Georgia Power Company
333 Piedmont Avenue
Atlanta, Georgia 30308
Telephone 404 526-3195

Mailing Address:
40 Inverness Center Parkway
Post Office Box 1295
Birmingham, Alabama 35201
Telephone 205 868 5581

the southern electric system

W. G. Hairston, III
Senior Vice President
Nuclear Operations

February 8, 1991

Docket Nos. 50-321 50-424 HL-01466
50-366 50-425 ELV-02504

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

Gentlemen:

PLANT HATCH - UNITS 1 AND 2
PLANT VOGTLE - UNITS 1 AND 2
REPORT OF UNSATISFACTORY PERFORMANCE TESTING

10 CFR [illegible]endix A, paragraph 2.8 requires that blind performance test specimens be submitted to each HHS-certified laboratory performing drug screens for the licensee. On January 8, 1991 two presumptive positive samples were forwarded from the Southern Nuclear Operating Company screening facility to SmithKline Beecham Clinical Laboratories (SBCL) for confirmation testing. One sample was a known blind positive and the other was an actual sample. On January 15, 1991 both samples were reported to be negative by the Medical Review Officer. Since the blind positive sample had not been reported to Southern Nuclear as a positive test, an investigation was begun.

The subsequent investigation determined that an error had occurred on the part of SBCL. The blind positive sample and an actual sample were assigned consecutive log numbers by SBCL on January 9, 1991. Both of these two samples tested positive in the initial screening for amphetamines. An administrative mistake was then made during the confirmatory testing using a gas chromatograph-mass spectrometer. The results of the tests of these consecutively numbered samples were reversed. On January 18, 1991, as a result of the discovery that a mistake was made, both samples were retested by SBCL and the actual results were made known. The Medical Review Officer had originally dispositioned the employee sample as negative when it was received by him from SBCL due to prescribed medications the individual was taking which the Medical Review Officer believed would generate a positive test result. Therefore, no personnel sanctions had been imposed against any individual. SBCL has taken action to prevent recurrence of this kind of error in the future.

A022
1/1

This is the second report of unsatisfactory performance testing against SBCL by a Southern Company utility, (Ref: Alabama Power Company to U. S. Nuclear Regulatory Commission letter of May 25, 1990). As a result of this second unsatisfactory performance, the Corporate Quality Services organization of Southern Nuclear Operating Company will be auditing SBCL in the near future.

Enclosed are the findings and corrective actions taken by SBCL as reported from William Shaw, Ph.D., of SBCL. This letter is considered to satisfy the reporting requirements of 10 CFR 26 Appendix A, paragraph 2.8.

If you have any questions, please advise.

Respectfully submitted,

W. G. Hairston, III

WGH,III/JMG

Enclosure

cc: Georgia Power Company
Mr. J. T. Beckham, Jr., Vice President - Nuclear, Plant Hatch
Mr. C. K. McCoy, Vice President - Nuclear, Plant Vogtle
Mr. W. B. Shipman, General Manager - Plant Vogtle
Mr. H. L. Sumner, Jr., General Manager - Plant Hatch
NORMS

U. S. Nuclear Regulatory Commission, Washington, DC
Mr. K. N. Jabbour, Licensing Project Manager - Hatch
Mr. D. S. Hood, Licensing Project Manager - Vogtle

U. S. Nuclear Regulatory Commission, Region II
Mr. S. D. Ebneter, Regional Administrator
Mr. L. D. Wert, Senior Resident Inspector - Hatch
Mr. B. R. Bonser, Senior Resident Inspector - Vogtle

SmithKline Beecham
Clinical Laboratories

January 29, 1991

TO: Paul Bizjak cc: W. Mercer, Ph.D.

FROM: William Shaw, Ph.D. W. Shaw

SUBJECT: **Amended Amphetamine Results On Southern Company Samples**

Two samples from the Southern Company, C910008 and C910020, were received into this laboratory for drug testing on 1/9/91 about 3:00 am. These samples were assigned SBCL log numbers 090195G and 090196G, respectively. Both samples were aliquotted for screening and tested positive for amphetamines. Since the screening tests were positive for amphetamines, both samples were pulled from temporary storage and aliquots were removed for confirmation. The aliquots for GC/MS confirmation were poured on 1/9/91 by the aliquotter and transferred to technologist A who performed the extractions and loaded the autosampler of the GC/MS. The contents of the vials were injected by the autosampler and reviewed by technologist B, checked by technologist C, and certified by a certifying scientist. Results were then released.

In the GC/MS run on 1/9/91, the employee sample 090195G was determined to be positive with an amphetamine value of 2702 ng/ml urine. The results for sample 090196G which we later learned was the blind sample, were negative for amphetamine. All quality control samples, standards, and blind samples were acceptable. The retention time and ion ratio values of the amphetamine on sample 090195G were all acceptable.

Less than one week after reporting these results, we were notified by the Southern Company that sample 090196G was a blind positive sample while SBCL had reported the results as negative. Based on these results, we repeated the screening tests and also repeated the GC/MS tests on each of the samples on 1/16 and 1/17/91. These results contradicted the 1/9/91 results. An additional GC/MS run on 1/18/91 demonstrated that sample 090195G was negative and sample 090196G was positive for amphetamine with a value of 2748 ng/ml. These results also contradicted the initial GC/MS run on 1/9/91. Furthermore, the similarity of quantitative results 2748 ng/ml for 090196G on the 1/18/91 run and 2702 ng/ml for sample 090195G on 1/9/91 led to the strong suspicion of a sample mixup between sample 090195G and sample 090196G. We received information from Paul Bizjak that the employee results had been reported to the company as a negative. The employee results tested positive on the screening test because the employee was on the drugs phentermine and tenuate, drugs related to amphetamine. This information was obtained from Mr. Bizjak from information obtained in the Southern Company drug screening program. Our GC/MS procedure is <u>not</u> subject to interference from phentermine or tenuate.

The use of phentermine by the employee explains why the screening test was positive since phentermine does give a false positive screening result with the EMIT test but not with the GC/MS test.

A summary of all tests results on the two samples is give in Table 1.

All of the data indicate that the screening tests were done correctly. Both samples were reactive with EMIT. The employee sample contained no amphetamine or methamphetamine but contained amphetamine-like compounds that gave a positive EMIT result. Such reactions are extremely common and I emphasize that this finding was not an error. The employee sample should have tested negative by the confirmation test but was somehow switched with the blind sample that differed by only one digit of the log (accession) number. The sample switch had to have been made from the time aliquots were taken for GC/MS to the time the extracts of the samples was loaded on the autosampler of the GC/MS. The mixup could have occurred at the time the sample was aliquoted for GC/MS, during extraction, or when the vials containing extracts were transferred to the GC/MS.

I reviewed each of the procedures for sample identification during each of these steps with each of the persons involved and found that all procedures for identification were followed. Barcode identification is used to remove aliquots for GC/MS so that I think it is unlikely (but still possible) that ar error occurred at this step.

I think that the error probably occurred during the extraction when manually written identification numbers are written on tubes and vials. The two identification (log) numbers differed by only a single digit (5 vs 6) in a seven digit code. Furthermore, a handwritten 6 at the end of the identification code may appear similar to a handwritten letter G. I had to stop several times when reading these numbers to prevent an error in writing this report. The Technologist A who performed the extraction is rated as a very good technologist. However, she stated that she was interrupted in the middle of the run by the need to attend a safety meeting. Her concentration or normal precautions may have been disrupted by the meeting.

The most likely cause of the error is a human error in which two identification codes (log numbers) differing in a single digit out of seven digits were misread. I have held a meeting with the entire staff in which all sample identification steps have been reviewed. Strict compliance to all sample identification steps has been re-emphasized to all staff. I have also asked Dave O'Bryan, Ph.D., a SBCL Vice-President in our corporate office to evaluate the feasibility of adding a system capability for barcode identification labels that match our log numbers and which would be placed on the vials containing extracts for positive sample verfication by the barcode readers of the autosamplers of the GC/MS systems.

This is the first error due to probable human error in over 100,000 samples processed. Furthermore, the error was detected and corrected within a week of its occurrence, demonstrating the fundamental soundness of the SBCL drug testing program. The accuracy rate for this laboratory for NIDA/NRC samples is 99.999%. However, we are not satisfied with this performance and will use this opportunity to make further improvements in our sample identification procedures so that we can achieve 100% accuracy.

I have completed meetings scheduled with all staff to review all aspects of sample identification and many good ideas have been generated which will be evaluated over the next several weeks. The critical nature of this testing has been re-emphasized to the staff and several enhancements for sample identification will be evaluated. A review of all sample identification procedures that are being evaluated should be completed by March 15, 1991 and improved procedures will be implemented before that date if increased reliability is evident.

Employees who make identification errors are subject to disciplinary action. However, disciplinary action was inappropriate in this case because the person making the error could not be definitely established. A full report on all identification enhancements will be forwarded to you within 30 days.

Table 1
Summary Of Test Results On Samples For Amphetamine Testing
From The Southern Company

Sample Identification	Initial EMIT Screen	Second EMIT Screen	1/9/91 GC/MS Amp.	1/16/91 GC/MS Amp.	1/17/91 GC/MS Amp.	1/18/91 GC/MS Amp.
C-910008 (090195G) Employee Sample Containing Tenuate and Phentermine	Amp. Positive	Amp. Positive	2702 ng/ml	Not Done	Negative	Negative
C-910020 (090196G) Blind Positive for Amphetamine	Amp Positive	Amp. Positive	Negative	2718 ng/ml	Not Done	2748 ng/ml