Lewis Sumner
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SOUTHERN COMPANY
Energy to Serve Your World℠

July 31, 2001

Docket Nos. 50-321
50-366

HL-6112

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

Edwin I. Hatch Nuclear 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 30, 2001 a specimen (ID# 257072114) was submitted to PharmChem Laboratories, Inc. in Fort Worth, Texas. The blind performance specimen had been prepared by ElSohly Laboratory and screened as positive at the Edwin I. Hatch Nuclear Plant on site testing facility. The performance specimen was certified by ElSohly as spiked with morphine at a level of 3570 ng/ml and also with codeine at a level of 3468 ng/ml.

The specimen in question was received by PharmChem on June 11, 2001 and tested on June 12, 2001. The specimen was initially screened as a presumptive positive for opiates. The batch containing the specimen for confirmation was started on June 28, 2001 and completed on June 29, 2001. The specimen was reported as negative on June 30, 2001. The FFD Coordinator at Plant Hatch became aware of this report on July 2, 2001 and notified PharmChem by e-mail on that day that a false negative blind performance error had occurred and requested an immediate investigation. PharmChem received the e-mail on July 5, 2001. PharmChem sent the investigation report of the performance error to Southern Nuclear on July 24, 2001. Southern Nuclear's consulting toxicologist, Dr. Christopher Frings, has conducted an independent review of the PharmChem report, which is attached. The findings represent unsatisfactory laboratory practices that will be the subject of further discussions between Southern Nuclear and PharmChem.

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The findings of PharmChem are enclosed. In addition to the cross-reactivity of the screening assays with other synthetic opiates, there was a large time gap between the generation of the screening data and the aliquoting of the first confirmation batch. A team of PharmChem individuals has been assigned to ensure that future samples are aliquoted for confirmation in a timely manner.

Southern Nuclear has utilized PharmChem Laboratories since January 1, 1994 and this is the third performance error experienced with this laboratory. Although Southern Nuclear has accepted the laboratory investigation, additional HHS facilities are under consideration for utilization. Southern Nuclear hereby 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,

H. L. Sumner, Jr.

HLS/JMG

Enclosure 1: PharmChem Laboratory Report (3 pages)
Enclosure 2: Dr. Christopher Frings Review of the PharmChem Report

cc: Southern Nuclear Operating Company
Mr. P. H. Wells, Nuclear Plant General Manager
Document Management – A2.001

U. S. Nuclear Regulatory Commission, Washington, DC
Mr. L. N. Olshan, Project Manager - Hatch

U. S. Nuclear Regulatory Commission, Region II
Mr. L. A. Reyes, Regional Administrator
Mr. J. T. Munday, Senior Resident Inspector - Hatch

Enclosure 1

PharmChem Laboratory Report
(3 pages)

PHARMCHEM INC.

July 24, 2001

Mr. Paul Bizjak
Southern Nuclear Company
40 Inverness Center Parkway
Building 40
Birmingham, AL 35242

RE: Investigation Report Specimen 11352624

Dear Mr. Bizjak,

Please find enclosed a copy of the above investigation report which involved a false negative result for the analytes codeine and morphine.

If I can be of further assistance or should you have any questions, please don't hesitate to contact me.

Sincerely,

Neil Fortner MS, FTS-ABFT; TC-NRCC
Vice President Laboratory Operations

cc: enclosure

4600 N. Beach Street / Haltom City, Texas 76137 / 817•605•5300 / Fax 817•581•3481

Investigation Report
On
Southern Nuclear #11352624

Issue – External PT sample reported out as a negative when it should have contained Morphine and Codeine.

The client contacted PharmChem via e-mail on 07/05/01 informing us of a false negative PT (ID# 257072114) reported by the laboratory on 06/30/01. The investigation was initiated by requesting the original data for review that was retrieved on 07/09/01. The review of this data shows that the sample was received on 06/11/01 and placed into batch 0611011046. This batch was run and released on 06/12/01 from the screening lab with a presumptive positive result for opiates of 462/347.

The confirmation data for this specimen was contained in confirmation batch W062801 OPT(869)-1. This batch assignment indicates the specimen was aliquoted for confirmation on 06/28/01. Upon further investigation, it was determined that this specimen had appeared on our late specimen- tracking program. This initiated a manual request for the confirmation aliquot. The confirmation testing was started on 06/28/01 and completed on 06/29/01. After being reviewed by the confirmation analyst, the analytical results were sent to the certifying scientist. A review of the analytical data indicated that while the chromatograms for this sample had several peaks in the respective windows for each analyte however the sample did not meet any of the qualitative or quantitative criteria for either codeine or morphine. A further review of the data indicated that there was no indication of either morphine or codeine above the limit of detection. Based on the fact that the quality control materials in this run met all qualitative and quantitative criteria, the certifying scientist released the data.

After reviewing this data, a retest of the specimen was requested. It was placed on batch W071001 OPT(869)-3, but failed and the specimen had to be resubmitted. The request for the specimen was submitted two more times, however the incorrect sample was pulled each time. These batches were W071301 OPT(869)-1 on 07/13/01 and W71401 OPT(869)-1 on 07/14/01. The investigator pulled the specimen for confirmation and it was placed in batch W071601 OPT(809)-3 on 07/16/01. The specimen was run at a 1:4 dilution and 1:10 dilution based upon the expected results of around 3000 ng/ml as stated by the client. The results of this test confirmed for morphine at 3320 ng/ml and codeine at 2716 ng/ml.

Resolution

The certifying scientist may have been more critical of the reported confirmation data, especially when compared to the screening results obtained. However the correlation of screening results with confirmatory results for the opiate class is difficult at best given the cross-reactivity of the screening assays with other synthetic opiates such as hydrocodone and hydromorphone.

In addition it was noted that there was a large time gap between the generation of the screening data and the aliquotting of the first confirmation batch. This was due to problems with the generation of the confirmation worklists during this period. This problem has since been corrected, and a team of individuals has been assigned to ensure that samples are aliquoted for confirmation testing in a timely manner.

Training of the following areas is being conducted as a result of the investigation:

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- Handling procedures to emphasize generation of the necessary GCMS worklists. A method has been developed and implemented to insure that all worklists are being generated and accounted for.

Data Review

- Comparison of screening results to confirmation results looking specifically at if that data supports the confirmation data being reported.

Investigator: David S. Lindman
QA/QC Supervisor

Laboratory Director/RP: Neil Fortner
VP Laboratory Operations

Enclosure 2

Dr. Christopher Frings Review of the PharmChem Report
(1 page)

Christopher S. Frings, Ph.D., CSP

Chris Frings & Associates

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Birmingham, AL 35226-2837
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July 26, 2001

Paul Bizjak
Southern Nuclear Company
P.O. Box 1295
Bin 018
Birmingham, AL 35201

Re: Opinion on false negative PharmChem report (Investigation Report Specimen 11352624)

Dear Paul:

You asked that I look into the false negative opiate report on a urine drug screen (Investigation Report Specimen 11352624) sent to PharmChem on May 30, 2001. I have read and studied the investigation report from PharmChem.

This report convinced me that PharmChem is 1) having a problem with their confirmatory method for morphine and codeine, 2) has an inadequate system for turning around positive lab results in a timely matter and 3) has an inadequate system for "pulling" the correct specimen from a previous run and rerunning. These are all serious flaws in the laboratory process. With these flaws, they will not be able to pass future SAMSHA (formally NIDA) inspections.

My conclusion is that the mistake PharmChem made was not a random error and that PharmChem has serious procedural problems. As we have discussed recently, I recommend that Southern Nuclear get one or two drug testing laboratories pre-certified and arrange to change laboratories as soon as practical. In the meantime, keep the pressure on PharmChem to produce timely and accurate results. You may want to send a copy of PharmChem's explanation to SAMSHA. SAMSHA needs to be aware that the quality has changed to an unacceptable level at this laboratory.

Please call at your convenience to discuss this opinion letter or if you have any questions.

Sincerely,

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