

Nuclear Group P.O. Box 4 Shippingport, PA 15077-0004 Telephone (412) 393-6000

December 18, 1990 NG3VPN:6460

United States Nuclear Regulatory Commission Attn: Document Control Desk Washington, DC 20555

Reference: Beaver Valley Power Station

BV-1 Docket No. 50-334, License No. DPR-66 BV-2 Docket No. 50-412, License No. NPF-73

Gentlemen:

Following is a report under 10CFR26, Appendix A, paragraph 2.8(e)(5), of the Fitness for Duty Rule:

Specifically, the above referenced guidelines require that the licensee promptly notify the NRC should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error.

As a result of an inquiry performed by our Fitness-For-Duty Program staff, we have determined that between October 23, 1990 and November 27, 1990, nineteen blind performance samples were incorrectly analyzed by Roche Biomedical Laboratory in Dublin, Ohio. Seven of the samples analyzed incorrectly were spiked at exactly the cutoff level of 100 ng/ml and metabolite dissipation might have been expected to yield a negative test result. All other samples were spiked at 140% or more of the cutoff level.

These blind performance test samples were obtained from Southgate Medical Laboratory System, Cleveland, Ohio and certified positive by the toxicologist for the substance claimed.

We were notified on December 7, 1990 that Roche Laboratory in Dublin, Ohio, was partially suspended from conducting confirmation testing for amphetamines until further notice and that confirmation testing for amphetamines will be referred to another NIDA certified Roche Laboratory.

A02

U. S. NRC Page 2 December 18, 1990

As a result, we have requested a retest by an independent laboratory of the nineteen samples originally reported as negative from Roche Laboratory. We continue to use quality control blind samples from Southgate Laboratory but we are in process of obtaining FDA approved blind samples for performance testing at Roche Laboratories. Roche Laboratories has consisted to continue their cooperation with NIDA to determine why this testing discrepancy occurred. We are continuing our efforts with Roche Laboratories to ensure that acceptable performance standards are maintained.

If you have any questions concerning this matter, please contact my office.

Very truly yours,

J. D. Sieber Vice President Nuclear Group

Enclosures:

Attachment I, Southgate's November 21, 1990 letter. Attachment II, Roche's December 6, 1990 letter. Attachment III, Request for Retest, November 30, 1990 letter.

cc: Mr. J. Beall, Sr. Resident Inspector

Mr. T. T. Martin, NRC Region I Administrator Mr. L. L. Bush, NRC Reactor Safeguards Branch

Mr. A. W. DeAgazio, NRC Project Manager

ATTACHMENT I



LABORATORY DIRECTOR EDWARD E BIEGLER M.D.

CHIEF EXECUTIVE OFFICER CHARLES J BRYERMAN JO

OWNED AND OPERATED BY BOUTHGATE MEDICAL SERVICES, INC.

21100 SOUTHGATE PARK BOULEVARD CLEVELAND, OHIO 44187-9054

1-800-382-8813 (0HI01 . 1-800-338-0188 (OUTBIDE OHIO)

BILLING INQUIRIES MAR DATA SYSTEMS 12161 581-1714 1-800-633-2455 (OHIO)

November 21, 1990

Darlene Kopp, R.N. Duquesne Light Beaver Valley Power Station Route 168 Shippingport, PA 15077

Dear Ms. Kopp,

Pursuant to your request, I have retrieved the quantitative results for the proficiency samples listed below, and have enclosed copies of the GC/MS quantitative reports. All of these samples are made up in pooled urine collected from the Toxicology staff, which is screened by EMIT and GC/MS to assure that the pool is negative. We then spike the individual pools using pure drugs or drug metabolites to levels that are normally 40% or more above the screening cutoffs specified in the DHHS Regulations. Additionally, you had also requested a Cannabinoid Pool that was at 100 ng/ml. I have listed below, what form of the drug or drug metabolite that we use, and the source from which we obtain these standards. All of these standards are check for purity prior to use.

Analyte/Form

Source

Amphetamine HCL

Alltech Applied Science

Methamphetamine HCL

Alltech Applied Science

Benzoyleogonine Tetrahydrate Alltech Applied Science

11-nor-delta-9-THC-COOH

Research Triangle Institute

(THO-COOH)

Certified Positive Urine Pool: Amphetamine, Methamphetamine lot 060190

Amphetamine

1450 ng/ml

45.0% above cutoff

Methamphetamine 1415 ng/ml

41.5% above cutoff

Certified Positive Urine Pool: Amphetamine, Methamphetamine, Cannabinoids lot 060190

41.4% above cutoff 1414 ng/ml Amphetamine

49.7% above cutoff Methamphetamine 1497 ng/ml

103 % above cutoff 203.4 ng/ml THC COOH

Certified Positive Urine Pool: Benroylecgonine, Cannabinoids lot 060190

Benzoylecgonine 995.1 ng/ml 231 % above cutoff

200.1 ng/ml 100 % above cutoff THC - COOH

Certified Positive Urine Pool: Cannabinoids 100 ng/m? lot 101890

106.6 ng/ml THC - COOH 103.5 ng/m1

> 105.1 ng/ml 5.1 % above cutoff mean

Should you require any additional information, or if I can be of further service, please call me at 1-800-338-0166 extension 256.

Sincerely

Neil A. Fortner, M.S.

Scientific Director - Toxicology

NOU 21 '90 14:07 TO 412 393 7920 FROM SOUTHGATE MED LAB T-988 P 04

*** Internal Standard ***

19 Jun 90 8:14 pm

19 Jun 90 8:14 pm

ATTACHMENT I

Operator: DP 06/19/90

Method File Name : AMINES.H

Sample Info : CERTIFIED POSITIVE LOT 060190 # 05968

Misc Info: MSD 3

Integration File Name : DATA:0819C19A.I . :

Method index : 2 Bottle Number : 19

Last Update: 20 Jun 90 8:41 am

Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time

Sample Amount: 0.000 Uncalibrated Peak RF: 0.000 Multiplier: 1.000

Pe	eak	Int	Ret	Sign	nal		Comppund		
Num	Type	Type	Time	Descr	iption		Name	Area	Amount
	ISTO		8.228	Mass	96.00	amu	AMPHET OS	6372228	200.0 NG/ML
2		180	9.031	Mass	91.00	amu	METHAMPHET	18526068	1415 NG/ML

*** Internal Standard ***

Operator: DP 06/19/90

Method File Name : AMINES.M

Sample Info : CERTIFIED POSITIVE LOT 060130 # 05968

Misc Info: MSD 3

Integration File Name : DATA: 0519C19A. I

Method index : 2 Bottle Number : 19

AMPHETAMINE IN URINE

Last Update: 20 Jun 90 8:22 am

Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time

Sample Amount: 0.000 Uncelibrated Peak RF: 0.000 Multiplier: 1.000

Compound Peak Int Ret Signal Description Area Amount Num Type Type Time Name 1 ISTD 18V 8.228 Mass 96.00 amu AMPHET DS 6372228 200.0 NG/ML 2 18V 8.258 Mass 91.00 amu AMPHETAMINE 18247277 1450 NG/ML

20 Jun 90 Sitt pm

NOV 21 '98 14:88 TO 412 393 7928 FROM SOUTHGATE MED LAB T-988 P. 05

ATTACHMENT I . .

19 Jun 90 8:41 pm

Opt #4:001 HK 60 06 00:90 Method File Hame : INC. N

Sample info : THE CERTIFIED POSITIVE LOT 050190 # 05967

Miss Info: 495 1

Internation File Name : DATH: Williams A. I.

Method index : Bottle umber : 5

THE-COOR IN URINE

Last Update: 1' Jun 90 7:51 am

Reference Peak Window: 9.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time Sample Amount: 0.000 Uncelibrated Flak RF: 0.900 Multiplier: 1.000

Compound Peak Int Ret Signal Compound

Num Type Type Time Description Name: Area Allount

1 15TD 188 8.629 Mass 374.00 amu THC-COOH D3 6332803 100.0 NG/ML 188A 9.859 Mass 371.00 and THC-COOH 34357014 203.4 NG/ML

*** Internal Standard ***

Openator: DP 08/19/80

Method File Name : AMINES.M

1

Sample Info : CERTIFIED POSITIVE LOT 050190 # 05967

Misc Info: MSD 3

Integration Filb Name : DATA:0519021A.1

Method index : 2 Bottle Number : 21

Last Update: 20 Jun 90 8:41 am Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time Sample Amount: 0.000 Uncalibrated Feak RF: 0.000 Multiplier: 1.000

Peak Int Ret Signal Compound

Num Type Type Time Description Name Area Amount

1 ISTO 18U 8.228 Mass 86.00 amu AMPHET DS 7113556 200.0 NG/ML

1 18U 9.032 Mass 91.00 amu METHAMPHET 21820818 1497 NG/ML Peak Int Ret Num Type Type Time

*** Internal Standard ***

Operator: DP 06/19/90

Method File Name : AMINES.M

19 Jun 90 8:41 pm

Sample Info : CERTIFIED POSITIVE LOT 050190 . 05957

Misc Info: MSD 3

Integration File Name : DATA: 0519021A.I

Method index : 2 Bottle Number : 21

AMPHETAMINE IN URINE

Lost Update: 20 Jun 30 8:22 am

Reference Feel Window: 5.00 % of Retention Time Non-Reference Peel Window: 5.00 % of Retention Time

Sample Amount: 0.000 Uncalibrated Peak RF: 2.000 Multiplier: 1.000

Peak ... Ret Int Signal Compound Num Type Type Time Description Name Amount Area 1 10Th 1011 0 556 M. ne na

NOV 21 198 14:89 TO 412 393 7928

*** Internal Stendard ***

T-988 P. 86

ATTACHMENT I

19 Jun 90 7:11 pr

20 Jun 90 5:47 pm

Operator: HR/GC 061990 Method File Name : BE.M.

Sample Info : BE CERTIFIED POSITIVE LOT #050190, #05964

Misc Info: MSD |

Integration File Name : DATA: 0619808A.1

Method index : 2 Bottle Number : 9

BENZOYLECGONINE IN URINE

Last Update: 20 Jun 90 7:58 am

Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time

Sample Amount: 0,000 Uncelibrated Peak RF: 0.000 Multiplier: 1,000

Peak	Int	Ret	Sig	rie l		Compa	und			
Num Type	Type	Time	Descr	iption		Nen	10	Area	fmount	
1 +1STD		8.684	Mass	243.00	emu	BE	03		200.0 NG/M	
2	180			240.00		40.46		24463681	885, I NG/MI	40.

*** Internal Standard ***

Operator: HR/60 06/20/80 Method File Name : THC.M

Sample Info : THO CERTIFIED POSITIVE LOT 060190 # 05964

Misc Info: MSD 1

Integration File Name : DATA: 0620A10A. I

Method Index : | Bottle Number : 10

THO-COOH IN URINE

Last Update: 21 Jun 90 7:51 am

Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time

Sample Amount: 0.000 Uncalibrated Peak RF: 0.000 Multiplier: 1.000

Pe	tak	Int	Ret	510	ná l		Compound				
Num	Type	Type	Time	Descr	iption		Name			100	
- 1	ISTO	188	9.622	Mass	374.00	ORU	THO-000H	03	4858933	100.0	NG/ML
2		IBV	9,849	Mass .	371.00	amu	TH0-000H		13089020	200.1	NG/ML

ATTACHMENT 1

*** Internel Standard ***

Openator: HR 11/05/90 Method File Name : THO.M Semple Info : 100 NG/ML THC-COOH POOL Mise Info: MSD I Integration File Name : DATA: 1106A09A. 1 6 Nov 90 1:50 pm

Method index : 1 Bottle Number : 9

Last Update: 6 Nov 90 7:51 pm Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time Sample Amount: 0.000 Uncelibrated Peak RF: 0.000 Multiplier: 1.000

Pe	e i	Int	Ret	Sign	al .		Compound			
tium	Type	Type	Time	Descri	ption		Name		Area	Amount
1	ISTD	IBV	9.133	Mass	874.00	emu	THO-000H (03	11150728	100.0 NE/ML
2		150					THO-COOH			105.5 NG/ML

*** Internal Standard ***

Operator: HR 11/05/90 Method File Name : THC.M Sample Info : 100 NG/ML THC-COOH POOL Misc Info: MSD 2

6 Nov 90 2:03 pm

Integration File Name : DATA:1108A10A.I

Method index : 1 Sottle Number : 10

Lest Up ate: 8 Nov 80 7:51 pm Reference Peak Window: 5.00 % of Retention Time Non-Reference Peak Window: 5.00 % of Retention Time Sample Amount: 0.000 Uncalibrated Peak RF: 0.000 Multiplier: 1.000

Pe	ah.	Int	Ret	510	nal		Compound			
Num	Type	Type	Time	Descr	iption		Name		Area	Amount
- 1	1570	IBV	9.134	Mess	374.00	amu	THC-COOH	03	10847473	100.0 NB/ML
Ž.		184	9,159	Mass	371.00	emu	THC-COOH		12023202	103.5 NG/ML

Roche Biomedical Laboratories



a subsidiary of Hoffmann-La Roctie Inc.

Hoche Biomedical Laboratories, Inc. 6364 Dublin Industrial Lane Dublin, Ohio 43017

Telephone (614) 88s 761

December 6, 1990

Dear Client:

Roche Biomedical Laboratories (RBL) received notification from the National Institute on Drug Abuse (NIDA) that our Dublin, Ohio facility has been partially suspended from conducting confirmation testing for amphetamines, one of the drugs tested under the NIDA program. The Dublin, Ohio facility remains certified by NIDA to conduct screening for amphetamines as well as screening and confirmation for the other drugs tested under the NIDA program. Until the suspension is lifted, we will refer all presumptive positive amphetamines to one of Roche Biomedical's other NIDA certified laboratories for confirmation.

As our client, however, you can expect your service to continue uninterrupted and unaffected. RBL remains committed to providing quality laboratory services.

Roche has substituted the method in question with an alternative procedure for amphetamine confirmation. Since the new procedure is now in place, Roche Biomedical anticipates that NIDA will lift the partial suspension soon. Moreover, we will continue our cooperation with NIDA to determine why this testing discrepancy occurred.

If you have any questions or concerns, please contact Dr. Donald Long, Director of Toxicology or Steve Jones, General Manager for our Dublin, Ohio facility, or we. We can be reached at (800) 282-7300.

Sincerely,

James R. Mott

Senior Vice President

Central Region

JRM/pd



Nuclear Group P.O. Box 4 Shippingport, PA 15077-0004 Telephone (412) 393-6000

November 30, 1990 NMS: 0034

Don'ld W. Loug, Ph.D. Roche Labs
P.O. Box 2289
Columbus, OH 43216

Dear Dr. Long:

The following 19 proficiency samples were sent to Roche Biomedical Laboratory from October 23, 1990 through November 27, 1990:

303-714-0306-0	B-9756314-D	10-29-90
303-714-0319-0	B-9756323-D	10-29-90
298-714-0426-0	B-9886793-D	10-24-90
299-714-0253-0	B-9886760-D	10-25-90
305-714-0337-0	B-9756336-D	11-01-90
306-714-0287-0	B-9756380-D	11-02-90
305-714-0347-0	B-9756347-D	10-31-90
306-714-0215-0	B-9756386-D	11-02-90
296-714-0486-0	B-9886318-D	10-23-90
296-714-0487-0	B-9886316-D	10-23-90
298-714-0318-4	B-9886795-D	10-24-90
299-714-0305-4	B-9886764-D	10-25-90
299-714-0357-4	B-9886756-D	10-25-90
303-714-0324-0	9-9886754-D	10-29-90
309-714-0430-0	B-9756355-D	11-01-90
306-714-0277-0	B-9756352-D	11-01-90
305-714-0336-0	B-9756335-D	10-31-90
332-714-0277-0	B-9756499-D	11-27-90
324-714-0360-0	B-9756494-D	11-19-90

Upon receipt of the results, several discrepancies were noted, primarily in the cannabinoid and methamphetamine spiked samples.

We are requesting a retest of the samples, including GC/MS, by and independent NIDA certified laboratory, at the expense of Duquesne Light Company. The listed samples are to be sent to:

Clinical Pathology Facility, Inc. 711 Bingham Street Pittsburgh, PA 15203

ATTN: Fred Fochtman, Ph.D. (DABFT) or James E. McLean, Director of Marketing Services

Donald W. Long, Ph.D. November 30, 1990 NMS: 0034 Page 2

Dr. Fochtman stipulated that Roche Labs may provide the above samples with a Roche chain of custody form or contact Clinical Pathology Facility, Inc. (412-488-7500) to provide their chain of custody forms. If there is any further information required, please contact me at 412-393-7847.

Sincerely,

Gregory S. Zernich, D.O.

Medical Review Sficer Beaver Valley Power Station

GSZ/mab

bc: Fred Fochtman, Ph.D. - Clinical Pathology Facility, Inc. Patricia A. Casasanta - Duquesne Light Company

