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50-335 St. Lucie Plant, Unit 1, Florida Power & Light Co. 05000335
50-389 St. Lucie Plant, Unit 2, Florida Power & Light Co. 05000389
AUTH.NAME AUTHOR AFFILIATION
BOHLKE,W.H. Florida Power & Light Co.
RECIP.NAME RECIPIENT AFFILIATION
Document Control Branch (Document Control Desk)

SUBJECT: Informs of 911022 unsatisfactory blind specimen samples performance testing incident.Samples reported negative w/no indication of problems.Caused by random periodic variation due to periodic problem w/Syva kit.Syva kit replaced.

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FPL

P.O. Box 14000, Juno Beach, FL 33408-0420

NOV 1 8 1991

L-91-315
10 CFR 26

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

Gentlemen:

Re: Turkey Point Units 3 and 4
Docket Nos. 50-250 and 50-251
St. Lucie Units 1 and 2
Docket Nos. 50-335 and 50-389
10 CFR 26 Unsatisfactory Performance
Testing Incident Report

Pursuant to 10 CFR 26, Appendix A, Section 2.8(e)(4), Florida Power and Light Company (FPL) is submitting to the NRC the enclosed report of an unsatisfactory performance testing incident. FPL submitted a blind performance test specimen to FPL's contract Department of Health and Human Services (DHHS) certified laboratory, Roche Biomedical Laboratories. The enclosed report details the investigative analysis of the unsatisfactory blind specimen results, the identification of causes, and the corrective actions taken by the laboratory to prevent recurrence.

Please contact us if additional information is required.

Very truly yours,

W. H. Bohlke
Vice President
Nuclear Engineering and Licensing

WHB/DMB

Attachment

cc: Stewart D. Ebneter, Regional Administrator, Region II, USNRC
Senior Resident Inspector, USNRC, Turkey Point Plant
Senior Resident Inspector, USNRC, St. Lucie Plant

250051

A002

Roche Biomedical Laboratories

a subsidiary of Hoffmann-La Roche Inc.

Roche Biomedical Laboratories, Inc.
1912 Alexander Drive
Research Triangle Park, North Carolina 27709

Telephone: (919) 361-7700

November 4, 1991

Dr. Kendall Green
Medical Review Officer
Florida Power & Light Company
700 Universe Blvd.
Juno Beach, FL 33408

Dear Dr. Green:

The following information is provided as the report on the testing of the Florida Power and Light Blind Quality Control sample identified as RBL accession # 295-700-5207-0.

The sample was tested on 22 October 1991 with the Syva EMIT^{R} 50 ng/ml THC immunoassay kit using an Olympus 5000 instrument. The instrument reports out readings in delta-absorbance (ΔOD) units. The instrument is set to read +50 OD for the 50 ng/ml calibrator with negative sample reading one to two hundred below zero. The sample in question gave a reading of -22 ΔOD with most of the "negative" samples running in the -200 ΔOD range. The quality control values were all within acceptable limits as defined by the laboratory (and by the National Institute on Drug Abuse). The -22 ΔOD reading might indicate the presence of some THC metabolite; however, it is below the cutoff. There were no indications of problems, based on the acceptable quality control results. Thus the specimen was reported negative.

At your request, the sample was retested by both the Syva EMIT^{R} immunoassay and by GC/MS. The Syva EMIT^{R} gave a reading of +184ΔOD, well above the cutoff value, and the GC/MS quantitated at 172 ng/ml of Carboxy-THC. There was no indication of any problems with the make-up of the quality control sample.

We have been experiencing some random periodic variation with the Syva EMIT^{R} 50 ng/ml THC test. The variation appears as erroneous low random readings on samples that contain THC metabolite. This variation has been a periodic problem with the Syva kit that has been experienced throughout the drug testing industry.

We have been evaluating a new THC (50 ng/ml) immunoassay kit that is more stable and reliable than the Syva kit. This new kit was placed in use on 29 October 1991. The stability of this new kit should eliminate the type of error that occurred with this Blind Quality Control sample.

If you need further information please contact me at (919) 361-7778.

Sincerely,

John Irving