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SUBJECT: Forwards rept on chemical testing lab performance testing, as part of fitness-for-duty program.

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CP&L

Carolina Power & Light Company

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FITNESS FOR DUTY - REPORT ON CHEMICAL TESTING LABORATORY PERFORMANCE TESTING

Gentlemen:

10 CFR Part 26, Appendix A requires licensees to report unsatisfactory performance testing results as part of the Fitness-for-Duty Program. Carolina Power & Light Company (CP&L) submits blind performance test specimens to the certified laboratory from which we purchase chemical testing services. In three instances since the inception of CP&L's program, results for blind performance test specimens have been mistakenly reported as negative. In all three of these instances, the performance test errors involved blind samples prepared near the screening cut-off value for amphetamines. For this reason, CP&L did not initially consider these instances of false negative reports to indicate unsatisfactory test results. However, it has recently come to our attention that the Nuclear Regulatory Commission (NRC) wishes to be informed of any false negative test results.

Accordingly, CP&L's investigative report concerning these instances is attached. As required by 10CFR Part 26, Appendix A, Section 2.8 (e) (4), a record of the investigative findings and the corrective action taken by the laboratory, dated and signed by the individuals responsible for the day-to-day management and operation of the laboratory, is also attached.

411 Fayetteville Street • P. O. Box 1551 • Raleigh, N. C. 27602

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For further information about this subject, please contact Mr. Fred Underwood, CP&L's Fitness-for-Duty Coordinator at (919) 546-6180.

Yours very truly,

L. L. Loflin
Manager
Nuclear Licensing Section

ONH/mbc (777SNP)

Attachment

cc: Mr. R. A. Becker
Mr. S. D. Ebneter
Mr. L. Garner (NRC - HBR)
Mr. N. B. Le
Mr. R. Lo
Mr. R. L. Prevatte
Mr. J. E. Tedrow

REPORT ON FALSE NEGATIVE BLIND PROFICIENCY SAMPLES

During the first six months of l990, 55 blind proficiency samples which were prepared as positive by CP&L's vendor were submitted to the primary NIDA-certified laboratory which performs urinalyses as part of the Fitness For Duty Program. Sixteen of these samples were prepared by the vendor as positive for amphetamines or methamphetamine (at a target level of 1,250 ng/ml). Three of these samples that were prepared as positive for amphetamines were reported as negative. Each had screened negative by the enzyme immunoassay method. Subsequent GC/MS analysis on one of these samples indicated an amphetamine concentration of 1,182 ng/ml.

Based on the primary laboratory's internal investigation of these incidents, information received from the proficiency samples provider and our own evaluation, these false negative reports do not appear to represent an ongoing systematic deficiency in the analytical methods used by the NIDA-certified laboratory. This conclusion is based on this evidence:

1. The laboratory's internal investigation revealed that the EMIT values for each of the samples were within one per cent of their cut-off values and that this could have been due to their use of calibrator and quality control samples that are prepared with racemic d-amphetamine while the vendor proficiency samples are prepared with d,l-amphetamine which is less immunochemically reactive than the d- isomer alone. See the attached report from the primary laboratory.

2. The vendor of the blind proficiency samples reported similar incidents of false negative results for amphetamines with other clients using other NIDA-certified laboratories.

3. If the NIDA criteria for evaluation of proficiency testing are applied to these period of the primary laboratory's performance, all are met:

Criterion # 1: More than 90% of the samples prepared as positive should be identified with the correct drug metabolite's presence .
Lab Performance: 95% of the prepared positive samples were correctly identified and confirmed.

Criterion #2: At least 80% of the quantitative measurements should not differ from the target value by more than 20%.
Lab Performance: 83 % of the quantitative measurements were within 20% of the target values

Criterion #3: No value should differ from the target value by more than 50%.
Lab Performance: Each of the reported values were within 50% of the target value.

Criterion #4: There should be no false positives.
Lab Performance: No false positive were reported.

It appears that the most probable explanation for the false negative reports is the 80-90% cross-reactivity of d-amphetamine compared with d,l-amphetamine. The primary laboratory's report lists the corrective action they are taking to reduce the probability of false negative amphetamine analyses.

We will take these actions to investigate each false negative report should it occur again:

1. The primary laboratory shall be immediately notified to re-analyze any presumed positive sample that is reported as negative.

2. If the second analysis at the primary laboratory remains negative, an aliquot of the sample shall be sent to another NIDA-certified laboratory for analysis.

3. Documentation of the blind proficiency sample vendor's analysis by a NIDA-certified laboratory, the analyses by the primary laboratory, and the analysis by the third NIDA-certified laboratory, if needed, shall be obtained and reviewed.

4. The results of the investigations shall be shared with each of the laboratories where the analyses were performed.

Compuchem Laboratories, Inc serves as our primary laboratory. Their report on these incidents is attached. CDT, Inc. is our vendor of the blind proficiency samples. Poisonlab provides analytical services for CDT, Inc.

Gary N. Greenberg, MD, MPH

September 7, 1990

COMPUCHEM LABORATORIES, INC. P.O. Box 12652 3308 Chapel Hill/Nelson Highway Research Triangle Park, NC 27709 (919) 549-8263

September 4, 1990

Dr. Gary Greenberg, MRO
Attn: Ms. Bette Wilder
CP&L Occupational Health Office
P.O. Box 1551
Raleigh, NC 27602

SUBJECT: Unacceptable Amphetamine Proficiency Samples

Dear Ms. Wilder,

Between the dates January 30, 1990 and March 20, 1990 CompuChem Laboratories received three samples from Carolina Power and Light Company (CP&L), identified as Newsome, Everette W. (SSN: 240-07-4171); Hollifield , Roy N. (SSN: 237-44-7885); and Farr, Paul R. (SSN: 238-18-7090). Each sample was subjected to our standard drug testing protocol which is in accordance with Nuclear Regulatory Commission guidelines whereupon each screened negative for all drugs.

Subsequently, we were informed by CP&L that each of these samples was an amphetamine positive blind proficiency sample with target concentrations (from the preparer/vendor) of 1250-1300 ng/mL. The "Newsome" sample was analyzed by GC/MS per retest request by CP&L and found to contain 1182 ng/mL of amphetamine.

An investigation was conducted in order to identify possible causes for the low EMIT results. The results (delta mA, 1000 ng/mL cut-off) of the amphetamine EMIT analysis of each of the samples as well as the data for standards and controls in the respective sample groupings are shown below:

1. Newsome, Everette W, analyzed on January 30, 1990,

Negative	Cut-off	1300ng/mL controls*	Sample
494	681	688 to 694	678

2. Hollifield, Roy N., analyzed on February 16, 1990,

Negative	Cut-off	1300ng/mL controls	Sample
497	672	686 to 689	668

3. Farr, Paul R., analyzed on March 20, 1990,

Negative	Cut-off	1300ng/mL controls	Sample
504	675	686 to 689	670

*range of observed values.

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As it can be seen, the responses the proficiency samples were slightly below those of their respective calibration standards. Explanations for why this might have occurred in these cases are as follows:

1) The urine samples may have not been adequately mixed prior to analysis. Since urine is not a homogeneous material, inadequate mixing of a urine sample prior to analysis may result in an unequal distribution of any drug substance which is present in the sample. When a subsample of only a few microliters is taken from a urine aliquot by the EMIT analyzer, the concentration of drug in this subsample may be lower than that of the urine in the original sample bottle possibly resulting in an analytical response which is below the cut-off.

2) The results may have been due to statistical variation. All analytical procedures exhibit some degree of insignificant variation when a given sample is analyzed repeatedly. If the magnitude of variation is sufficient and the concentration of the sample is close to that of a cut-off calibrator, there is a reasonable probability that any given single analysis of the sample may yield a result which is less than that of the calibrator.

3) The isomeric form of amphetamine used to the prepare the samples is less immunochemically reactive than the one used in our calibrators and quality control materials. The calibration standard which we use with the EMIT Amphetamine DAU test kit contains d,l-amphetamine at a concentration (certified by GC/MS) of 1000 ng/mL. We contacted a representative of the vending laboratory which prepared the proficiency samples and learned that the samples were from lots of urine which were fortified with 1250-1300 ng/mL of d-amphetamine. Our experience in the laboratory has indicated that the cross-reactivity of d-amphetamine versus d,l-amphetamine is approximately 80-90% at concentrations near 1000 ng/mL. Therefore, samples prepared with a target concentrations of 1250-1300 ng/mL of d-amphetamine would be expected to give results equivalent to 1000-1170 ng/mL of d,l-amphetamine. Such samples would have a probability of as high as 50% of giving results below the cut-off upon analysis. We have observed that samples prepared with d-amphetamine give the most consistent "positive" responses versus a 1000 ng/mL d,l-amphetamine calibrator when the target concentration range is 1500-2000 ng/mL.

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Any one or all of these situations may have contributed to the low EMIT result for the samples in question versus the 1000 ng/mL cut-off. In order to minimize or eliminate the effects of these situations, we have taken or will take the following corrective actions:

1) We have restated to laboratory personnel the importance of adequate mixing of samples and sample aliquots prior to analysis on the automated analyzer.

2) We are in the process of reviewing the acceptance criteria for the performance of our 1200-1300 ng/mL controls versus the 1000 ng/mL calibration and may institute more stringent analytical "separation" requirements between these two assay parameters.

3) We plan to evaluate the EMIT monoclonal antibody Methamphetamine/Amphetamine DAU test kit which is designed to yield a high degree of reactivity with d-amphetamine, d,l-amphetamine and d-methamphetamine.

We hope that these steps will minimize the chances of "negative" results for samples which contain amphetamine at concentrations greater than 1000 ng/mL. If you have any questions concerning this matter please call me at (919) 248-6804.

Sincerely,

Edwin D. Hart
Assistant Director,
FDT Technical Programs