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SUBJECT: Forwards 10CFR26 unsatisfactory performance testing incident rept.

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FPL

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

SEPTEMBER 2 9 1990

L-90-333
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.2.8(e)(4), Florida Power & Light Company (FPL) is submitting to the NRC the enclosed report of unsatisfactory performance testing incidents.

In accordance with the requirements of 10 CFR 26, Appendix A, Section 2.8(e), 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/lef

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

September 21, 1990

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:

We have completed the investigations concerning the blind quality control samples which were identified as incorrect reports. In each case, the corrected report has been issued.

Enclosed is a summary of the investigations, and statements of corrective action.

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

Sincerely yours,

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

Blind Quality Control Sample #183-000-5035

PROBLEM:

The report for blind quality control sample #183-000-5035 (RBL# 184-700-0828) indicated the presence of codeine. The blind quality control sample was positive for morphine.

ANALYSIS:

The blind quality control sample identified above was received at the Roche Biomedical Laboratory in Research Triangle Park, NC, on July 3, 1990. The Accessioning Clerk assigned the laboratory number 184-700-0828 to the chain of custody request and blind quality control sample bottle.

The blind quality control sample was screened on July 3, 1990 and found to be positive for opiate(s). The re-screen was also positive for opiates. The blind quality control sample was scheduled for GC/MS confirmation of opiates (codeine and morphine).

The blind quality control sample was extracted in preparation for GC/MS on July 6, 1990. The analysis was completed, and the result of 368 ng/ml morphine was transcribed onto the Batch Confirmation Chain of Custody (Aliquot) form. During the transcription, the morphine result was entered under the column designated as codeine. This worksheet was used to enter the result into the computer system. Thus, the resultant entry into the computer system indicated codeine, rather then morphine. The chain of custody form was also completed with the codeine report.

The erroneous report was brought to the attention of Mr. O. C. Blount by D. A. Brodnick on July 10, 1990. Mr. Blount gave the pertinent information concerning the sample to Dr. Paula Childs. Following a review of the documentation, it was determined that the morphine had been incorrectly transcribed onto a worksheet as codeine. This was incorrectly entered into the computer system, and onto the chain of custody form as codeine. The correct result was morphine. Corrected reports were prepared to properly reflect the morphine result.

IDENTIFICATION OF THE CAUSE:

Following a review of the data with the individual responsible for the transcription error, it was determined that the transcription error was not identified during the review process. The same individual performed all three levels of review, and also entered the data into the computer and signed the report.

CORRECTIVE ACTION:

The review of all data (initial testing and confirmation) will be completed by different individuals. The form used for the transcription of data has been modified to include a designated column for each specific drug. The final review includes verification of transcription of information.

Blind quality control sample #192-000-5032

PROBLEM:

The report for blind quality control sample #192-000-5032 (RBL# 193-700-1025) indicated the blind quality control sample was negative. The blind quality control sample was positive for secobarbital.

ANALYSIS:

The blind quality control sample identified above was received at the Roche Biomedical Laboratory in Research Triangle Park, NC, on July 12, 1990. The Accessioning Clerk assigned the laboratory number 193-700-1025 to the chain of custody request and blind quality control sample bottle.

The blind quality control sample was screened on July 12, 1990 and found to be positive for barbiturates. The re-screen was also positive for barbiturates. The blind quality control sample was scheduled for GC/MS confirmation of barbiturates (including amobarbital, secobarbital, butalbital, butabarbital, pentobarbital, and phenobarbital).

The blind quality control sample was extracted in preparation for GC/MS on July 13, 1990. The GC/MS run was completed, but the result for the blind quality control sample was not completed because during review of the GC/MS run it was determined to be not acceptable for accurate quantification of secobarbital in blind quality control samples. The blind quality control sample was re-extracted with another GC/MS run and found to contain 594 ng/ml secobarbital. The chain of custody was completed with this information.

The entry of initial test results was made incorrectly, resulting in a "negative" report for the blind quality control sample. This was brought to the attention of Dr. Paula Childs by D. A. Brodnick on July 13, 1990. Dr. Childs reviewed of the documentation and determined that the transfer of initial test information into the computer system was made incorrectly. At the time of notification of the error, the confirmation (GC/MS) testing for secobarbital was already in progress. The confirmation test for secobarbital was completed and reported as a corrected report.

IDENTIFICATION OF THE CAUSE:

Following a review of the data with the individuals responsible for the transcription error, it was determined that the transfer of the initial test results had not been verified by another individual, and compared to the original results or the re-screen results.

CORRECTIVE ACTION:

The review of all data for the initial testing (screening) now includes additional verifications of the screening results prior to entry of the information into the computer. Further, since much of the analysis and review of data takes place during the third shift (11 p.m. to 8 a.m.), Roche Biomedical Laboratory has added a full time supervisor. This person also performs the function of certifying official during the third shift. Thus, the data is being scrutinized during three separate and independent review steps. The transcription of data into the computer is being verified against the original results from the initial testing.

This has resulted in the timely review of results and the ability to complete the review of result entry prior to completion of the final report.

Blind Quality Control Sample #197-000-5017

PROBLEM:

The report for blind quality control sample #197-000-5017 (RBL# 198-700-1326) indicated the blind quality control sample was negative. The blind quality control sample was positive for amphetamine.

ANALYSIS:

The blind quality control sample identified above was received at the Roche Biomedical Laboratory in Research Triangle Park, NC, on July 17, 1990. The Accessioning Clerk assigned the laboratory number 198-700-1326 to the chain of custody request and blind quality control sample bottle.

The blind quality control sample was screened on July 17, 1990 and found to be positive for amphetamines. The positive flag "H" was not detected during the review process, and the blind quality control sample was reported as negative.

This incorrect report was brought to the attention of Dr. Paula Childs by D. A. Brodnick on July 20, 1990. Dr. Childs reviewed the documentation and determined that the initial test results were indeed positive for amphetamines, and that the incorrect information had been entered into the computer system.

Following this review, the blind quality control sample was scheduled for confirmation of amphetamines (amphetamine and methamphetamine), with a result of 1775 ng/ml amphetamine. This was issued as a corrected report electronically and on the chain of custody.

IDENTIFICATION OF THE CAUSE:

Following a review of the data with the individuals responsible for the error, it was determined that the flag "H" for a positive was not detected by the reviewers, and the blind quality control sample was reported as negative.

CORRECTIVE ACTION:

The review of all data for the initial testing (screening) now includes additional verifications of the screening results prior to entry of the information into the computer. Since this process is presently conducted without the assistance of the computer, the reviewers will use two different methods of reviewing the data - a horizontal review to initially highlight the "H" flags, followed by a vertical review to check that all the "H" flags in a column have been identified.

Further, an experienced full time supervisor has been hired for third shift. This person also performs the certification review of data generated on second and third shift.

In summary, several improvements to the process of review of data and entry of data into the computer system have been accomplished during the past month. This will result in the ability to review and report results in a correct and timely manner.

Within the next several months, Roche Biomedical Laboratories will be developing an automated system for review and transfer of data directly from the screening instrument(s) to the computer system. This will further enhance the ability to verify specimen results in a timely manner.

Respectfully submitted

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

September 21, 1990