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

Subject: Waterford 3 SES
Docket No. 50-382
License No. NPF-38
Investigation of Unsatisfactory Performance Testing

Gentlemen:

On June 14, 1994, an unsatisfactory result from a blind performance sample was returned from Waterford's confirmatory laboratory. Attached is the investigation of this matter as required by 10CFR 26 Appendix A Section 2.8(e)(4).

Very truly yours,

R.F. Burski
Director
Nuclear Safety

RFB/GCS/tjs
Attachment

cc: (w/Attachment)
L.J. Callan (NRC Region IV), R.B. McGehee,
N.S. Reynolds, NRC Resident Inspectors Office

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Statement of Concern:

A blind performance specimen spiked positive for phencyclidine was tested at the Waterford 3 site lab and yielded positive results. The sample was shipped to our confirmatory lab, Doctors & Physicians Laboratory (DP&L) for further analysis. Negative results were returned.

Upon discovery of the negative result from the confirmatory lab, Waterford 3 contacted the company supplying the spiked sample to verify the quantitative results that should have been received using gas chromatography/mass spectrometry (GC/MS). The specimen had been tested at two different laboratories and returned positive results of 39 ng/ml and 27.6 ng/ml. Waterford 3 contacted the confirmatory laboratory and informed them that a portion of a previous sample would be re-submitted to them and that they should retest it using fluorescence polarization immunoassay (FPIA) and GC/MS regardless of the results from the FPIA screening. It was verified that the only methodology used when testing a sample from Entergy site is FPIA for screening and GC/MS for confirmatory testing. (As part of the corrective action to a previous unsatisfactory blind sample test by DP&L Waterford 3 informed them that all samples sent for testing shall only be tested by FPIA technology for initial screening and any samples yielding positive results from this screening will be further analyzed by GC/MS.)

Upon testing the re-submitted portion of the previous sample at the confirmatory lab, a positive result for both the FPIA screening and the GC/MS confirmation was obtained.

Investigation Results:

DP&L informed Waterford 3 that the sample in question had tested negative on the initial screening and therefore not run with GC/MS. Waterford 3 requested a copy of the data (control and sample values, control and sample positions in testing cartridge) from DP&L regarding the sample in question (B94544).

A review of the data from the first time sample B94544 was tested at DP&L shows control results equal to 26.29 ng/ml and 26.32 ng/ml. These values are within the acceptable range of 31 ng/ml plus or minus 20%. Also no positions (sample location in the cartridge) were positive or had results close to the cutoff with the exception of the positions containing the controls. This fact lessens the possibility that the sample was placed into the wrong cartridge position by the confirmatory lab.

Waterford 3 also reviewed the data from DP&L that represented the results of our re-submittal of sample B94544. The review shows control results equal to 29.65 ng/ml and 29.74 ng/ml. Again these values were within the acceptable range of 31 ng/ml plus or minus 20%. Also a review of the data of the second test from DP&L indicated that with the exception of the control value and sample B94544, no other position had positive results or results near the cutoff. This leads to the conclusion that sample B94544 was placed correctly into the cartridge and the results given were accurate.

In addition, based on the review of Waterford 3's data, it was determined that the values of the control samples used were in the acceptable range and that the correct sample was tested.

Finally, DP&L could not explain or duplicate the error associated with their first test on sample B94544 and a review of the data does not indicate any human error. The cause of this event is believed to be indeterminate; however, in an effort to possibly preclude another occurrence, DP&L stated that "We will pay better attention to our QAS control, and when the PCP value approaches the lower end of acceptability, we will calibrate the PCP assay."

Actions to Prevent Recurrence:

The annual audit for the confirmatory lab is scheduled for August, 1994. The audit team has been directed by Waterford 3 to look into the statistical basis for testing and the quality control methodology of the lab during this audit.

Note: Investigation results from the confirmatory laboratory are attached.

SB
SmithKline Beecham
Clinical Laboratories

July 5, 1994

Michael I. Schaffer, Ph.D.

Joan O. Kieff
Coordinator for Fitness for Duty
Fatargy Operations, Inc.
Waterford 3
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Killona, LA 70066

RE: False Negative Test Reporting

Dear Ms. Kieff:

Per your request of 1 July 1994, I will respond to the false negative finding for PCP.

1. TDX printout from 5/29/94 shows position # 3 with a TDX readout of 24.57 for the PCP assay. This is below the 25.0 ng/ml cutoff for PCP and was therefore signed out as negative. QAS control read 26 ng/ml in position #s 5 and 15. The lab's target value for the PCP QAS control was 31 plus or minus 20% or 25 to 37 ng/ml. Since the QAS control was in range, and the negative was negative or Low and the Biorad read Hi the results were accepted.

2. TDX printout from 06/15/94 shows position # 5 with a TDX readout of 34.25 ng/ml. This is above the 25 ng/ml cutoff and was therefore reflexed as a positive result for GC/MS confirmation. The lab's QAS in positions # 5 and # 11 read 29 ng/ml. Both of these values were within the acceptable range for QC within the batch.

3. The specimen was forwarded to GC/MS and confirmed positive for phenacyclidine.

4. I have submitted the TDX printouts for the two days that are in question on the PCP samples submitted to this laboratory. Unfortunately we cannot re-run the specimen submitted originally, which was determined to be 24 ng/ml.

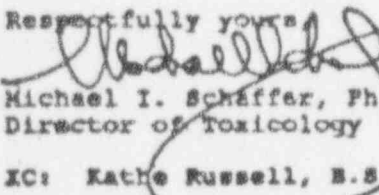
I cannot explain this occurrence, as two separate QC specimens within the first batch were positive for PCP, although at the low end of acceptability. Since we cannot re-run these specimens when this occurs, we must report out the results as demonstrated by the TDX printout. I wish I had a better response at this time but unfortunately I do not.

We will pay better attention to our QAS control, and when the PCP value approaches the lower end of acceptability, we will recalibrate the PCP assay.

I have enclosed the information I believe that you requested. If you should have any more questions, or comments, please do not hesitate to contact me at your earliest convenience.

Regarding specimen # B94513, B94527 and A94304, all these specimens screened positive by FPIA, and were forwarded to GC/MS for confirmation. In all three cases the screening results were not confirmed by GC/MS.

Respectfully yours,


Michael I. Schaffer, Ph.D., D.A.B.F.T.
Director of Toxicology

IC: Kathie Russell, B.S.