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 50-389 St. Lucie Plant, Unit 2, Florida Power & Light Co. 05000389

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SUBJECT: Forwards rept of unsatisfactory performance testing incident to NRC.

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L-90-232
10 CFR 26
JULY 27 1990

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.

FPL is working with Roche to expedite their permanent corrective action now scheduled to be completed in October 1990. Until final corrective action in the form of computer-to-computer communication is implemented by Roche, FPL will closely monitor their performance and encourage more stringent controls during manual data transcriptions, if necessary.

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

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WHB/GRM/slh

Enclosure

cc: Stewart D. Ebnetter, 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
1447 YORK COURT
BURLINGTON, N.C. 27215

July 12, 1990

INVESTIGATIVE FINDINGS AND CORRECTIVE ACTION FOR
AN UNSATISFACTORY BLIND PERFORMANCE TEST RESULT

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 and Light Company (FPL) submitted blind performance test specimens to Roche Biomedical Laboratories. Of the blind specimens, a fraction of the samples were fortified with drugs. After receipt of results, FPL notified Roche Laboratories of one unsatisfactory result on a drug fortified urine specimen. The following report details the investigative analysis of the problem, the identification of the cause and the corrective action taken.

Specimen number: 115-000-5013-0

ANALYSIS:

This sample was fortified with amphetamine. A review of our screening data shows that this was an administrative error. The sample screened positive for amphetamines but was transcribed to the worksheet as a negative result. Standard procedure requires that a second individual review the transcribed results. This procedure had been done as evidenced by signature. However, the second reviewer did not detect the error. A review of approximately 500 records preceding and following this incident showed this to be an isolated administrative error.

IDENTIFICATION OF CAUSE:

Review of the data indicates that this false negative resulted from an inadvertent transcription error in the initial phase of testing. A second reviewer failed to detect the error.

CORRECTIVE ACTIONS:

At the time of our move to the RTP laboratory, we implemented an additional review step which we believe will greatly reduce the probability of a reoccurrence of this administrative error. We have added a requirement for a certifying scientist to review the screening data prior to entry into our data system.

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— *Journal of the American Medical Association*, 1967, 201: 1031-1032.

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10. The Commission has been informed that the Government of the Republic of Armenia has agreed to accept the findings of the Commission's investigation and to take the necessary measures to ensure that the rights of the victims are protected and that the perpetrators are held accountable. The Commission has also been informed that the Government of the Republic of Armenia has agreed to provide financial support for the victims and their families.

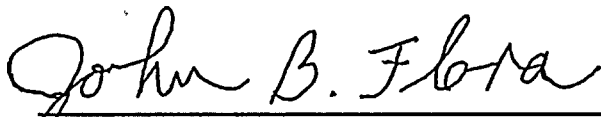
[illegible][illegible]

The screening data is now subjected to a three-step review. First, it is reviewed by the screening technician, this is followed by a supervisor review, and finally, the data is reviewed by a certifying scientist. Following the analytical reviews, a technician enters the results into our data system and then prints the result entry information. A second individual reviews the printout against the analytical data prior to release. We believe the multi-stage review process will greatly reduce the probability of a reoccurrence of such an error in the interim period until development of our on-line data interface which is due to be completed around October, 1990. The on-line interface is currently operational for our true NIDA profile. Because we offer additional cut-off levels and expanded profiles to our other clients, additional programming is required to accommodate these options. This system will provide for direct transmission of the data following the three level review of analytical data.

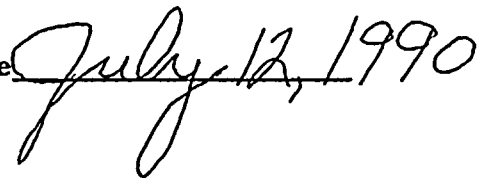
SUMMARY:

This report is being submitted for FPL to forward to the Nuclear Regulatory Commission in accordance with the 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:



John B. Flora, Director

Date 

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1. The first part of the document discusses the importance of maintaining accurate records of all transactions and activities. It emphasizes that proper record-keeping is essential for transparency and accountability, particularly in financial matters.

2. The second part outlines the various methods and tools used to collect and analyze data. This includes both traditional manual methods and modern digital technologies, highlighting the advantages of each approach.

3. The third part focuses on the interpretation of results and the drawing of conclusions. It provides guidelines on how to effectively communicate findings to stakeholders and make informed decisions based on the data.

4. The final part discusses the challenges and limitations of the research process. It acknowledges that while data-driven approaches are powerful, they are not without their own set of complexities and potential biases.

5. In conclusion, the document stresses the need for a balanced and systematic approach to data analysis. By combining rigorous methodology with critical thinking, researchers can maximize the value of their data and contribute meaningfully to their field.

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