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50-389 St. Lucie Plant, Unit 2, Florida Power & Light Co. 05000389
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BOHLKE,W.H. Florida Power & Light Co.
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SUBJECT: Forwards unsatisfactory performance testing incident rept.Sample transmitted as negative then corrected to positive for PCP.Caused by error in transcription of results.

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

JANUARY 29 1991

L-91-28
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 & Light Company (FPL) is submitting to the NRC the enclosed report of an unsatisfactory performance testing incident. FPL submitted blind performance test specimens to FPL's contract Department of Health and Human Services (DHHS) certified laboratory, Roche Biomedical Laboratories. The enclosed report details the investigative analysis of 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

Enclosure

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

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Roche Biomedical Laboratories
a subsidiary of Hoffmann-La Roche Inc.

Roche Biomedical Laboratories, Inc.
P.O. Box 13973
Research Triangle Park, North Carolina 27709

Telephone: 919 361-7700

January 7, 1991

Mr. Art Cummings
Fitness for Duty Supervisor
Florida Power and Light
700 Universe Boulevard
P.O. Box 14000
Juno Beach, FL 33408-0420

Dear Mr. Cummings:

The investigation concerning the blind quality control sample is described in the attached report.

The customized software program which summarizes the hard copy printout of positives from the Olympus instrument has been undergoing an extensive evaluation. The review process now includes a review of the summary printouts, prior to completion of the re-screen list. We will update you when the evaluation of this software has been completed.

Should you require additional information please call me at (919) 361-7712. Thank you for your cooperation.

Sincerely yours,

Paula S. Childs

Paula S. Childs, Ph.D., D-ABFT
Co-Director, Toxicology

Blind Quality Control Sample #317-000-5516

PROBLEM:

The initial report for blind quality control sample #317-000-5516 (RBL# 318-700-5811) was transmitted as "Negative". The report was corrected and then transmitted as "Positive" for PCP. The blind quality control specimen was positive for PCP.

ANALYSIS:

The blind quality control sample identified above was collected on November 13, 1990, and received at the Roche Biomedical Laboratory in Research Triangle Park, NC, on November 14, 1990. The Accessioning Clerk assigned the laboratory number 318-700-5811 to the chain of custody request and blind quality control sample bottle.

The blind quality control sample was screened on November 14, 1990 and found to be positive for PCP. The re-screen (performed on November 15, 1990) was also positive for PCP. The blind quality control sample was scheduled for GC/MS confirmation of PCP.

The initial test results and re-screen results were transcribed correctly to the worksheet for posting into the computer system. However, during the transcription of the screening data for this specimen, the PCP result was posted as "Negative". This error was not detected until the next morning during the review of the posted results. The Medical Review Officer was notified by the staff at Roche Biomedical Laboratory that an incorrect report had been transmitted, and that a corrected report was forthcoming.

The blind quality control sample was extracted in preparation for GC/MS confirmation of PCP on November 15, 1990. The analysis was completed, indicating 176 ng/mL PCP. The result was reviewed and transcribed to the computer system and chain of custody report.

The corrected report was transmitted as "PCP positive 176 ng/mL" upon the completion of the GC/MS confirmation of PCP.

CORRECTIVE ACTION:

The corrective action which took place was immediate notification of the Medical Review officer to notify his office of the incorrect posting of the negative result. This error was identified during the review process which takes place following the posting of results. The posted results cannot be reviewed until they have been posted in the computer system, and once they have been posted, they are available for electronic transmission to the client. This result was transmitted prior to the completion of the review process. Thus, the client was notified to expect a corrected report.

Roche Biomedical Laboratory has initiated the development of a computerized program which would accomplish the following goals:

1) Allow the direct transfer of data from the screening instrument (Olympus) to a computer for review. (This will eliminate the manual transcription of "positive" and "negative" results from the hard copy printout to the computer.)

2) Allow the specimens which have screened "positive" to be placed in a "hold" status until the re-screen testing has been completed and the results have been reviewed by the certifying official.

3) Provide a place in the data base in the computer system for the re-screen result.

The initial procedure to develop this system includes development of the hardware/software interfaces, evaluation of data transfers, and evaluation of the effect on the reporting aspects of the computer system. The initial evaluations are expected to be completed by March 31, 1991. The final programming changes are expected to be implemented by June 1991.

Respectfully submitted,

Paula S. Childs

Paula S. Childs, Ph.D., D-ABFT
Co-Director, Forensic Toxicology