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MORTON,T.C. Carolina Power & Light Co.
RECIP.NAME RECIPIENT AFFILIATION
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SUBJECT: Forwards unsatisfactory fitness-for-duty performance testing,IAW 10CFR26.Review of testing data received from Forensic Urine Drug Testing Lab - LabCorp revealed that test results for four urine samples were incorrectly reported.

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Carolina Power & Light Company
PO Box 1551
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Serial: PE&RAS-99-061
September 9, 1999

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

Sir or Madam:

In accordance with 10 CFR 26, Appendix A, Subpart B, Section 2.8 (e)(4), Carolina Power & Light (CP&L) Company is submitting the enclosed report of unsatisfactory Fitness-For-Duty (FFD) performance testing. A review of testing data received from the Forensic Urine Drug Testing Laboratory - LabCorp (LabCorp) revealed that the test results for four urine samples (i.e., three quality control samples and one client sample) were incorrectly reported to CP&L as negative.

Enclosed is the record of investigative findings and corrective actions taken by the laboratory. The report was signed on September 7, 1999, by the individual responsible for the day-to-day management and operation of LabCorp.

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

Sincerely,

Terry C. Morton
Manager - Performance
Evaluation & Regulatory Affairs

DSL
Enclosure

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c: L. A. Reyes, Regional Administrator - Region II
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USNRC Resident Inspector - HBRSEP, Unit No. 2
R. Subbaratnam, NRR Project Manager - HBRSEP, Unit No. 2
J. A. Sanford - North Carolina Utilities Commission

Carolina Power & Light Company
Investigation of Unsatisfactory Laboratory Performance

This report documents an investigation of unsatisfactory performance testing by the Health and Human Services (HHS) certified laboratory (i.e., The Forensic Urine Drug Testing Laboratory - LabCorp) providing chemical testing services to Carolina Power & Light (CP&L) Company.

On July 2, 1999, a review by CP&L of testing data received from LabCorp revealed that the test results for three quality control urine samples which had been "spiked" with amphetamines were inaccurately reported to CP&L as negative. Also on July 2, 1999, CP&L notified LabCorp of the occurrence.

The investigation of this occurrence found that a total of four CP&L specimens that had screened positive for amphetamines on LabCorp's primary immunoassay screen were reported as negative based on the results of the secondary screen (i.e., rescreen). Three of these specimens were blind samples submitted by CP&L that had been spiked with amphetamines at levels greater than 2000 ng/mL and thus were expected to yield positive results. The fourth specimen was an actual client sample assayed within the same time frame. This client sample was subsequently treated as a presumptive positive after retesting performed by LabCorp revealed that the initial test results were inaccurate.

The false negative test result was traced to an error in the calibrator settings for the amphetamine assay on the Olympus AU 800 instrument used for rescreens. At the time of this occurrence there was no system in place to control parameter changes made by technologists on the screening instrument and no verification by another technologist of parameter changes to ensure the changes were indeed correct.

The root cause was determined to be a lack of control over the changing of critical instrument parameter settings on the Olympus AU 800.

The menu of the Olympus AU 800 was changed on June 21, 1999. Any change to the menu of the Olympus AU 800 requires that all instrument parameters be reset. This led to erroneous settings for the previously correct calibration parameters for the amphetamine rescreen on this instrument. The system did not have the capability to alert the operator by generating an error message when it did not receive a sample where expected. The technologist changing the instrument parameters was negligent in rechecking the calibrator settings for all tests when the menu was changed.

The following corrective actions have been completed:

- Instrument Parameter Control:

  A Password protection function for the Olympus AU 800 has been implemented so that only approved personnel can make changes to the instrument parameters. In addition, a second level of review for changes in instrument parameters has been implemented so that all changes in parameters and calibrators for the instrument will be reviewed by another qualified technologist or supervisor before the instrument is used.

- Quality Control Procedures:

  Following instrument parameter changes, reagent changes and calibration, the instrument is tested by a special quality control (QC) procedure in which a sample will be spiked at a concentration approximately two times greater than the highest calibrator. This is done before donor specimens are analyzed and it will demonstrate that screening instruments are responding correctly. This change will verify assay performance at the high end of the expected analyte concentration range and thus will alert the analyst to any instrument or reagent related problems at these concentration levels. The addition of a high amphetamine screening control is the most effective remedial action that will ensure, on a day-to-day basis, that the screening assay performs properly throughout the expected analyte concentration range and that any potential problems related to either reagents or the instrument itself will be detected by the analyst and/or the data reviewer.

R. C. Gill 9/7/99

Robert C. Gill Date
Manager, Corporate Security
Carolina Power & Light Company

Francis M Esposito 9/7/99

Francis M. Esposito Date
Laboratory Director, Forensic Urine Drug Testing Laboratory - LabCorp