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SUBJECT: Submits rept of unsatisfactory performance testing incident, per 10CFR26,App A,Section 2.8(e).

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MAY 29 1990

L-90-199
10 CFR 26

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

Gentlemen:

Re: Turkey Point Units 3 and 4
St Lucie Units 1 and 2
Docket Nos. 50-250, 50-251, 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 the enclosed report of an unsatisfactory performance testing incident to the NRC.

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,

R. J. Acosta

R. J. Acosta
Acting Vice President
Nuclear Energy

RJA/GRM/slh

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.
Post Office Box 2230
Burlington, North Carolina 27216-2230

Telephone: 919 584-5171

May 22, 1990

INVESTIGATIVE FINDINGS AND CORRECTIVE ACTIONS FOR UNSATISFACTORY BLIND PERFORMANCE TEST RESULTS

PROBLEM STATEMENT:

In fulfillment of the requirements specified in 10 CFR part 26 Fitness for Duty Programs, Appendix A, Section 2.8(e), Florida Power & Light Company (FPL) submitted blind performance test specimens to Roche Biomedical Laboratories. Of the blind specimens submitted, a fraction of the samples were fortified with the drugs. After receipt of the results, FPL notified Roche Laboratories of unsatisfactory results for four (4) of the drug fortified urine specimens. The following report details the investigative analysis of the problem, the identification of the causes and the corrective actions taken.

CODEINE/BENZODIAZEPINE FORTIFIED SAMPLES

Specimen Numbers: 003-000-5042-0
037-000-5090-0

Analysis:

Both of these samples were fortified with benzodiazepine and codeine. A review of the data revealed that both substances were initially identified by the EMIT screening method.

Gas Chromatography Mass Spectrometry (GC/MS) confirmation testing resulted in reporting a positive for benzodiazepines for both specimens but negative for codeine. A review of the GC/MS data indicates that codeine was likely present. However, in each case the samples were subjected to the GC/MS analysis two times, and in both cases, for each sample, the relative abundance data for one of the ion masses monitored did not meet our specifications. Our S.O.P. requires that the relative abundance for the monitored ion masses must be within 20 % of that obtained for the standards in each batch.

Unless all criterion are met for a positive confirmation, a negative result is reported, as was the case for these specimens. If the qualitative criterion had been met, the quantitative results obtained for the specimens for codeine were as follows:

003-000-5042-0	1026 ng/ml,	921 ng/ml
037-000-5090-0	800 ng/ml,	646 ng/ml

Identification of Cause:

Our personnel have audited a number of our GC/MS packets for opiate confirmations, and have encountered a few other samples which gave similar data to the above two specimens. The problem could not be identified but is most likely due to an interference in our assay in certain samples. Based upon our analysis, following action has been taken.

Corrective Actions:

We have initiated development of a method using a different extraction column and a different derivatization. Previously we have used an XAD resin; the new method uses a bonded phase. The old procedure used butyl derivatives whereas the new procedure uses TMS derivatives. It is anticipated that this procedure will provide cleaner extracts and an improved chromatographic performance.

The development and validation of new assay procedure was completed in early May. The procedure was evaluated on samples which have given problems with the old method, and was found acceptable. The new procedure was implemented on May 10, 1990.

AMPHETAMINES/OPIATES FORTIFIED SAMPLES

Specimen Number: 061-000-5107-0

Analysis:

This sample was fortified with amphetamines and opiates. A review of the analyses revealed that the initial screening test was positive for amphetamine and opiates. A technician inadvertently transcribed the opiate result to the worksheet as a negative. Our procedure requires that the screening results be transcribed into our data system. A second individual is required to review the result entry. This procedure was documented as performed. However, the review had compared the manually transcribed result to the data in the computer and did not identify the error. A review of approximately 5000 records preceding and following this incident showed this to be an isolated administrative error.

Identification of Cause:

A review of all of the reports indicated that a technician inadvertently transcribed the result as negative and a negative result was issued. Additionally, the individual responsible for the review of the data entry did not identify the problem because the second review compared the data entry against the manually transcribed worksheet instead of against the instrument printout.

Corrective Actions:

I have reconfirmed with our staff that the confirmation review must compare the data entry to the instrument printout of results. Additionally, we are in the process of implementing a bar code identification system with an on-line transmission of data after supervisory and certifying official review. Implementation of this system is anticipated to be completed by August 1990.

MORPHINE/CODEINE FORTIFIED SAMPLES

Specimen Number: 086-000-5069-0

Analysis:

This sample was fortified with morphine and codeine. The test results reported were a positive for codeine and negative for morphine. A review of the analyses revealed that the sample screened positive for opiates.

Further GC/MS testing resulted in reporting a positive for codeine. A review of the GC/MS data indicate that morphine was probably present at approximately 800 ng/ml. However, after a repeat analyses, we were unable to obtain a definitive confirmation for morphine. The ion ratios were not acceptable for a positive confirmation.

Identification of Cause:

This is similar to the validation problems identified for the first two specimen problems in this report. The cause is believed to be the same as for samples (003-000-5042-0 and 037-000-5090-0).

Corrective Action:

As stated for the corrective action for the first two samples we have implemented a new validation procedure and have found it to perform to our satisfaction. The new procedure was implemented on May 10, 1990.

The procedure uses a solid phase extraction (bonded phase) and derivatization with BSTFA and TMCS. Several samples which appeared to contain morphine and /or codeine by the old procedure, but failed to meet specifications were tested by the new procedure with satisfactory results.

Summary:

This report is being submitted for FPL to forward to the Nuclear Regulatory Commission in accordance with 10 CFR 26, Appendix A, Section 2.8 (e) (4) and is signed by the individual responsible for the day to day management and operation of our HHS-certified laboratory.

Respectfully Submitted by (insert name, title)

John B. Fobia — 5-22-90

Signed — date