



Consumers
Power

**POWERING
MICHIGAN'S PROGRESS**

Big Rock Point Nuclear Plant, 10269 US-31 North, Charlevoix, MI 49720

Patrick M Donnelly
Plant Manager

January 25, 1995

Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

**DOCKET 50-155 - LICENSE DPR-6 - BIG ROCK POINT PLANT - FITNESS-FOR-DUTY
PROGRAM: UNSATISFACTORY PERFORMANCE TESTING INCIDENT.**

On January 5, 1995, the Medical Review Officer (MRO) questioned a report from South Bend Medical Foundation Laboratory. The report concerned a "negative" blind performance test specimen spiked with amphetamine/methamphetamine, and a positive employee specimen for the same substances. A retest was ordered by the MRO, and the blind performance specimen was reported positive; and the employee specimen was reported negative. An immediate investigation determined that the error was administrative (clerical); and in accordance with 10 CFR 26 Appendix A, 2.8(e)(5), the NRC (Mr. G. Pirtle) was promptly notified on January 5, 1995 at 1330 EST. On January 6, Mr. Pirtle contacted the Big Rock Point Plant Safety and Licensing Director and remarked that Loren Bush, the Fitness-For-Duty Program director (Office of Nuclear Reactor Regulation - Safeguards Branch) had been notified and concurred with the reporting basis.

Also, in accordance with 10 CFR 26 Appendix A, 2.8(e)(4), an investigation of the unsatisfactory performance testing result was conducted; and the record of the investigative findings and the corrective action taken by the laboratory, is attached.

Patrick M Donnelly
Plant Manager

CC: Administrator, Region III, USNRC
NRC Resident Inspector - Big Rock Point

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ATTACHMENT

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ATTACHMENT

CONSUMERS POWER COMPANY
BIG ROCK POINT PLANT
DOCKET 50-155

FITNESS-FOR-DUTY PROGRAM
UNSATISFACTORY PERFORMANCE TESTING INCIDENT

JANUARY 25, 1995



**SOUTH BEND
MEDICAL
FOUNDATION**

530 North Lafayette Boulevard • South Bend, IN 46601-1098
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DEPARTMENT OF
FORENSIC TOXICOLOGY
PRENTISS JONES, JR., M.B., T.C. - HRCC
Technical Director
MITCHELL F. LEBARD
Administrative Manager
PAUL F. MOORMAN
Technical Manager

January 13, 1995

Ms Judith A. Smith
Fitness For Duty Administrator
Consumers Power
212 West Michigan Avenue
Jackson, MI 49201

RE:
False Positive Report - Control Number: B843336
False Negative Report - Control Number: B843381

Dear Ms Smith:

The information contained in this correspondence represents a detailed account of the events surrounding the inadvertent release of erroneous results for two urine specimens submitted by Consumers Power Company to the South Bend Medical Foundation for Forensic Drug of Abuse Testing.

To facilitate your review and understanding of the processes related to this incident, all transactions regarding this matter have been presented in chronological order.

Specimen Receipt

December 28, 1994

The South Bend Medical Foundation Department of Forensic Toxicology received two urine specimens for drug of abuse testing identified as Control Number B843336 and Control Number B843381. The initial inspection of the transport package and specimen tamper-evident seals was performed by Technical Clerk A (hereafter referred to as Tech A). During this inspection process, a positive correlation was made between the Control Numbers appearing on each External Chain of Custody (ECC) and the Control Numbers identifying each specimen container. Forensic criteria necessary to ensure the integrity of the specimen was met for each specimen. The specimens were

Ms: Judith Smith
Page Two
January 13, 1995

placed into temporary storage in the Secure Room Accessioning Area by Tech A pending the subsequent assignment of Forensic Toxicology Accession Numbers (FT Number). This transaction was annotated on the ECOC and represents the last entry for the chain of custody section of the ECOC. The ECOCs are filed in the Secure Room until results are ready for verification. All subsequent transactions involving the original specimen container are recorded on the Specimen Internal Chain of Custody.

Specimen Accessioning

December 28, 1994 14:00:

A second Technical Clerk, Technical Clerk B (hereafter referred to as Tech B) continued the accessioning process for the forementioned specimens by assuming custody of the specimens and initiating the second phase of the accessioning process. The second phase requires entry of Donor demographic information and FT Number assignment via utilization of the Laboratory Computer System. The Technical Clerk performing this function must ensure that the ECOC and the specimen containers are properly paired prior to ordering the requested Drug Abuse Panel. Once the appropriate Drug Panel has been ordered, the computer assigns an FT Number to the specimen. This computer assigned FT Number is affixed to the specimen container lid, specimen container side, ECOC (Copies One and Two), Specimen Internal Chain of Custody (SICOC), EIA Aliquot Chain of Custody (EACOC), and the EIA aliquot tube. Once a specimen has been accessioned, internal tracking is performed via the FT Number.

***** Source of Error *****

Tech B incorrectly paired the ECOC for Control Number B843381 with the specimen container identified as Control Number B843336 and likewise mismatched the ECOC for Control Number B843336 with the specimen container identified as Control Number B843381. Using the ECOC for specimen B843381, a NRC Drug Panel was ordered resulting in the designation of the FT Number, FT94-100405. Labels identified as FT94-100405 were affixed to ECOC B843381 (Copies 1 and 2), specimen container B843336, the SICOC, EACOC, and an aliquot tube. The ECOC for specimen B843336 was used to order the Drug Panel, resulting in the designation of FT Number FT94-100407. Labels identified as FT94-100407 were affixed to ECOC B843336 (Copies 1 and 2), specimen container B843381, the SICOC, EACOC, and an aliquot tube.

Upon completion of the steps outlined in the second phase, Tech B returned the labeled specimens to temporary storage pending aliquot pour-over. All transactions performed by Tech B was documented on the SICOC.

Ms. Judith Smith
Page Three
January 13, 1995

Aliquot Pour-Over

December 28, 1994 16:27

To perform the aliquot pour-over, Technical Clerk C (hereafter referred to as Tech C) assumed custody of the specimens, the SICOC and EACOC. To create aliquots, the FT Numbers on the specimens were compared to the FT Numbers of the EIA aliquot tubes. Having verified a match between the numbers on the specimens and tubes, Tech C broke the tamper-evident seal (only one specimen was handled at a time) and poured a small urine volume from the original specimen container into its corresponding pre-labeled aliquot tube.

Once the aliquots were poured, the original specimen containers were placed into the Secure Refrigerator, awaiting testing results. Shortly after, Tech C released custody of the aliquots to the EIA screening Technologist.

*** NOTE ***

The error committed by Tech B was not discovered by Tech C at this point because, the specimen, the aliquots and internal chain of custody documents were tracked solely via the FT Number.

EIA Analysis

December 28, 1994 16:57

The aliquots in question (i.e., FT94-100405 and FT94-100407) were analyzed on the Technicon Chem One Plus analyzer as part of analytical Run #2 12-28-94. The EIA analyzer was calibrated prior to analysis of the Donor aliquots and demonstrated acceptable values for the quality control samples. Upon completion of the analysis, all aliquots from Run #2 were placed in a locked secure drawer pending review of the generated analytical data. All transactions were duly noted on the EACOC.

Review/Verification

December 28, 1994 21:10

Review of generated data for Aliquot FT94-100405 demonstrated Technicon values ranging from 62.9% to 85.3% for the tested analytes, with positive defined as greater than or equal to 100%. This specimen was identified as a "negative drug test". Review of the data generated for Aliquot FT94-100407 demonstrated a Technicon value of 134.3% for Amphetamines, while the remaining analytes values ranged from 63.2%

Ms. Judith Smith
Page Four
January 13, 1995

to 83.2%. This specimen was considered presumptive positive for Amphetamines and was scheduled for confirmatory testing for Amphetamines via Gas Chromatography/Mass Spectrometry (GC/MS). Following the review of the chain of custody documents and other pertinent information, specimens from Run #2 which demonstrated results consistent with a negative specimen and were not part of a NRC batch were released. Aliquots from Run #2 previously stored in the secure drawer were discarded thereby signifying the completion of EIA testing.

***** NOTE *****

The error was still undetectable due to the fact that the FT Numbers and Control Numbers on the ECOC matched the computer designation. A post-accessioning check of the specimen container against the computer assignment was not required prior to this incident.

GC/MS Confirmation

December 29, 1994 06:40

Specimen identified as FT94 100407 was removed from the secure refrigerator. An aliquot from this specimen was poured into an aliquot tube. Custody of this aliquot was released to the Technologist for extraction of Amphetamines and analysis by GC/MS (Run 12/29/94). The specimen was returned to the secure refrigerator with all transactions being appropriately documented on the SICOC.

Verification of GC/MS Results

December 30, 1994 06:20

Prior to performing GC/MS analysis, the GC/MS instrument was calibrated and deemed acceptable for use. Review of the analytical data demonstrated acceptable performance for the quality control material included in the run. Results generated for FT94-100407 demonstrated the presence of Amphetamine at a quantitative value of 1864 ng/mL and a quantitative Methamphetamine value of 1915 ng/mL.

***** NOTE *****

Error undetectable due to previously cited reasons.

Ms. Judith Smith
Page Five
January 13, 1995

Release of Reports

December 30, 1994 07:41

The final reports for B843381 (FT94-100405) and B843336 (FT94-100407) were documented as "Negative" and "Positive for Amphetamine and Methamphetamine", respectively and released.

Initial Notification From Dr. Keith's Office

January 2, 1995

Telephone call was made to the South Bend Medical Foundation Forensic Toxicology Department regarding a potential reporting error on a forensic drug of abuse test result. The toxicology employee receiving the call informed the caller that due to observance of the New Years Day holiday, the individuals that could assist them were scheduled off for the day but would be in on Tuesday January 3, 1995. The caller agreed to call back as advised.

Second Notification From Dr Keith's Office

January 3, 1995

Specific information regarding the Control Numbers and perceived problem was taken. The caller was informed that SBMF would return their call after an investigation was conducted.

Review of Pertinent Data and Related Documents

January 3, 1995

Review of all pertinent data did not reveal any discrepancies with the analytical integrity of the test results, however, retrieval of the original specimen containers indicated that a potential specimen mismatch had occurred (FT Numbers on the specimens containers did not match the FT Numbers on the ECOC).

Notification to Dr. Keith's Office Regarding Preliminary Findings

January 3, 1995

Dr Keith was contacted regarding the findings and informed that a repeat analysis would be necessary to substantiate the alleged error.

Ms. Judith Smith
Page Six
January 13, 1995

Repeat Analysis Performed

January 3, 1995

Results generated for the repeat EIA test proved the occurrence of a specimen mismatch. Control Number B843336 demonstrated EIA values consistent with a Negative specimen. Control Number B843381 was designated as presumptive positive for Amphetamines and scheduled for confirmatory analysis via GC/MS.

Notification to Dr. Keith's Office Regarding Results for Control Number B843336

January 3, 1995

Dr. Keith was informed that a corrected report for the specimen identified as Control Number B843336 would be sent to him via facsimile transmission before the end of the business day.

Repeat GC/MS Confirmation Performed

January 4, 1995

An aliquot was taken from the specimen container identified with the Control Number B843381. The aliquot was extracted for Amphetamines and submitted for GC/MS analysis.

Review of GC/MS Data/Release of Results for Control Number B843381

January 5, 1995

The specimen identified as Control Number B843381 demonstrated analysis positive for Amphetamine and Methamphetamine, which quantitated via GC/MS at a value of 1844 ng/mL and 1892 ng/mL respectively. Dr. Keith was notified that a corrected report for said specimen would be issued via facsimile transmission before the end of the business day.

Correspondence received from Judy Smith

January 5, 1995

Notification given to SBMF regarding an onsite visit by NRC personnel to be conducted on January 10, 1994. Additionally, a request was made for a written explanation of the circumstances surrounding the origin of the erroneous results.

Ms. Judith Smith
Page Seven
January 13, 1995

Onsite Visit

January 10, 1995

Judy Smith and Janice Hoffman visited the Department of Forensic Toxicology and reviewed the specimen accessioning process.

CORRECTIVE ACTIONS

It is our expectation that each employee strictly adhere to the letter and intent of our established protocols, however, review of these reporting errors revealed an area in our accessioning process where divergence in the protocol could occur without detection. The fact that the error could be ascribed to a specific cause has prompted us to develop and enact measures which should ensure that only scientifically valid and forensically sound results are reported.

Resolution

January 3 1995 through January 10, 1995

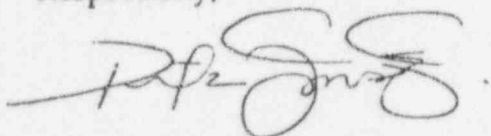
1. An internal audit was conducted of all specimens residing in the Secure Refrigerator (Temporary Storage). A total of 805 specimens were examined, there were no incidents of specimen mismatches.
2. Disciplinary actions were taken with the employee responsible for the infraction.
3. A mandatory secondary check which is performed after the specimens are accessioned was instituted. This check ensures that discrepancies between the information on the specimen container, External Chain of Custody, and Computer is discovered prior to release of negative results.

Ms. Judith Smith
Page Eight
January 13, 1995

4. In addition to the second check for Negative specimens, all positive specimens undergo a triple-check verification of all identifying numbers.

If you have any questions on the information contained herewithin please contact my office.

Respectfully,

A handwritten signature in cursive script, appearing to read "Prentiss Jones, Jr.", with a large, stylized initial "P" and "J".

Prentiss Jones, Jr., M.S., TCNRCC
Technical Director
Forensic Toxicology

PJ/mjk