ENTERGY

Entergy Operations, Inc.
P.O. Box B
Killona, LA 70066
Tel 504 739 6774

R. F. Burski
Director
Nuclear Safety
Waterford 3

W3F1-93-0146
A4.05
PR

May 25, 1993

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 March 30, 1993, 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/TSB/ssf
Attachment

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

A027
1/1

Statement of Concern:

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

To eliminate the chance of error on the part of the site lab, a split of the original sample was retested on site, yielded positive results for amphetamines, and was shipped to DP&L. DP&L again returned negative results on all assays.

Upon receiving negative results on the sample the second time, DP&L was then informed that the specimen was a blind performance sample that should have yielded positive results for amphetamines. They were requested to reanalyze the sample using gas chromatography/mass spectrometry (GC/MS). The results from GC/MS showed positive results.

Investigation Results:

DP&L was contracted to analyze specimens using the same technology as our site labs, fluorescence polarization immunoassay (FPIA), for initial screenings. Any initial positives were to be subjected to confirmatory testing using GC/MS. Investigation concerning this result found DP&L using a second screening method, enzyme immunoassay (EIA), as a quality check.

Results of the testing at DP&L yielded positive results for amphetamines using FPIA technology, but negative results using EIA technology. Because of the inconsistency in results, the specimen was reported out as negative and not analyzed using GC/MS.

It is contended by DP&L that a combination of D & L isomers of amphetamine and methamphetamine were contained in the blind performance sample. This combination did not react with the EIA technology and therefore the second screening did not give a positive result.

It was confirmed with the company supplying the blind performance specimens that the spiked sample did contain a combination of D & L isomers. Previous blind performance samples were purchased from another vendor and were confirmed to contain the D isomers only. DP&L had returned favorable results for these samples.

The last blind performance sample spiked for amphetamines that returned positive confirmatory results was submitted in May of 1992. Since then, seven samples have been screened above the cut-off for amphetamines at Waterford's site lab. Of these seven samples, DP&L returned positive results for only one of these samples and this sample was later confirmed negative by our Medical Review Officer (MRO). DP&L results from comfirmatory FPIA screening gave negative results on four of the remaining samples and positive results on the last two. These two samples were analyzed under GC/MS and yielded negative results.

Actions to Prevent Recurrence:

Entergy's contract with DP&L does not request a second screening on specimens tested above the cut-off using the FPIA technology. The contract specifies that specimens submitted for testing shall be initially tested by FPIA. Initial positives will be subjected to confirmation testing. Confirmatory testing shall be done by GC/MS.

Using FPIA and GC/MS only, positive results would have been returned for the blind performance sample. Entergy's Contracts department will make it clear to DP&L that all samples sent for testing shall only be tested by FPIA technology for initial screening. Any samples yielding positive results from this screening will be further analyzed by GC/MS.

NOTE: Investigation results from the confirmatory laboratory are attached.

DOCTORS & PHYSICIANS LABORATORY

William H. Shutze, M.D.
Thomas M. Techmanr, M.D.

Diplomates American Board of Pathology

April 9, 1993

Joan Kieff
Fitness for Duty Coordinator
Waterford 3
P. O. Box B
Killona, La 70066

Re: 3610827
3637065

Dear Ms. Kieff:

An investigation into the above mentioned cases revealed the following information:

1. Specimen 3610827 was received at DPL on 16 March 1993. The specimen's user ID # was A93154. The shipping container and specimen were received intact and noted.
2. Specimen 3610827 was tested for amphetamines by the TDX and determined to be positive for that assay with a value of 4570 ng/ml.
3. Specimen 3610827 was therefore sent over for confirmation testing and a QC check, i.e., rescreening on our Hitachi 717 analyzer utilizing EIA technology.
4. Specimen 3610827 was determined to be negative on rescreen on the Hitachi 717 analyzer, and was therefore signed out as negative. A positive value on the Hitachi would be any positive integer starting with 0. Specimen 3610827 tested at a -133, clearly negative. The Hitachi uses Syva Monoclonal Amphetamine assay, which is very sensitive to the D-isomer of amphetamine and methamphetamine.
5. Specimen 3637065 was received at DPL on 1 April 1993. The specimen's user ID # was A93154. The shipping container and specimen were received intact and noted.
6. Specimen 3637065 was tested for amphetamines by the TDX and determined to be positive for that assay with a value of 4601 ng/ml.
7. Specimen 3637065 was therefore sent over for confirmation testing and a QC check, i.e., rescreening on our Hitachi 717 analyzer utilizing EIA technology.
8. Specimen 3637065 was determined to be negative on the Hitachi 717 analyzer, and was therefore signed out as negative. Again a positive value on the Hitachi would be any positive integer starting with 0. Specimen 3637065 tested at a -37, clearly negative.

William H. Shutze, M.D.
Thomas M. Techman, M.D.

DOCTORS & PHYSICIANS LABORATORY

Diplomates American
Board of Pathology

9. NIDA/HHS guidelines requires all testing to be positive within any individual sample. That is, on rescreen, we must adhere to the same criteria as the initial testing protocol for standards, calibrators, qc specimens and results.
10. On 6 April 1993, we were in receipt of your fax which stated : Please run GC/MS on sample 3637065. This is a blind performance sample and should have returned positive results. Please include quantitative results on the run. Please fax results back to Dr. McCune (Waterford 3's MRO) as soon as possible.

11. GC/MS was performed on specimne 3637065. The results were positive for amphetamine at a concentration of 1111 ng/ml.
12. Because of problems in the past with QC specimens which are forwarded to us for amphetamine testing we include a D amphetamine and D methamphetamine in our normal assay protocol. The reason we instituted this was because we were receiving amphetamine blind QC specimens which were actually made up of D & L isomers of amphetamine and methamphetamine, which were weighed in at the proper weight, but did not react with our system and test postive for amphetamines.
13. I believe that this specimen is a mixture of the two isomers of amphetamine, and that some methamphetamine was added to the sample to produce the high reading on the TDX.
14. We have never had this problem with your agency in the past.
15. I can institute a no rescreen policy on your specimens if you so desire to resolve this issue for you.
16. I do believe utilization of the D isomer of amphetamine, since this is the active one, will also resolve the problem.
17. Although we do differentiation of the D & L isomers of methamphetamine we are unable to perform the same testing for D & L amphetamine. We can locate a laboratory that can perform this testing if that is determined to be necessary.
18. Our institution of a rescreen policy was made to further bolster our QA program by the addition of a check on the second aliquot which is poured for confirmation. Although this is not part of any contractural agreement with any of our customers, it acutally affords DPL with a second check on the aliquot that is poured as well as a check on our GC/MS section. I firmly believe that this approach is both helpful and adds another degree of quality control to make the system a better and more accurate one.

Post Office Box 499050 • Leesburg, Florida 34749-9050 • 904-787-9006 • Fax: 904-365-2869 • 800-342-9520

William H. Shultze, M.D.
Thomas M. Techman, M.D.

DOCTORS & PHYSICIANS LABORATORY

Diplomates American
Board of Pathology

I believe that the above investigation into this matter represents the scientific facts as demonstrated by the testing on these two specimens.

I hope that we can resolve your immediate problem, and return your amphetamine blind performance samples to you with the correct results.

If you should have any questions or comments, please do not hesitate to call me at your earliest convenience.

Respectively submitted,

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

XC: Kathe Russell, B.S.
V.P. Technical & QA

Post Office Box 499050 • Leesburg, Florida 34749-9050 • 904-787-9006 • Fax: 904-365-2869 • 800-342-9520

DOCTORS & PHYSICIANS LABORATORY, INC.
LEESBURG, FLORIDA

William H. Shutze, M.D.
Thomas M. Techman, M.D.

Prep'd by _____ Date 4/27/93
Accept'd by _____ Date 4/27/93
Rev'd by ____ Date _____
Rev'd by ____ Date _____

MEMORANDUM

Effective 27 April 1993, DPL will immediately cease performing rescreens on all specimens initially testing positive on the ABBOTT TDX system. This means that for amphetamines, benzoylecgonine, opiates and phencyclidine, a sample of urine will not be sent to the Hitachi 717 analyzer for rescreening purposes after the first TDX test was positive for the above mentioned drugs.