



**Consumers  
Power**

**POWERING  
MICHIGAN'S PROGRESS**

General Offices: 1945 West Parnall Road, Jackson, MI 49201 • (517) 788-0550

May 29, 1990

Nuclear Regulatory Commission  
Document Control Desk  
Washington, DC 20555

DOCKET 50-255 - LICENSE DPR-20 - PALISADES PLANT -  
UNSATISFACTORY PERFORMANCE TESTING OF FFD PROGRAM BLIND SAMPLES

Please find attached to this cover letter an investigation report concerning unsatisfactory performance testing of Fitness For Duty Program blind performance test samples. Included in the report is a summary of events which specifies the contributing factors to the erroneous test results and Consumers Power Company's continuing investigative actions, two reports from our Fitness For Duty NIDA approved Laboratory, plus letters to and from our Medical Review Officer concerning the subject.

This event is reportable per 10 CFR 26 subpart B 2.8(e)(4).

Brian D Johnson  
Staff Licensing Engineer

CC Administrator, Region III, USNRC  
NRC Resident Inspector - Palisades

Attachment

*Add: NRR/DRIS/RSG/B  
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OC0590-0028-NL04

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F. PDC

A CMS ENERGY COMPANY

ATTACHMENT

Consumers Power Company  
Palisades Plant  
Docket 50-255

UNSATISFACTORY PERFORMANCE TESTING OF FFD PROGRAM  
BLIND SAMPLES

May 29, 1990

8 Pages

OC0590-0028-NL04

#### EVENT SUMMARY

On March 18, 1990, Consumers Power Company's Fitness For Duty NIDA approved Laboratory, submitted an erroneous report on one of the blind performance test samples. The blind specimen #31466, contained PCP, however, Laboratory results submitted to our MRO identified the specimen as a negative test result.

#### REASONS FOR THE ERRONEOUS TEST RESULTS

Based upon the content of attached reports from our Fitness For Duty NIDA approved Laboratory dated March 30, 1990 and April 27, 1990, we believe the following factors could have contributed to erroneous test results:

1. Low level of PCP in the blind sample may have deteriorated prior to reaching the NIDA laboratory.
2. The Laboratory providing the blind specimen, may not have spiked the sample with 56 ng/ml as reported.
3. Our NIDA Laboratory may have been solely responsible and corrective actions as outlined in Attachment 4 may be sufficient.

#### CONTINUING INVESTIGATIVE ACTION

1. Quality Assurance audit of the NIDA Laboratory will include a toxicologist on the Audit Team and this entire issue will be part of the audit scope.
2. Quality Assurance will contact other utilities who use the same Laboratory as their blind specimen provider. If similar problems are occurring at these utilities, QA will conduct an audit of that Laboratory.



## South Bend Medical Foundation, Inc.

530 North Lafayette Boulevard South Bend, Indiana 46601-1098  
219-234-4176 • Elkhart 294-1519 • Indiana 800-544-0925

JJD	JPB
GEL	WBM
DLR	MHM
JJB	JAS
	RLU

APR 2 1990

Corporate Safety and Health Dept.

Sr Secy	Sys Asst
Secy-CS&H	File
Secy Med	TOSS
Stat	Legal

March 30, 1990

Ms. Judy Smith  
Consumers Power  
212 West Michigan Avenue  
Jackson, MI 49201

Dear Ms. Smith:

RE: SPECIMEN NO. 31466

The South Bend Medical Foundation received a urine sample on 3-13-90 from Consumers Power Company, identified as Control Number 31466, for forensic drug testing in accordance with Nuclear Regulatory Commission guidelines.

This sample was assigned the internal control number AFT-12488 and submitted to standard forensic urine drug testing protocol.

Aliquots of this specimen exhibited a delta-absorbance greater than the calibrator cut-off of 25 ng/ml PCP, on both initial and subsequent secondary testing utilizing EMIT methodology.

Gas Chromatography/Mass Spectrometry confirmation following positive PCP EMIT screening, demonstrated the presence of the chemical PCP (phenylcyclohexylpiperidine) at a quantitative level of 22.25 ng/ml. This drug confirmed as being present; however, the quantitative level was below the administrative cut-off level of 25 ng/ml for declaration of a positive PCP urine test. A result of negative for all tested drugs was reported on 3-18-90 for this sample.

Information received through Consumers Power Company indicates this specimen (Control No. 31466) was a blind sample submitted as part of the internal blind quality control program as dictated by the Nuclear Regulatory Commission, with a target result to indicate PCP positive.

Review to rule out possible laboratory analytical problems has been subsequently performed in response to the aforementioned information. Review of open quality control PCP samples, blind quality control PCP samples, QC samples within the GC/MS run containing the test sample, and recent National Institute on Drug Abuse Proficiency Testing PCP results has been performed. Testing results for these samples have been satisfactory, with established acceptable target values being quantitated.

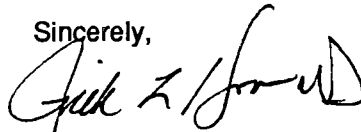
At the present time, no corrective action is warranted following analytical review of PCP drug testing. This sample tested negative for PCP utilizing NIDA-NRC cut-off guidelines; however, did exhibit the presence of PCP at a level just below the established cut-off. Explanations for how this might have occurred include:

- 1) Target value spiked just above the cut-off by QC sample vending laboratory, which may routinely test negative by a second laboratory, with both laboratories performing proper analysis (NIDA recognizes acceptable variances between laboratories, usually in the range of up to +/- 20%).

- 2) Specimen degradation due to aging, non-ideal storage conditions, heat, cold, etc.
- 3) Actual spiked level of sample below target value reported as being associated with testing sample.

To further investigate the above results, it would be helpful for the laboratory (South Bend Medical Foundation) to be provided with the actual quantitative target levels for all PCP positive samples which have been reported for this year, as well as the reported target value for the sample submitted as Control No. 31466. This would allow further investigation of any potential analytical problems or quantitative bias within the testing parameters.

Sincerely,



Rick L. Hoover, M.D.  
Scientific Director  
Department of Forensic Toxicology

RLH/md



**Consumers  
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General Offices: 212 West Michigan Avenue, Jackson, MI 49201 • (517) 788-0550

April 3, 1990

Thomas F Allen  
Healthcare Directions  
300 Roosevelt  
Holland, MI 49424

RE: BLIND SPECIMEN ANALYSIS ON CHAIN OF CUSTODY #31466

The attached letter describes South Bend's results from an initial investigation made into the inaccurate reporting of Blind Specimen #31466. Please note South Bend's request for the actual quantitative target levels for all PCP positive samples as well as the level for Specimen #31466.

Please include me on all correspondence involving this situation as I am required to submit all data to the NRC within thirty days.

Judith A Smith  
Fitness For Duty Administrator

JAS: 122-90

# HEALTHCARE DIRECTIONS

April 16, 1990

Judith Smith  
Consumers Power Company  
212 West Michigan Avenue  
Jackson, MI 49201

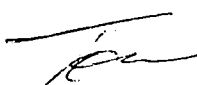
Dear Judy:

I talked with Dr. Hover of South Bend Medical Foundation on April 4, 1990. The subject was the false negative report on a blind specimen. I gave him the following information:

1. Eight blind specimens containing PCP were submitted (on three different dates) from the same batch.
2. According to El Sohley Lab (supplier of the blinds) each contained 56 ng/ml.
3. Seven of the eight were reported positive to the M.R.O.
4. One was reported negative.

As of this date I have heard nothing more from Dr. Hover.

Sincerely,



Tom Allen  
Vice President

TA:bf

— JJD —	— JPB —
— GEL —	— WBM —
— DLR —	— MMH —
— JJB —	— JAS —
	— RLU —

APR 20 1990

Corporate Safety and Health Dept.

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— Secy-CS&H —	— File —
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R. L. HOOVER, M.D.  
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Diplomates, American Board of Pathology



## South Bend Medical Foundation, Inc.

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— JJD —      — JPB —  
— GEL —      — WBM —  
— DLR —      — AMM —  
— JJB —      — JAS —  
                 — RLU —

April 27, 1990

MAY 1 1990

Corporate Safety and Health Dept.

— Sr Secy —      — Sys Asst —  
— Secy-CS&H —      — File —  
— Secy Med —      — TOSS —  
— Stat —      — Legal —

Ms. Judy Smith  
Consumers Power  
212 W. Michigan Avenue  
Jackson, MI 49201

RE: FINAL REVIEW / SPECIMEN NO. 31466

Dear Ms. Smith:

In reply to our letter of March 30, 1990, the South Bend Medical Foundation Department of Forensic Toxicology was informed of the target value for the blind quality control PCP (phenylcyclohexyl piperidine) positive sample, identified as Control Number 31466. Additionally, to further evaluate the problem of a reported false-negative in respect to Control No. 31466, seven (7) additional PCP positive blind quality control samples which had been forwarded to SBMF were identified.

Results for EMIT-GC/MS testing are as follows:

<u>Control No.</u>	<u>GC/MS Quantitation</u>	<u>Reported Results</u>
* 31466	22.25 ng/ml	Negative
31465	44.3 ng/ml	PCP Positive
23448	44.9 ng/ml	PCP Positive
23441	45.1 ng/ml	PCP Positive
32030	42.2 ng/ml	PCP Positive
32040	44.6 ng/ml	PCP Positive
32105	45.2 ng/ml	PCP Positive
45662	45.8 ng/ml	PCP Positive

\* - Reported False Negative

The vending laboratory providing these specimens indicated their laboratory quantitation of 56 ng/ml for all of the above specimens, which all resulted from the same preparatory batch. Excluding the sample identified as Control No. 31466, the additional seven (7) samples exhibited a range of 42.2 ng/ml to 45.8 ng/ml; a mean of 44.6 ng/ml; a Standard Deviation of 1.15 ng/ml; and a Coefficient of Variation of 2.58%.



Ms. Judy Smith  
April 27, 1990  
Page Two

Following evaluation of provided specimen results and quantitations, further examination of generated GC/MS data for Control No. 31466 was performed. Examination of extracted ion data for ion mass 205 amu for PCP internal standard demonstrated an abundance ranging from 2,100,808 to 3,133,410 on standards and controls. The abundance for the internal standard ion mass of 205 amu on Control No. 31466 was 4,469,173, more than twice the value for the calibrating standard. This data, in conjunction with the reported quantitation of 22.25 being nearly exactly 50% of the mean for the other seven (7) PCP samples, indicates a probable error in the delivery of the internal standard to Control No. 31466 during sample GC/MS preparation. Review would suggest the sample was delivered two (2) separate deuterated internal standard aliquots. This, in effect, would double the area of the internal standard, and reduce the quantitation of the patient (donor) sample by a factor of 50%.

Due to variation in the extraction procedure, however, this perceived error cannot be determined with any degree of absolute certainty. GC/MS runs will not infrequently exhibit wide fluctuations in internal standard ion abundances even greater than that seen with this PCP problem and still remain within proper analytic parameters. One alternate explanation to this problem although in our opinion one which is less likely, would be specimen degradation of Control No. 31466 due to non-ideal storage conditions. Alternatively, specimen contamination or improper individual specimen preparation might have occurred.

In response to the reporting of a probable false negative result for Control No. 31466 due to an error in internal standard delivery to the specimen during preparation for GC/MS, the following procedure steps have been performed or adopted:

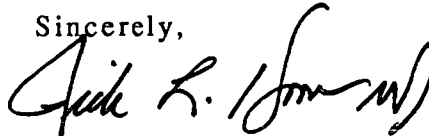
1. Corrective counseling with the GC/MS technician who performed the probable error.
2. Notification of all GC/MS technicians of error, to forewarn of its potential to occur.
3. Adoption of laboratory standard operating procedure to require no interruptions by additional duties, telephone, etc., for GC/MS technicians during GC/MS sample preparation steps requiring addition of reagents or standards.
4. Adoption of additional Forensic Review process to include examination of absolute and relative internal standard abundances in reference to the calibrating standard, to evaluate extraction variabilities and identify, in the future, any possible similar error which could result in incorrect sample quantitation.

Ms. Judy Smith  
April 27, 1990  
Page Three

5. Evaluation of possible visual detection system, i.e., colored indicator dye such as safarin at high dilutions added to internal standard working solution, to demonstrate when internal standard has been added to sample by change from a colorless to a minimally visually colored appearance.

We appreciate Consumers Power Company's information and cooperation with the laboratory in evaluating the discordant results for specimen No. 31466. If further information or clarification is required, please contact me.

Sincerely,



Rick L. Hoover, M.D.  
Scientific Director  
Department of Forensic Toxicology

RLH/lsh