10 CFR 26, Appendix A, Subpart B, 2.8(e)(4)

Progress Energy

PO Box 1551
411 Fayetteville Street Mall
Raleigh NC 27602

Serial: PE&RAS-03-065
June 6, 2003

United States Nuclear Regulatory Commission
ATTENTION: Document Control Desk
Washington, DC 20555

BRUNSWICK STEAM ELECTRIC PLANT, UNIT NOS. 1 AND 2
DOCKET NOS. 50-325 AND 50-324/LICENSE NOS. DPR-71 AND DPR-62

SHEARON HARRIS NUCLEAR POWER PLANT, UNIT NO. 1
DOCKET NO. 50-400/LICENSE NO. NPF-63

H. B. ROBINSON STEAM ELECTRIC PLANT, UNIT NO. 2
DOCKET NO. 50-261/LICENSE NO. DPR-23

CRYSTAL RIVER UNIT 3 NUCLEAR GENERATING PLANT
DOCKET NO. 50-302 / LICENSE NO. DPR-72

10 CFR 26 UNSATISFACTORY FITNESS-FOR-DUTY BLIND PERFORMANCE TESTING RESULTS

Ladies and Gentlemen:

On April 29, 2003, Progress Energy Carolinas, Inc. (PEC) (also known as Carolina Power & Light Company) and Progress Energy Florida, Inc. (PEF) (also known as Florida Power Corporation) notified via telephone the NRC of the occurrence of an administrative error on a blind performance test specimen, pursuant to 10 CFR 26, Appendix A, Subpart B, Section 2.8 (e)(5).

The PEC and PEF investigation of the incident was concluded on June 2, 2003. The Director, Forensic Toxicology, has reviewed the investigative findings and corrective actions, as documented in a signed letter dated June 5, 2003. The Director, Forensic Toxicology, is the person responsible for the day-to-day management and operation of the Department of Health and Human Service (HHS) certified laboratory.

Based on discussion with the NRC, the attached report on the investigation and the letter signed by the laboratory's Director, Forensic Toxicology, are being submitted pursuant to 10 CFR 26, Appendix A, Subpart B, Section 2.8 (e)(4).

This document contains no new regulatory commitment.

Please contact me at (919) 546-6901 if you need additional information.

Sincerely,

James W. Holt

James W. Holt
Manager - Performance
Evaluation & Regulatory Affairs

HAS
Attachments

A022

c: L. A. Reyes, USNRC Regional Administrator – Region II
USNRC Resident Inspector – BSEP, Unit Nos. 1 and 2
USNRC Senior Resident Inspector – CR3
USNRC Senior Resident Inspector – SHNPP, Unit No. 1
USNRC Senior Resident Inspector – HBRSEP, Unit No. 2
G. West, USNRC NSIR/DNS/LPSS-OWFN, A 4 D8
B. L. Mozafari, NRR Project Manager – BSEP, Unit Nos. 1 and 2; CR3
C. P. Patel, NRR Project Manager – SHNPP, Unit No. 1; HBRSEP, Unit No. 2
J. A. Sanford - North Carolina Utilities Commission

ATTACHMENT 1
Investigation Report

Attachment 3
Sheet 1 of 1
Adverse Condition Investigation Form
Form CAP-NGGC-0200-3-7

Action Request Number: 91108

1. Event Description

• CONFIRMATION LAB REPORTED RESULTS FOR TWO BLIND SPECIMENS INCONSISTENT WITH THE PRIMARY LAB. MRO CONTACTED AND REQUESTED BOTH THE PRIMARY AND SECONDARY LAB TO RE-ANALYZE THE SPECIMENS.

2. Problem Description / Investigation Summary:

Consider elements such as the following, as applicable:

• What Should Be: the requirement, standard, norm, or expectation:

Code of Regulations 10 part 26, Appendix A, 2.8 (e) requires licensee blind performance test procedures to be conducted at a quarterly rate of 10% of all samples submitted to the lab with an 80:20 negative/positive ratio as a quality assurance control. Progress Energy purchases control specimens from an HHS certified lab and submits them to Laboratory Corporation of America (LabCorp). LabCorp's specimen results are compared with the known blind sample. A minimum of 10% of the blind samples submitted to the primary laboratory are forwarded to Progress Energy's secondary laboratory, Quest Diagnostics, for testing.

• What Is: the existing, as-found condition:

Quest Diagnostics reported two blind specimens with results inconsistent with the blind supplier and the primary lab.

Specimen Number	El Sohly	Lab Corp Report	Quest Report
0157561663	Morphine 452 ng/ml Codeine 438 ng/ml	Morphine 440 ng/ml Codeine 408 ng/ml	**Negative**
0157561762	Negative	Negative	**Morphine 431 ng/ml** **Codeine 402 ng/ml**

Progress Energy's Medical Review Officer was notified immediately and requested both the primary and secondary lab to reanalyze the samples. LabCorp's reanalysis confirmed their initial results. Upon reanalysis, Quest Diagnostics reported results consistent with the blind supplier and the primary lab.

Quest Diagnostics performed an internal investigation and determined that an administrative error by the certifying scientist had occurred at the result entry stage of the certification process, resulting in incorrect results being reported. Additionally, the certifying scientist responsible for the error did not follow the laboratory's standard operating procedure for handling re-test specimens.

On 4/29/03 Lori Hayes, Sr. Regulatory Analyst, Nuclear Security, notified the NRC via telephone.

Time Line of Events

4/11/03 Blind specimen 0157561663 submitted to Lab Corp.

4/12/03 Lab Corp received specimen 0157561663.

4/15/03 Blind specimen 0157561762 submitted to Lab Corp.

4/16/03 Lab Corp received specimen 0157561762.
Lab Corp reported negative results for specimen number 0157561762.

4/17/03 Lab Corp reported positive opiate results for specimen 0157561663.

4/17/03 Progress Energy's Medical Review Officer requested Lab Corp to send Bottle B of specimens 0157561663 and 0157561762 to Quest Diagnostics for split sample testing.

ATTACHMENT 1
Investigation Report

4/20/03	Quest Diagnostics received specimen numbers 0157561663 and 0157561762.
4/21/03	Quest Diagnostics reported at 2247 hours specimen 0157561663 as failed to reconfirm. Quest Diagnostics reported at 2247 hours specimen 0157561762 as positive for opiates.
4/22/03	Quest Diagnostic's reports for specimen numbers 0157561663, and 0157561762 reviewed and the reporting discrepancy identified. AR initiated. Medical Review Officer notified. Lab Corp and Quest Diagnostics requested to reanalyze specimens 0157561663 and 0157561762.
4/24/03	Quest Diagnostics reported re-analysis of specimen 0157561663 as positive for opiates. Quest Diagnostics reported re-analysis of specimen 0157561762 as negative.
4/28/03	Quest Diagnostic's investigative response submitted to Progress Energy.
4/29/03	Lori Hayes notified NRC via telephone.
5/01/03	Lab Corp reported re-analysis of specimen 0157561762 as negative.
5/03/03	Lab Corp reported re-analysis of specimen 0157561663 as positive for opiates.

3. Inappropriate Acts / Equipment Failures

- For each Inappropriate Act(s) identify the Work Group involved

4. Apparent Causal Factor associated with each Inappropriate Act / Equipment Failure

- Q2 External Entities, Vendor/Supplier

5. Corrective Action Plan

Apparent Causal Factor #	Planned / Completed Action (Annotate Committed Assignments as Committed)	Assignment Type	Assignee / Concurred By	Initial Due Date
1	Reanalysis of specimens by the Lab Corp	CORR	Lab Corp	Complete
2	Reanalysis of specimens by Quest Diagnostics	CORR	Quest	Complete
3	Retrain certifying scientist on applicable protocols and procedures to include secondary review of ten analytical batches of data by a senior lab representative	CORR	Quest	Complete
4	Capture event in the next NRC Six Month Summary Report		Cindy Cunningham	8/30/03

ATTACHMENT 2
Director, Forensic Toxicology, Letter

Quest Diagnostics Incorporated

5175 Presidential Drive
Atlanta, GA 30340

June 5, 2003

Cindy Cunningham
Carolina Power & Light Co.
412 S Wilminton Street
Raleigh, NC 27601

Dear Ms. Cunningham:

It is the policy of Quest Diagnostics Incorporated to conduct a thorough investigation and to provide an accurate response to each client's request in a timely - manner. Pursuant to your request and as the individual responsible for the day-to-day management and operation of this HHS-certified laboratory, I have reviewed the investigative findings and corrective actions taken by the laboratory, as documented in Progress Energy's investigation for AR 91108. In particular, the event was caused by an administrative error by the certifying scientist during the result entry stage, resulting in incorrect results being reported. The certifying scientist responsible for the error did not follow the laboratory's standard operating procedure for handling re-test specimens. As corrective actions, the individual was re-trained on all applicable protocols and procedures to include secondary review of ten analytical batches of data by a senior lab representative. These corrective actions have been completed.

If you have any questions regarding the contents of this letter, please contact me directly at (800) 729-6432 x6107.

Respectfully,

Edward A'Zary
Director of Forensic Toxicology