT was very helpful and cooperative during the audit.

Significant Observations

1. The laboratory has participated extensively in the EPA intercomparison program with acceptable results. They also participate in the Department of Energy QA program.

2. Control charts are generally in use for all counting instrumentation. It was noted, however, that a radionuclide check source was not being used to check daily instrument performance for the alpha spectroscopy surface barrier detectors. For alpha spectroscopy, an electronically generated pulse was used for instrument performance control charts.

3. Control limits for instrument performance have been defined and are consistent with generally accepted radiochemical laboratory QA/QC practices.

4. Software documentation, data entry, and data review seem very good. It was noted that data review procedures are currently being developed that will define criteria for re-analyzing samples for reasons such as low chemical yield, etc.

5. Efficiency curves exist for Sr-89, Sr-90, gross alpha, and gross beta, etc. However, the efficiency curves were stated to be the average of efficiencies for three different counting instruments (gas flow proportional counters), with 16 detectors for each instrument.

6. We noticed that the laboratories were neat, orderly, and well-maintained. Lab chemicals, in general, were properly stored and labelled.

7. Radioactive standards were stored properly and well-documented.

8. It was noted that the frequency of calibration of alpha spectroscopy was not specified.

AUDIT REPORT FOR DATACHEM INC.

On August 18, 1992, Robert Holloway and John Akridge performed a laboratory audit of Datachem Laboratories in Salt Lake City, Utah. Our primary contacts were Ron Marsden, QA Section Manager, Charles Walker, Radiochemistry Manager, Jim Johnston, Project Manager, James Perkins, Vice-President and Lance Eggenberger, QA Department Manager. The staff of Datachem Laboratories was very helpful and cooperative during the audit.

Significant Observations

1. The laboratory has participated extensively in the EPA intercomparison program with acceptable results. They do not participate in the Department of Energy QA program.

2. Control charts are not in general use for instrument check sources and backgrounds. The data is present in most cases in the form of tables. Some control charts exist for precision and accuracy of results.

3. Control limits for instruments and analytical results have not been defined in written procedures.

4. Calibration frequency is not defined in QA manual or in written procedures. Some confusion seems to exist among the staff about calibration, performance checks, etc. and the purposes of these quality control elements.

5. Software verification exists but should be more detailed and more formally documented.

6. No efficiency curves exist for Sr-89 even though the written procedures require this item.

7. We noticed that the laboratories were neat and orderly.

8. Some calculations are still being done by hand, with possibly more chance of error compared to computerized calculations.

9. Radioactive standards are stored properly and certificates are available.

10. Training documentation is acceptable.

11. Internal audits are being done but the audits are not very comprehensive with only three problems noted.

12. We asked to see some comparisons of the measured values of typical spiked samples versus the known values.

This proved to be almost impossible to obtain, which suggests that the QC results are not being used for their intended purpose.

Summary

The elements of a good quality assurance program are present at Datachem. What is lacking is the integration and implementation of those elements. For example, an adequate number of QC results are being produced but there is no good mechanism for tracking and reviewing these results and comparing them with the expected values.

Recommendations

1. Datachem should participate in the Department of Energy QA program.

2. Control charts should be used for instrument check sources and backgrounds, even though the data is present in tables.

3. Control limits for instruments and analytical results should be defined by written procedures.

4. Calibration frequency for instruments should be defined in written procedures.

5. Written procedures should define the requirements for software verification. The verification requirements should be formal and detailed enough to provide confidence in the quality of the software and to document that it was tested.

6. Efficiency curves should be generated for Sr-89.

7. Calculations should be converted to computer programs rather than done manually.

8. A more effective system for reviewing and tracking QC information should be developed. This should include information for duplicates, blanks and spiked samples.

9. Based on the EPA intercomparison results and the results of this audit, we believe that Datachem is operating at an acceptable level of quality, however an additional improvement could be gained by implementing these recommendations.

5. It is recommended that the frequency of calibration of alpha systems be specified in a SOP.