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Vice President
Hatch Project Support

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October 18, 2001

Docket Nos. 50-321
50-366

HL-6138

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

Edwin I. Hatch Nuclear Plant
Report of Unsatisfactory Testing Follow-up Correspondence

Ladies and Gentlemen:

On July 31, 2001, Southern Nuclear Operating Company submitted a letter to the NRC regarding the unsatisfactory performance of PharmChem Laboratory. After receiving this report from Southern Nuclear, the NRC requested an investigation be performed by the National Institute on Drug Abuse (NIDA) which is a part of the National Institute of Health - a component of the U.S. Department of Health and Human Services.

The subsequent investigation performed by NIDA determined that, in addition to the blind performance-testing problem that instigated Southern Nuclear's initial report, an additional error occurred with the same specimen batch at the laboratory. At the direction of NIDA, PharmChem was directed to retest all positive specimens for the batch in question which resulted in the retesting of specimen #257072118 (H010904). Based on the September 8, 2001 retest, the specimen was determined to be negative. PharmChem then sent a negative report to the Southern Nuclear MRO on September 9, 2001 and it became evident that the error involved a specimen for an actual employee at Plant Hatch. On June 30, 2001 PharmChem had reported this specimen as positive for opiates; however, based on the MRO interview with the affected employee, the MRO report was negative and no disciplinary action was taken against the employee.

PharmChem's investigation of the laboratory error states that a review of the original batch of specimens revealed that the labels and worksheet information were handwritten for both specimens being processed. Normally, computer-generated labels are made by scanning the bar codes on the bottle. These labels are placed on each aliquot tube and used in the various steps in the extraction, including the creation of the GC/MS worksheet. This ensures the identification of the specimen being handled is correct. Since this was not done on the original testing, PharmChem reports there is the possibility that a handling mistake was made in this instance.

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PharmChem reports that this process has now been changed so that the use of handwritten labels or worksheets is not acceptable. To further aid prevention of potential processing errors, a daily audit has been implemented by the quality assurance group at PharmChem to look for variations in testing similar to the issue brought about by this investigation. The results and corrections to the deficiencies are reported to the Vice President of Laboratory Operations as they are completed. The PharmChem investigation is attached.

Southern Nuclear has utilized PharmChem Laboratories since January 1, 1994. Since that time, PharmChem has had three blind performance errors, one false negative blood alcohol, and the false positive specimen reported in this letter. Although Southern Nuclear has accepted the laboratory investigation attached, a decision was made by SNC management in July 2001 to discontinue our use of PharmChem due to their poor performance. SNC has contracted with two new HHS certified laboratories in Georgia and Alabama to provide laboratory services.

Although the July 13, 2001 letter provided the required report to identify the laboratory inadequacies in accordance with 10 CFR Part 26 Appendix A, Paragraph 2.8, Southern Nuclear believed this issue warranted a follow-up correspondence to the NRC. Should you have any further questions, please advise.

Respectfully submitted,



H. L. Sumner, Jr.

HLS/JMG

Enclosure 1: PharmChem Laboratory Report (5 pages)

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
TO
SOUTHERN NUCLEAR OPERATING COMPANY
LETTER HL-6138

Edwin I. Hatch Nuclear Plant
Report of Unsatisfactory Testing Follow-up Correspondence

PharmChem Laboratory Report dated September 24, 2001



7610 PEBBLE DRIVE - FORT WORTH, TX 76118 - (817) 605-5300 VOICE (817) 605-6400 FAX

September 24, 2001

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

RE: Investigation report on Specimen 257072118

Dear Mr. Bizjak,

Please find enclosed a copy of the above investigation report, which involved an incorrect report 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,

David S. Lindman
QA/QC Supervisor

Cc: enclosure



7610 PEBBLE DRIVE - FORT WORTH, TX 76118 - (817)215-8800 VOICE (817) 215-8863 FAX

**Investigation Report
On
Southern Nuclear #257072118**

Issue – Retest of specimen 257072118 in response to investigation into Southern Nuclear blind resulted in a negative result when this specimen was originally reported as a positive.

As a result of an investigation into a false negative PT (ID# 257072114) reported by the laboratory on 06/30/01, specimen 257072118 was retested and gave a negative response when it had originally been reported as positive for morphine and codeine.

The investigation was initiated by requesting the original data for review. This specimen was originally 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 356/347.

The data pack that can be found for the specimen in the confirmation lab is W062801 OPT(869)-1 which indicates the specimen was aliquoted for confirmation on 06/28/01. The specimen aliquot chain of custody was manually written indicating a problem with the computer generated form. The specimen was late which triggered the aliquot into this batch. The batch was extracted and run on 06/28/01 and 06/29/01 when it was released to GCMS for review. The data from this batch was reported on 06/30/01 as positive for morphine (2893 ng/ml) and codeine (2664 ng/ml).

A retest of the specimen was requested on 09/08/01 as the result of an investigation into a Southern Nuclear blind PT performance issue. This PT was reported as negative when it should have been positive for morphine and codeine. The only other specimen in the batch was 257072118, thus the need for a retest. The specimen was re-accessioned into the computer as specimen id 911093549 and accession number 11929063. These numbers were cross-linked to the original specimen id 257072118 and accession number 11352640. It was placed on batch W090801 OPT(869)-1 and run on 09/08/01. The results of this test failed to confirm the presence of morphine or codeine.

The retest of specimen 257072118 was reported out to the MRO electronically on 09/09/01 under the specimen barcode number of 911093549 and accession number 11929063 (a copy to be included with this investigation).

Resolution

In reviewing the original batch it was noted that the labels and worksheet information were handwritten for both specimens being processed. Normally computer-generated labels are made by scanning the barcode on the bottle. These labels are placed on each aliquot tube and used in the various steps in the extraction, including the creation of the GC/MS worksheet. This ensures the identification of the specimen being handled is

correct. Since this was not done on the original testing, there is the possibility that a handling mistake was made in this instance.

The process has now been changed so that the use of handwritten labels or worksheets is not acceptable. If handwritten entries are found, the processing of that specimen is stopped and another aliquot is requested. Both the confirmation lab and data review have been instructed that no results are to be released if handwritten specimen identification is used in the testing process. Failure to follow these procedures will result in disciplinary actions up to and including termination.

To further aid in prevention of potential processing errors, a daily audit has now been implemented by the quality assurance group, to look for variations in testing like the issue brought up by this investigation. The results and corrections to deficiencies are reported to the Vice President of Laboratory Operations as they are completed.

A handwritten signature in black ink, appearing to read 'D. S. Lindman', with a stylized flourish at the end.

Investigator: David S. Lindman
QA/QC Supervisor

PHARMCHEM INC.
4600 N. Beach Street, Haltom City, TX, 76137

LABORATORY
REPORT

<<< RE-ANALYSIS OF SAMPLE ID 257072118 ACCESSION NUMBER 011352640 >>>

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ACCOUNT NUMBER:	687230301	BARCODE NUMBER:	0911093549
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RESULTS TO:	SPECIMEN ID:	H.010904
ATT: Geoffrey Conner, M.D.	SPECIMEN ID:	
Southern Nuclear Company	SPECIMEN DATE:	05/30/2001
1608 Meadows Lane	TEST TYPE:	12
Vidalia, GA 30474	LOCATION CODE:	

FFD Account	ACCESSION NUMBER:	011929063
	DATE RECEIVED:	09/07/2001
	DATE REPORTED:	09/09/2001

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TEST METHODS AND DETECTION LEVELS

Drug or Drug Class	Initial Test		Confirmation Test	
	Method	CutOff	Method	CutOff
Codeine Retest	GC/MS	30 ng/ml		
Morphine Retest	GC/MS	50 ng/ml		

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TEST RESULTS

Drug or Drug Class/ Analyte	Test Result	Drug or Drug Class/ Analyte	Test Result
Codeine Retest	negative	Morphine Retest	negative

COMMENTS:

* TEST RESULT *
* NEGATIVE *

6-MAM TESTED ONLY IF MORPHINE IS POSITIVE

I certify that the specimen identified by this accession number is the same specimen that bears the specimen identification barcode number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable requirements, and that these results are for that specimen.

Results Certified by: LANGLEY GEE



Date: 09/09/2001

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