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PRUNTY,R.W. Carolina Power & Light Co.
RECIP.NAME RECIPIENT AFFILIATION
Document Control Branch (Document Control Desk)

SUBJECT: Forwards rept of false positive,special processing drug test,per 930920 discussion w/LL Bush.Potential reasons for results included improper use of pasteur pipette.Roche CompuChem Lab will re-train GC/MS staff.

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FITNESS FOR DUTY INFORMATION REPORT: RANDOM SCREENING - FALSE POSITIVE TEST RESULTS

Gentlemen:

The purpose of this letter is to provide the NRC information on a recent incident within the general scope of 10 CFR 26, Appendix A, Section 2.8(e). This incident report is not required by 10 CFR 26; however, within the intent of 10 CFR 26, Appendix A, Section 2.8(e), Carolina Power & Light Company (CP&L) is providing this report for information only.

A random sample was initially screened negative for drugs; however, due to the low creatinine level, special processing using Limit of Quantification (LOQ) was authorized. The LOQ result was positive for drugs. Level of Detection (LOD) analyses performed by another laboratory were negative, and additional LOQ analyses by the initial screening laboratory also were negative.

Carolina Power & Light Company's investigative report is enclosed for your information. There was no adverse impact on the test subject, and no further action by CP&L is required. A record of findings and corrective actions from the laboratory is also enclosed.

This incident was discussed with Mr. L. L. Bush of your staff on September 20, 1993.

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

A022
1/1

(2090INA)

For further information regarding this subject, please contact Mr. Fred Emerson at (919) 546-7573.

Yours very truly,

R. W. Prunty
Manager
Generic Licensing Section

DBB/jbw
Enclosures

*cc: Mr. L. L. Bush - NRC (w/enclosures)
Mr. S. D. Ebneter
Mr. N. B. Le
Mr. P. D. Milano
Ms. B. L. Mozafari
Mr. W. T. Orders
Mr. R. L. Prevatte
Mr. J. E. Tedrow
*without enclosures

REPORT OF A FALSE POSITIVE, SPECIAL PROCESSING DRUG TEST

SUMMARY

Roche CompuChem Laboratory in Research Triangle Park, NC performs drug testing to support CP&L's FFD Program (FFDP). CP&L's Medical Review Officer authorizes special processing of a FFD drug testing urine sample anytime the creatinine for that sample is less than 20 mg/dl. This special processing includes GC/MS analyses for cocaine and marijuana at Roche CompuChem's Limit of Quantification (LOQ) for each drug class. Before a positive result from special processing is considered as the basis for a FFDP violation, an aliquot of the sample is tested by PDLA in Princeton, NJ, at its Limit of Detection (LOD) for the specific metabolite to confirm the initial LOQ analysis.

A special processing LOQ analysis by Roche CompuChem in August, 1993 was positive for cocaine (782 ng/ml). Two LOD analyses by PDLA were negative for cocaine. Two additional LOQ analyses by Roche CompuChem were also negative.

The false positive test report involved a sample that was analyzed by a special testing protocol that extends beyond the methods and practices approved by the Department of Health and Human Services (DHHS) and the basic testing requirements of the Nuclear Regulatory Commission (NRC) FFD regulations.

Roche CompuChem was unable to determine the immediate cause of the false positive test report. Their quality control safeguards (scientist's review of test results) did not have an automated or other tracking system that:

1) forced the comparison of special processing test results with normal screening test results for the same sample, or

2) prevented the release of a special processing test result prior to a full review by a certifying scientist.

The only impact to the test subject was a delay in receiving a report of the test. The drug test was reported as negative (in compliance) by the Medical Review Officer. The practice of using another laboratory to confirm positive results of special processing analyses prevented adverse consequences to the test subject.

Minimal corrective actions were required. Records of the re-tests for the sample and other information were added to the subject's chart to document a negative (in compliance) drug testing report.

The laboratory is taking these actions to prevent future similar occurrences:

1) re-training of its GC/MS staff, and

2) use of a computer software system to identify inconsistencies in testing results and to require special (independent) reviews by the laboratory's management prior to the release of the results.

SEQUENCE OF EVENTS

Aug 3 Sample (random test) was collected.

Aug 4 Sample was received at Roche CompuChem. Drug screening (negative) and creatinine (8 mg/dl) analyses were completed. The initial report was released. Initial report was received at CP&L by MRO's staff. MRO authorized special processing of the sample due to low creatinine.

Aug 9 An aliquot of the sample was batched for GC/MS extraction and analysis (delay between August 4 and August 9 was due to scheduling oversight at the laboratory).

Aug 10 LOQ GC/MS analysis for cocaine was positive (782 ng/ml).

Aug 11 Second screening analysis was negative (for cocaine and other drugs); LOQ GC/MS analysis for marijuana was negative; positive report for cocaine was released.

Aug 12 LOQ Special Processing report received at CP&L by MRO's staff. MRO's staff (a Registered Nurse) called Roche CompuChem to request a letter from the certifying scientist (normal practice) and to note the high concentration of cocaine for an LOQ Special Processing report.

Aug 16 Certifying letter from Roche CompuChem scientist received at CP&L by MRO's staff. MRO authorized Roche CompuChem to send an aliquot of the sample to PDLA and authorized PDLA to perform an LOD analysis for cocaine.

Aug 17 PDLA received an aliquot of the sample.

Aug 20 PDLA's report (negative for cocaine) of its initial test was received at CP&L by the MRO's staff. MRO authorized PDLA to perform a re-test for cocaine at the laboratory's LOD. MRO authorized Roche CompuChem to perform a re-test for cocaine at the laboratory's LOQ.

Aug 23 PDLA released its (negative) report of the re-test at its LOD for cocaine. MRO's staff called Roche CompuChem to notify them of the negative test result from PDLA.

Aug 26 Roche CompuChem reported that the re-test was negative. MRO requested an investigation by Roche CompuChem into the initial Special Processing result.

Sept 1 Roche CompuChem's initial report (attached with deleted identification of the test subject) of its investigation was received at CP&L by the MRO's staff.

Sept 2 MRO released report of the drug test as negative (in compliance). MRO made on-site visit to Roche CompuChem to review their investigation.

Sept 7 Roche CompuChem's follow-up report (attached) on items discussed at the Sept 2 meeting was received at CP&L.

CAUSE

The false positive test result involved a sample that was analyzed by a special testing protocol that extends beyond the methods and practices approved by the DHHS and the basic testing requirements of the NRC FFD regulations. While Roche CompuChem performs a substantial portion of the nation-wide testing required by NRC FFD regulations, no other client requires special processing like CP&L.

While Roche CompuChem was unable to determine the specific and immediate cause of the false positive report, their investigation identified four <u>potential</u> reasons for the result:

1) improper use of pasteur pipette,

2) not maintaining a clean extraction area for GC/MS processing,

3) improper use of the extraction box, or

4) switching of specimens.

Roche CompuChem's internal investigation deemed Item 4 to be the least likely of the potential causes because all of the samples in the batch were positive for cocaine.

Roche CompuChem identified a weakness in its process for review of special processing reports: No specific procedure or system required the comparison of special processing results to previous screening and confirmation results for the same sample. While their staff did identify a potential problem with the special processing result, their internal systems did not control the release of the report.

IMPACT

The MRO's reporting of the drug testing report was delayed by approximately two weeks beyond the normal time required to complete a special processing sample.

There was no adverse impact on the test subject. The sample was reported as negative (in compliance) by the MRO. An opportunity for the test subject to explain a positive laboratory report was **NOT** invoked.

CORRECTIVE ACTIONS

Minimal corrective actions were required. Records of re-tests at both Roche CompuChem and PDLA were added to the subject's chart to document the negative (in compliance) test result.

PREVENTIVE ACTIONS

Roche CompuChem has committed to an aggressive program of refresher training for its GC/MS staff to emphasize the potential for cross-contamination and sample switching, and how to avoid these situations. Roche CompuChem has also initiated an interim method to assure comparison of special processing test results to other tests of the same sample prior to the release of a report. It is developing an automated system to force this review of test results, and prevent the release of a report prior to this review when there is a discrepancy between special processing and other analyses.

CP&L will continue its practice of obtaining a second (LOD) analysis by another DHHS-laboratory for any positive report from a special processing sample <u>prior</u> to accepting the initial report as the basis for determining a FFDP violation.

9/30/93
Date

David E. Owen, Director, Occupational Health and Field Safety Support

COMPUCHEM
LABORATORIES, INC.
A subsidiary of Roche Biomedical Laboratories, Inc.

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

August 31, 1993

Ms. Vera W. "Betty" Wilder, RN, COHN
Carolina Power & Light Company
411 Fayetteville Street
P.O. Box 1551
Raleigh, NC 27602

Dear Ms. Wilder:

Enclosed please find the summary report concerning the urine specimen for [redacted]. The complete documentation package will be provided to you on Thursday afternoon.

I have attached an outline of the Extractions Training Program and prototype of the proposed Discrepancies/Certified Review Laboratory Management System screen.

If you need further information please call me at (800) 833-3984, extension 6810.

Sincerely,

Michael A. Peat, Ph.D.
Vice President of Toxicology

MAP/lmm

Enclosure

REF: SSN [redacted]

CCN 0088605589 (ID# 0234982974)
CCN 0084755255 (Confirm THC, COC)
CCN 0082638206 (Retest COC)

The specimen referenced above was collected on August 3, 1993 and shipped to the Roche CompuChem Laboratory. It was received on August 4, 1993, assigned a lab accession number (CCN 00[illegible]860589), and subjected to initial testing for amphetamines, cocaine, opiates, phencyclidine, and cannabinoids. The sample was also tested for the presence of creatinine. The test results of the drug analyses were all negative, and the creatinine was 8 mg/dL. These results were sent to Dr. Siebens (Medical Review Officer for CP&L).

On August 4, 1993, Ms. Trish Murray was notified by fax to process the specimen at the Limit of Quantitation for cocaine and cannabinoids. This request was initiated, and Bottle "A" was pulled for testing and assigned a mate number (CCN 0084755255). Due to a scheduling oversight, the sample was not batched for the cocaine confirmation until August 9, 1993. The Cocaine Batch (#59427) was extracted on August 10, 1993. The GC/MS result for cocaine metabolite was 782 ng/mL. The THC (cannabinoid) result was not complete at the time the cocaine metabolite was posted.

During the review of the cocaine data, it was noted that the immunoassay test was negative. A second immunoassay test was ordered, and this test was also negative (completed on August 11, 1993). The GC/MS cannabinoid testing was completed and posted as negative.

After receiving the positive cocaine report, Dr. Siebens requested that an aliquot of the "A" bottle be sent to PDLA laboratory for cocaine at the Limit of Detection. PDLA contacted Dr. Siebens to report their finding that the aliquot was negative for cocaine metabolite. Ms. Betty Wilder notified Ms. Trish Murray of the discrepancy in the two reports. A second GC/MS analysis was performed at Roche Compuchem, with a negative result for cocaine metabolite. Ms. Wilder was notified of this finding.

A complete investigation was initiated to determine the cause of the incorrect result and to develop appropriate corrective action to prevent recurrence.

The investigation included examining the areas of aliquoting, verification, extraction, GC/MS, and data review. This review was unable to identify the exact cause or location of the error, although it most probably occurred during the extraction procedure.

The corrective action steps include two areas:

1) Employees who perform extractions will receive additional training in the sources of possible sample contamination and ways to prevent contamination during the extraction procedures. The training will be completed by September 10, 1993.

2) The software package which is used for posting positive GC/MS results will be revised to include the following enhancements:

   a) Comparison of GC/MS test results with initial test results to identify inconsistencies.

   b) Individual (and separate) review and resolution of inconsistencies from a).

   c) Mandatory review by Laboratory Director (or designated alternate) of inconsistencies prior to release of results.

   The programming changes are already in progress. Completion of the changes will take several weeks. However, a change similar to that described in a) will be completed within a few days.

PROPOSED CERTIFIED REVIEW (continued)

MODE: E ACTION: FDT9999P

ROCHE COMPUCHEM, INC.
CERTIFIED REVIEW

23-AUG-1993
10:32

HOMETRAY 7822134 COMPUCHEM NUMBER

COMPUCHEM NUMBER	REGULATED	********** DISCREPENCIES ********** DESCRIPTION	NOTED	CURRENT LEVEL	PUSH TO NEXT LEVEL?	MANAGER APPROVAL
41263468	N	THC screening results are negative, but the confirmation results are positive.		C1 → C2		
41263443	N	Quantitations for AMP subdrugs do not match quantitation for class.		C1 → C2		N/A
41263450	Y	none	N/A	C2 → C3		N/A
41263476	N	none	N/A	C1 → C3	Y	N/A
41263484	N	none	N/A	C1 → C3	Y	N/A
41263492	Y	none	N/A	C1 → C2		N/A
41263500	N	none	N/A	C1 → C2	Y	N/A
41263518	Y	You are unauthorized to review this sample.	N/A	C2	N/A	N/A
41263526	N	none	N/A	C1 → C3	Y	N/A

EXTRACTIONS TRAINING PROGRAM

Following the recent incident, all extractors will be retrained in techniques involved in the transfer and treatment of urine specimens. These training sessions will be held at the beginning of each shift and will be coordinated by Dr. Paula Childs and Ms. Barbara O'Brien. The program will focus on the items listed below and emphasis will particularly be placed on the care and attention necessary to achieve a clean extraction.

1. **Proper use of pasteur pipette:** At several stages during extraction, urine and/or solvent are transferred using pasteur pipettes. If these pipettes were reused, it could lead to contamination of extracts. The proper use of these pipettes will be re-emphasized.

2. **Maintaining a clean extraction area:** It is possible that "splashes" from either urine or concentrated extract could contaminate the GCMS injection vials. The extractors will be trained to maintain a clean extraction area and to keep this area free of injection vials, etc.

3. **Proper use of the extraction box:** If the needles on the extraction box are not properly cleaned and/or if a gravity feed process has not been used, residues can be cross-contaminated. The extractors will be retrained in the SOP requirement to use gravity feed for cocaine extractions.

4. **Switching of specimens:** Obviously incorrect results would be obtained if specimens or extracts are interchanged at any time. The extractors are to be retrained in the requirement to handle only one specimen at a time.

COMPUCHEM LABORATORIES, INC.
a subsidiary of Roche Biomedical Laboratories, Inc.

Post-it™ brand fax transmittal memo 7671 | # of pages ▸ 1

To David Owen	From Paula Childs
Co. CP&L	Co. R-CCL
Dept.	Phone # 248-6703
Fax # 546-6911	Fax # 248-6462

MEMORANDUM

TO: MR. DAVID OWEN, CP&L

FROM: DR. PAULA CHILDS, ROCHE COMPUCHEM

DATE: SEPTEMBER 7, 1993

SUBJECT: FOLLOW-UP TO SAMPLE SSN [redacted]

The following information was requested at our meeting with you on September 2, 1993.

1. The individuals who have clearance to authorize reporting of results which have been identified through the "Certified Review" program include:

   Dr. Michael Peat, Vice President of Toxicology
   Dr. Paula Childs, Vice President of Toxicology Operations
   Mr. James McCarthy, Vice President of Operations
   Ms. Azita Wilson, Manager of Data Review and Certification

2. During the assessment of the results for the specimen in question, the following details in the extraction process were examined to determine the most likely cause of the error:

   No other "negative" samples were identified in the batch. This indicated that a sample "switch" in the process from aliquoting through GC/MS analysis probably did not occur.

   There were very concentrated (>10,000 ng/mL benzoylecgonine) samples in the GC/MS batch. This information supported the identification of the problem as one of possible contamination during the extraction process.

3. The "Certified Review" system which was described to you includes the matching of two separate lab accession numbers (CompuChem numbers). The computer system allows an original CCN to be "mated" with a new CCN, as was the case for the sample in question. This "mate" number is included in the computer review of consistency between the GC/MS result with the screening result.

   The re-test of a sample that originally screened "negative" and is tested by GC/MS at Limit of Detection (LOD) will require one of the authorized individuals listed in #1 (above) to review the data and release the result for reporting.