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RECIP.NAME RECIPIENT AFFILIATION
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SUBJECT: Forwards rept of unsatisfactory performance testing results as part of fitness-for-duty program.Blind proficiency test sample submitted to lab for analysis conflicted w/known content of test sample.

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Nuclear Services Department
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FEB 05 1992

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FITNESS FOR DUTY - LABORATORY PERFORMANCE TESTING RESULTS

Gentlemen:

10CFR 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) submitted a blind proficiency test sample to a certified laboratory for analysis. The laboratory analysis conflicted with the known content of the test sample.

Accordingly, CP&L's investigative report concerning this instance is enclosed. Enclosures identified in the investigative report are not enclosed, and reference to them has been lined through. As required by 10CFR26, Appendix A, Section 2.8(e)(4), a record of the investigative findings and the corrective action taken by the laboratory is also enclosed. Enclosures identified in the laboratory report are not enclosed, and reference to them has been lined through.

For further information about this issue, please contact Mr. Fred Underwood at (919) 546-6180.

Yours very truly,

S. D. Floyd

S. D. Floyd
Manager
Nuclear Licensing Section

DBB/jbw

Enclosures

cc: Mr. S. D. Ebneter
Mr. L. Garner
Mr. N. B. Le
Mr. R. Lo
Ms. B. L. Mozafari
Mr. R. L. Prevatte
Mr. J. E. Tedrow

A022 1/1

(1513GLU)

CP&L

Carolina Power & Light Company

Company Correspondence

MEMORANDUM

TO: Mr. Fred Underwood

FROM: David E. Owen

DATE: January 20, 1992

SUBJECT: Blind Proficiency Testing at CompuChem Laboratories

EVENTS

A blind proficiency test sample was prepared positive for codeine, positive for morphine, and negative for MAM by Elsohly Laboratories. This sample was submitted to CompuChem Laboratories for analysis under FFD rules. CompuChem reported this sample as positive for codeine, morphine, and MAM.

As part of the investigation into this false positive report for MAM, an aliquot of the original sample was sent to Princeton Diagnostic Laboratories (PDLA). PDLA reported the sample positive for codeine and morphine, and negative for MAM. PDLA performed the MAM analysis to their limit of detection, 1.9 ng/ml. The results of the three laboratory's analyses are shown below:

	ElSohly	CompuChem	PDLA
Codeine	876 ng/ml	882 ng/ml	936 ng/ml
Morphine	528 ng/ml	547 ng/ml	557 ng/ml
6-MAM	negative	10 ng/ml*	negative

* 10 ng/ml is the cut-off value for MAM analyses at CompuChem.

CompuChem had intended to retest the original sample several days after the aliquot was sent to PDLA but was unable to locate the sample in its long term storage area.

The cause, impact, and preventive actions are described separately below for these two events: 1) false positive report for MAM, and 2) loss of a stored sample. No corrective actions were appropriate or feasible in either case.

The appendices cited below refer to specific section's of the laboratory's report of their investigation into these two events and their actions taken to prevent a re-occurrence. This report is attached.

CAUSE OF FALSE POSITIVE REPORT FOR MAM

The laboratory's investigation revealed that the most probable cause of the false positive MAM report was inadvertent spiking of the blind proficiency sample with MAM in addition to spiking the batch calibrator sample. The circumstantial evidence for this theory includes:

1. The last two digits of the laboratory's accession number for the batch calibrator sample and the blind proficiency test sample are the same, 46;

2. Similar levels of MAM were detected in the calibrator sample and the blind proficiency test sample, 10.0 and 10.4 ng/ml, respectively; and

3. Other blind proficiency test samples from the supplier's same lot were reported as negative for MAM.

The false positive report for MAM appears to have been caused by the preparation of the MAM batch calibrator sample at the time of extraction of all samples in the batch being prepared for GC/MS analysis. ~~See Appendix B.~~ This preparation of MAM batch calibrator samples by the extractor is unique to MAM samples. The batch calibrator sample and other quality control samples for all other drug groups are prepared by internal quality control, not by the extractor during batch preparation. These calibrator and other quality control samples are added to the batch by receiving/accessing personnel, not the extractor.

IMPACT OF FALSE POSITIVE REPORT FOR MAM

The laboratory's investigation revealed that the false positive report was limited to the single proficiency testing sample in question. The laboratory reviewed the data records and performed re-analyses for each of the 16 samples positive for MAM during the period of July 1 thru December 31, 1991. Each sample was confirmed as positive for MAM. There was no correlation between the concentration of MAM in these samples and the concentration of the batch calibrator samples used for these analyses. ~~See Appendix C.~~

PREVENTIVE ACTION FOR FALSE POSITIVE REPORT FOR MAM

The laboratory changed its Standard Operating Procedures (SOP) to prevent a reoccurrence of this type of error and to strengthen their review of MAM data. The preparation of calibrator quality control samples will be performed daily by the Quality Control group and supplied to the Receiving/Accessing group which makes up a batch of sample aliquots for extraction and GC/MS analysis. This change not only deletes preparation of the calibrator from the Extractor's duties, it also introduces the calibrator sample at a different point in the process. ~~See Appendix D.~~

The SOP also requires specific review by the Technical Director (or his designee) of data for any sample that is positive MAM and the concentration of morphine is less than 5,000 ng/ml. This change will trigger the detailed data review when the results could be pharmacologically implausible. ~~See Appendix D.~~

CAUSE OF LOSS OF A STORED SAMPLE

The specific cause of the lost sample could not be determined. While the chain of custody documentation was complete (see Appendix A), the laboratory's investigation could not reveal a specific event that could have resulted in the loss.

IMPACT OF LOSS OF A STORED SAMPLE

Since the last known presence of the sample was during the preparation of an aliquot for shipment to another laboratory, the investigation focused on this aspect of sample handling. The availability of all samples that were aliquoted for shipment to another laboratory during the month of December 1991, was confirmed in January, 1992. The impact of sample loss is limited to the single sample in question.

PREVENTIVE ACTIONS FOR LOSS OF A STORED SAMPLE

The retrieval and replacement of a sample in long term storage is the only step in sample handling that did not require independent verification. The laboratory has changed its SOP to require independent verification during the retrieval and replacement of samples in long term storage. ~~See Appendix F~~

David E. Owen
Director Industrial Health and
Field Safety Support

DEO

c: Mr. Robert L. Barham - no attachment
Dr. David K. Broadwell - no attachment
Mrs. Betty W. Wilder, RN, COHN - no attachment

Attachment

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

MEMO TO FILE

RE: SPECIMEN 240-06-4171, CCN 40519746

FROM; Michael A. Peat, Ph.D.

SEQUENCE OF EVENTS

1. The above-referenced specimen was received on November 20, 1991 and tested positive by EMIT for opiates on November 20, 1991.

2. The results of GCMS analysis on November 21 and 22, 1991 were as follows:

Morphine	547 ng/ml
Codeine	882 ng/ml
MAM	10 ng/ml

3. On December 6, 1991 an aliquot was transferred under chain of custody to PDLA at the request of Carolina Power and Light (hereinafter referred to as "CP&L").

4. On December 5, 1991 Dr. S. Brinkley discussed with Ms. Betty Wilder the results of the MAM assay.

5. Subsequent to December 5, 1991 I reviewed Dr. Brinkley's records and noted the potential discrepancy concerning the MAM result. I then requested that the specimen be retrieved and retested for morphine, codeine and MAM.

6. The original specimen bottle could not be located even though the chain of custody indicates that it was returned to Long Term Storage on December 6, 1991. An extensive search of the freezer for specimens received from October to December 1991 failed to locate the specimen.

7. A partial litigation package was prepared covering the MAM analysis and chain of custody documents. No apparent errors were observed in reviewing this information. A copy of this document is included in Appendix A.

8. I met with Mr. David Owen and Ms. Betty Wilder, RN of CP&L on January 6, 1992. Discussions with them resulted in the following:

a) PDLA's results were codeine: 936 ng/ml, morphine: 557 ng/ml and MAM: none detected.

b) The specimen (SSN 240-06-4171) was packaged by ElSohly Laboratories and shipped to CP&L who then forwarded it to CompuChem. At least two other opiate specimens were shipped at the same time. These were received and given CCNs 40520090 and 40519829, neither was positive for MAM although both were positive for morphine and codeine.

c) Dr. ElSohly indicated to CP&L that the specimen should not have contained MAM. This was confirmed by myself in a telephone conversation with Dr. ElSohly on 1/07/92.

d) Ms. Wilder contacted PDLA and found that their limit of detection for MAM, was 1.9 and that none of the aliquot remained for retesting.

9. A further and more detailed review of the MAM batch indicated that the LOW (calibrator) had the CCN 40716946, the last two digits were the same as the specimen in question (40519746). Secondly, the specimen contained 10.4 ng/ml of MAM and the LOW is spiked at 10 ng/ml. In the absence of other information it is likely that specimen 40519746 was also spiked with MAM because the extractor failed to read the entire CCN and compare that with the batch traveller. Unlike other assays, the Quality Control section does not supply the calibrator for the MAM assay. It was the responsibility of the extractor to prepare the LOW (calibrator), LOQ and MED by spiking MAM into the certified negative urine at the time of extraction. ~~A copy of the SOP in effect during November is included in Appendix B.~~

10. Reanalysis of other specimens in the original GCMS batch for MAM confirmed them as negative. These included 40520090 and 40519829.

11. Since July 1, 1991 there have been 16 other specimens in which MAM has been confirmed. All of these were retested and the presence of MAM confirmed.

12. A Quality Assurance audit of the original data on these 16 specimens showed that a similar scenario to that which occurred with 40519746 did not occur with these 16 specimens because:

a: The CCNs were different ~~(see Appendix C)~~ and,
b. The concentrations in all cases, but one, were above 10 ng/ml. One specimen (39265129) contained 9 ng/ml and was originally reported negative. On retesting the presence of MAM was confirmed in this specimen.

COMPUCHEM LABORATORIES, INC.

13. The technician responsible for the inadvertent spiking of specimen 40519746 has been disciplined and counselled.

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CORRECTIVE ACTION

Three areas of concern were noted:

a) an inadvertent spiking of a donor's specimen with drug during GCMS confirmation.

b) loss of a positive specimen during removal from Long Term Storage for aliquoting.

c) an inappropriate data review process, a specimen containing 882 ng/ml of codeine, 537 ng/ml of morphine and 10 ng/ml of MAM would be pharmacologically impractical.

Corrective actions addressing these concerns are listed in the same order.

a) apart from the analysis of MAM and the qualitative separation of d and l-methamphetamine, calibrators for all other GCMS assays are prepared by the Quality Control Section and supplied to the Extractions Laboratory. This was not originally done for the MAM assay because of concerns about the stability of MAM. However to prevent a reoccurrence of inadvertent spiking Quality Control will now supply MAM calibrators to the laboratory. They will also prepare LOQ and MED pools and supply these to the laboratory. ~~The revised SOP is included in Appendix D.~~

b) to prevent specimens from being inadvertently discarded during aliquoting for retesting, two verification steps will be incorporated into the procedure. When the evidence clerk removes specimens from Long Term Storage he/she will list them on the form included in Appendix E. After removing them he/she will transfer them to a second evidence clerk who will verify that all specimens have been retrieved. After completing the aliquoting process the evidence clerk will batch the specimens for return to Long Term Storage and this batching will be verified by a second evidence clerk.

c. The Data Review Section has been instructed that all positive MAM specimens containing less than 5000 ng/ml of morphine have to be approved for reporting by the Technical Director or his/her designee. From all the pharmacological data available to date it is unlikely that a specimen containing less than 5000 ng/ml of morphine will contain MAM and therefore such situations as occurred with 240-06-4171 would result in a retest request by the Technical Director.

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SUMMARY

The incorrect reporting of MAM in specimen 240-06-4171 was an isolated incident. All other MAM specimens were confirmed on reanalysis. This error was caused by the technician inadvertently adding the calibrator to the specimen. To prevent a reoccurrence Quality Control will now supply calibrators to the laboratory.

The failure to locate the specimen remains unexplained. However to ensure adequate tracking of specimens in and out of Long Term Storage two verification steps have been added to the protocol.

An additional data review step has now been incorporated preventing reporting of positive MAM specimens containing less than 5000 ng/ml of morphine without the approval of the Technical Director or his/her designee.

In closing I am of the opinion that this was an isolated, although regrettable incident. Prompt and corrective action has been taken to prevent its reoccurrence.

cc: Ms. Boone
Mr. McCarthy
Mr. Verkerk

Appendix A

NOTARIZED LABORATORY REPORT

The urine specimen identified as compuchem number (CCN): 40519746, and social security number (SSN): 240-06-4171, was tested at this laboratory and the results were as follows:

Date	Analytical method	Results
Nov 20, 1991	Enzyme immunoassay (EMIT)	**POSITIVE:** EMIT indicated the presence of opiates in the urine.
Nov 22, 1991	Gas chromatography/ mass spectrometry (GC/MS)	**POSITIVE:** GC/MS confirmed the presence of opiates in the urine at a level of 882 ng/ml of codeine and 547 ng/ml of morphine.
Nov 21, 1991	Gas chromatography/ mass spectrometry (GC/MS)	**POSITIVE:** GC/MS confirmed the presence of 6-*mono* acetylmorphine in the urine at a level of 10 ng/ml.

I certify that this is a true and accurate report for the urine specimen identified as CCN: 40519746 and SSN: 240-06-4171.

JAN 0 6 1992
Date

Laboratory Certifying Official
Shirley A. Brinkley, PhD
Senior Technical Analyst

Subscribed and sworn to before me this 6th day of January, 1992.

Vicki Gaillard
Notary Public

My commission expires: 10/22/96

Form: opimam