C. K. McCoy
Vice President
Vogtle Project

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Operating Company, Inc.
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SOUTHERN COMPANY
Energy to Serve Your World℠

June 23, 1997

Docket Nos. 50-424
50-425

LCV-1064

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

VOGTLE ELECTRIC GENERATING PLANT
REPORT OF UNSATISFACTORY PERFORMANCE TESTING

Ladies and Gentlemen:

In accordance with 10 CFR Part 26, Appendix A, paragraph 2.8, Southern Nuclear Operating Company requires that blind performance test specimens be submitted to the Department of Health and Human Services (HHS) certified laboratory for testing. Southern Nuclear procedures require that these samples be tested on site and then forwarded to the laboratory for screening and subsequent confirmation. On May 15, 1997 specimen number V970483 was submitted to PharmChem Laboratories, Inc. in Menlo Park, California. The blind performance specimen had been prepared by ElSohly Laboratory and screened as positive at the Vogtle Electric Generating Plant on site testing facility. The performance specimen was certified by ElSohly as spiked with cocaine at a level of 768 ng/ml.

The specimen in question was received by PharmChem on May 16, 1997 and tested on May 17, 1997. The specimen was screened as negative for all analytes. Southern Nuclear notified PharmChem Laboratories on May 23, 1997 that a false negative blind performance error had occurred and requested an immediate investigation. PharmChem Laboratory provided a detailed review of the performance error on June 2, 1997. Southern Nuclear's consulting toxicologist, Dr. Christopher Frings, conducted a review of the PharmChem report and, by letter dated June 10, 1997, determined that the investigation and conclusions were satisfactory.

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A022

The findings of PharmChem and Dr. Christopher Frings are enclosed. The investigation shows no evidence of any systematic failure or fault that might be considered likely to produce the sort of error observed in the testing of this specimen. The results are

therefore classified as an outlier produced by an anomaly of automated analyzers. It should be noted that any drug positive outlier would be corrected by the application of the required independent confirmation test. Since this test screened as negative no confirmation was required.

Southern Nuclear has utilized PharmChem Laboratories since January 1, 1994 and this is the first blind performance error experienced with this laboratory. The laboratory reports high proficiency performance scores on HHS proficiency testing and nothing in the report indicates additional corrective action is required. Southern Nuclear therefore has accepted the laboratory investigation and submits this letter to satisfy the reporting requirements of 10 CFR Part 26 Appendix A, paragraph 2.8.

Should you have any further questions, please advise.

Respectfully submitted,

C. K. McCoy

CKM/JMG

Enclosure 1: PharmChem Laboratory Report (6 pages)
Enclosure 2: Evaluation by Dr. Christopher Frings (1 page)

cc: Georgia Power Company
Mr. J. B. Beasley, Jr.
Mr. M. Sheibani
NORMS

U. S. Nuclear Regulatory Commission
Mr. L. A. Reyes, Regional Administrator
Mr. L. L. Wheeler, Senior Project Manager, NRR
Mr. C. R. Ogle, Senior Resident Inspector - Vogtle

PHARMCHEM
LABORATORIES, INC.
1505A O'Brien Drive
Menlo Park, CA 94025

FACSIMILE COVER LETTER

Please deliver the following pages to:

NAME: Paul Bizjak

LOCATION: Southern Nuclear Operating Company

FAX PHONE: 205 992 6390

FROM: Tamara St Claire

CLASSIFICATION:
___ Ordinary
___ As Soon As Possible
_X_ Urgent
___ Confidential

We are transmitting 6 pages, including this cover letter.

DATE: 060297 TIME: 14:30

SUBJECT: QA Investigation

If you do not receive all pages, please call back ASAP.

COMMENTS: We are overnighting a hard copy

QUALITY ASSURANCE INVESTIGATION REPORT

Subject: False-negative report on sample submitted by Southern Nuclear Operating Company

DESCRIPTION OF EVENT:

The sample in question (LAN 971273589) was received on May 16, 1997. Shipping Receiving Department placed the sample in a screening batch, then placed the batch in temporary storage. The batch was accessioned and aliquoted early on May 17, 1997. The batch was screened by EMIT, reviewed and locked on the same day. The sample in question screened negative for all analytes requested.

On May 23, 1997 Ted Xenakis (Technical Specialist) received a call from April Brockson of Southern Nuclear Operating Company. She expressed concern that a blind control from El Sohly's laboratory had been reported as a negative. She informed Mr. Xenakis that the sample was positive for benzoylecgonine and had been confirmed by El Sohly's laboratory by GC/MS. On that date Mr. Xenakis had the sample pulled and requested reanalysis by GC/MS for benzoylecgonine. The sample confirmed positive for benzoylecgonine.

On May 27, 1997, April Brockson filed a report with Donna Brase of PharmChem laboratories and Ms. Brase brought the case to the attention of Tamara StClaire (QA Manager).

The EMIT pack and reanalysis data were pulled immediately for review. On May 28th the sample was submitted for reanalysis by EMIT; the specimen tested positive for cocaine.

QA INVESTIGATION

On May 27th, a QA Investigation into this matter was initiated. QA investigations serve to document the occurrence of a problem, identify the cause, direct corrective action to preclude the recurrence, and verify that corrective actions have been taken. This QA investigation followed several lines of inquiry to identify the cause of the analytical error:

1. Was the instrument used to perform the EMIT tests properly maintained and calibrated?
2. Were proper procedures followed in the chain of custody control and analysis of the specimen?
3. Were the EMIT chemistries used to test the specimen performing within normal parameters?
4. Was the analyzer used to test the specimen performing within normal parameters?

Certification of Preventive Maintenance:
The purpose of the preventive maintenance procedures is to ensure that all Olympus AU800 instruments function consistently and accurately by preventing problems that might occur. PharmChem Immunoassay Analysts perform maintenance functions both at start up and immediately after the last specimens have been run. All analysts are trained in the start-up and shutdown maintenance tasks. The preventive maintenance log for instrument #5, the instrument the initial batch was run on, was reviewed for the daily, weekly and monthly scheduled duties. All duties were performed as scheduled in accordance with SOP's.

Certification of Procedures:
Standard Operating Procedures were followed with respect to sample handling, testing and data review. Review of the Chain of Custody shows that all procedures followed guidelines outlined in the SOP's. Review of the EMIT data reveals the Laboratory Certifying Officers involved in certifying the data reviewed the batch following SOP guidelines. No personnel errors were found.

SAMHSA PT's:
The laboratory's scores for SAMHSA proficiency testing performed over the last twelve months have been excellent. The screening, confirmation and reporting scores have been 100% on all four cycles. The quantitation scores were 100% for the last three and 96.6% for the 4th cycle. There were no challenges outside of 50% of the participating laboratories' mean and no reported false positives in the last year.

EMIT Procedural Changes:
The Standard Operating Procedures were reviewed for changes which may have occurred since the last audit for Southern Nuclear by Dr. Frings in August of 1993. There were two minor changes. One was the change to a positive cocaine calibrator with a benzoylecgonine concentration of 3000 ng/ml. The second is an instrument change from Hitachi 747 to Olympus AU 800, an instrument widely used in the drug testing industry. The last four cycles of SAMHSA proficiency results, then are meaningful in assessing the accuracy of the EMIT tests performed upon this specimen.

Review of Samples:
The batch in question has been reviewed a second time by a Laboratory Certifying Scientist and deemed acceptable. The other Southern Nuclear samples which were in the original batch have been retested and each result reviewed and recertified. These other Southern Nuclear sample retests produced the same results as those originally reported.

Additional Documentation:

The original batch was closely reviewed to determine if any samples could have possibly been switched. There were no additional benzoylecgonine positives found in the batch which eliminates the possibility of sample mispour. To determine if matrix effects may have played a role in the result, all samples in the original batch were reviewed. Data from all analytes were examined for rate suppression which could be a symptom of reagent issues including contamination. To explore the instrument precision, PCP results from client specimens were examined. PCP results were negative for all specimens in the batch with little variability in absorbance values. Fluctuations in these results can be an indicator of instrument imprecision.

Results from the EMIT reanalysis are attached.

CONCLUSION

We have concluded that the most likely explanation for this false negative report is that the initial EMIT cocaine test result was an outlier. This conclusion is based upon the following considerations:

1. The analyzer used to perform the test was properly maintained and calibrated;
2. Proper procedures were used in the handling, testing, and review of the sample;
3. The EMIT assays used to test the sample are identical to those that have been in place for four years. These have been 100% accurate on SAMHSA proficiency samples over the past year;
4. All of the quality control samples in the original testing batch produced normal results;
5. Review of other data within the original testing batch indicate that analyzer precision within the batch was good, and that no unusual matrix effect in the subject sample was evident;
6. No cocaine positive was reported out of the original batch, so there is no evidence that another sample could have been switched with the subject sample;
7. All other SNC samples in the original batch have been retested, and produced the same results as those originally reported;
8. The subject sample has been retested by EMIT, and produced a positive result.

There is no evidence of any systematic failure or fault which might be considered likely to produce the sort of error observed in the testing of this specimen. Automated analyzers will occasionally produce aberrant (outlier) results, but this is quite rare. Any drug-positive outlier would be corrected by the application of the required independent confirmation test.

CORRECTIVE ACTION:

Since there is no practical way to preclude an anomalous result and the expected frequency is much smaller than the 10% false negative allowance provided by the SAMHSA guidelines, no corrective action is required.

Tamara St Claire — 060297
QA Manager — Date

COGNIZANT DIRECTOR'S SIGNATURE:

I have reviewed the QA investigation into the analytical error reported by Southern Nuclear Operating Company regarding the sample identified as LAN 971273589. I find that its contents are accurate, and I concur with the conclusion reached.

Vice President, Laboratory Operations — 060297
Date

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MILA Z. HERAMIA

PAGE 30

DATE 05/28/1997 09:08
OPERATOR

S.ID ANALYSIS NO.	S.NO. RACK NO. CUP POS.	L I H	MAMPH NTQ pH	BARB2 OP CREAT	BARB3 PCP	BENZ2 PROP	BENZ3 THC2O	THC50 ETOH	THC AMP*D	TRYC	COC DILAN	MD LSD
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Christopher S. Frings, Ph.D., CSP
Chris Frings & Associates
633 Winwood Drive
Birmingham, AL 35226-2837
205-823-5044
Fax: 205-823-4283
E-Mail: CFrings@compuserve.com

June 10, 1997

April Brockson
Occupational Health
Southern Nuclear Operating Company
P.O. Box 1295, Bin 018
Birmingham, AL 35201-1295

Re: PharmChem's investigation of performance error

Dear April:

You asked that I send you my written comments regarding the June 3, 1997 Quality Assurance Investigation Report from Tamara St. Claire of PharmChem that you faxed to me on June 3, 1997 for review. This report addressed the false negative benzoylecgonine PharmChem drug screen report of May 17, 1997.

After reviewing the report, I find that PharmChem answered the additional questions that Paul Bizjak and I requested that they answer to make the investigation of the false negative drug screen complete. I am convinced that this false negative report is an outlier.

When PharmChem ran the drug screen on the sample in question (LAN 971273589), it was close to the cut-off benzoylecgonine calibrator both times. It was slightly below the cut-off value the first time the sample was analyzed. It was slightly above the cut-off value the second time the sample was analyzed. When a sample contains a drug or drug metabolite that gives a readout close to the cut off calibrator, this can happen. It is, however, not a common happening to find the drug readout just at the cut-off; usually it is much below or much above the cut-off.

I recommend that you continue to monitor closely the results of PharmChem on future proficiency testing samples and call me if this occurs again.

Please call when I can be of assistance or if you have any questions.

Sincerely,

Christopher S. Frings, Ph.D., HCLD
Consulting Toxicologist