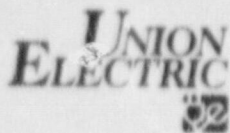


Callaway Plant  
Post Office Box 620  
Fulton, Missouri 65251

December 19, 1997



U. S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Mail Stop P1-137  
Washington, DC 20555-0001

ULNRC-03701

Gentlemen:

**DOCKET NUMBER 50-483  
CALLAWAY PLANT UNIT 1  
FACILITY OPERATING LICENSE NPF-30**

In accordance with 10CFR26, Appendix A, Section 2.8(e), Union Electric is providing notification that a blind proficiency specimen was reported incorrectly by the DHHS Certified Laboratory utilized by our Fitness for Duty Program.

At our request, an investigation was immediately initiated by Duo Research (our blind specimen provider) and Pharm Chem Laboratories. In addition, our MRO requested that the specimen be retested. The retest produced satisfactory results.

Review of the findings indicate an administrative error with appropriate corrective action. All documentation concerning this issue will be made available to our Technical Consultant for review. Any additional findings or additional corrective actions taken to resolve this concern will be provided to you.

If you have any questions, contact me at (573) 676-8246.

A handwritten signature in cursive script that reads "James R. Peavy".

James R. Peavy  
Manager, Emergency Preparedness  
& Organizational Support

9712310271 971219  
PDR ADOLK 05000483  
F PDR

JRP/jmw

Enclosure

*Handwritten note:* A022/1



cc: U. S. Nuclear Regulatory Commission (Original and 1 copy)

Attn: Document Control Desk

Mail Stop P1-137

Washington, DC 20555-0001

Mr. Ellis W. Merschhoff  
Regional Administrator  
U.S. Nuclear Regulatory Commission  
Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, TX 76011-8064

Senior Resident Inspector  
Callaway Resident Office  
U.S. Nuclear Regulatory Commission  
8201 NRC Road  
Steedman, MO 65077

Mr. **Barry C. Westreich** (2 copies)  
Acting Licensing Project Manager, Callaway Plant  
Office of Nuclear Reactor Regulation  
U. S. Nuclear Regulatory Commission  
Mail Stop 13E16  
Washington, DC 20555-2738

Manager, Electric Department  
Missouri Public Service Commission  
PO Box 360  
Jefferson City, MO 65102

Mr. Thomas A. Baxter  
Shaw, Pittman, Potts, & Trowbridge  
2300 N. Street N.W.  
Washington, DC 20037

Mr. Loren L. Bush, Jr.  
U. S. Nuclear Regulatory Commission  
Division of Reactor Program Management  
Safeguards Branch  
Washington, DC 20555-0001

# INVESTIGATION REPORT

## On a Blind Performance Test Sample

### Objective:

The licensee shall investigate any unsatisfactory performance testing result. A record shall be made of the investigative findings and the corrective action taken by the laboratory. The licensee shall send the document to the NRC as a report of the unsatisfactory performance-testing incident within 30 days.

### References:

1. 10 CFR 26 Appendix A, Subpart 2.0(e) (4)
2. FR 53, 11970 (1988), Subparts 3.19(b) (2) & (5)

### Observation:

On November 25, 1997, the licensee, Union Electric, Callaway Nuclear Plant, conducted an on-site screen of a blind quality control sample provided by Duo Research Inc. The sample contained a mixture of 500 ng/mL of oxazepam and 2,000 ng/mL of nordiazepam, the two major metabolites of diazepam ("Valium"). The licensee utilized Abbott FPIA benzodiazepine reagents on an AxSYM analyzer. The sample gave a positive result, quantifying at 1,873 ng/mL. The sample was sent to PharmChem Laboratories in Menlo Park, California for re-screening and confirmation. On November 28<sup>th</sup>, the laboratory reported the sample as negative. Subsequently, Dr. Richard Osbourn, the MRO for the licensee, requested the laboratory to re-analyze the sample, which was conducted on December 12<sup>th</sup>. This time, the laboratory reported it as positive, confirming it for the presence of oxazepam.

### Findings:

On-site Results - The FPIA assay uses nordiazepam as the calibrator, with a cutoff of 200 ng/mL. The on-site result of 1,873 ng/mL is consistent with the sample composition of 2,000 ng/mL of nordiazepam. The possible contribution of the oxazepam could not be determined, as the reagent package insert lists the assay cross-reactivities in an obscure manner. It only states that a concentration of 200 ng/mL of oxazepam gives a response greater than 40 ng/mL, the assays sensitivity level. How strong a response is not provided. Nevertheless, the on-site result is judged to be correct.

PharmChem Laboratories Results - Upon the initial inquiry by Dr. Osbourn, the laboratory reported that the original screening assay gave a result of "299" relative to that of the cutoff calibrator at "300," which is the cutoff. The laboratory utilizes enzyme immunoassay reagent, the Emit brand, which uses 300 ng/mL of oxazepam as the calibrator. The laboratory has always reported previous blind samples from the same lot as positive. Obviously, a sample containing 500 ng/mL of oxazepam should have given a positive response. The laboratory is investigating the exact cause for the 299 versus 300 response (a supplemental report will be provided).



## Investigation Report

Page 2

In the December 12<sup>th</sup> retest, the sample gave a positive screening result, with a response of 610 versus 410 for the 300 ng/mL calibrator (values are in absorbance units). GC/MS confirmation gave a concentration of 507 ng/mL, verifying the sample's composition. Note, the laboratory does not routinely confirm for nordiazepam. This retest result also verifies that the initial screening result was inappropriately low relative to the assay calibration, suggesting that the calibration was not properly established.

Recommendation:

A preliminary recommendation is that the laboratory completes the current investigation into the cause of the discrepancy between the initial screening result and the repeat two weeks later. It is possible that the calibration was off in the initial test and that the laboratory made a subsequent correction, such as replacing the controls. Any further recommendations will be made pending the receipt of the laboratory's findings.

Prepared for: Union Electric, Callaway Nuclear Plant

by: Robert E. Willette  
Robert E. Willette, Ph.D.  
Duo Research Inc.

Date: Dec. 17, 1997

**PHARMCHEM**  
LABORATORIES, INC.

---

1505A O'Brien Drive [Menlo Park, California 94025-1435] (650) 328-8200 [Fax: (650) 688-1122

December 18, 1997

Dr. Richard Osbourn  
Union Electric Company  
P.O. Box 620  
Fulton, Missouri 65251

Dear Dr. Osbourn:

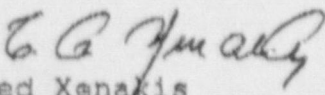
Upon your request an investigation was conducted regarding specimen bar code number 23982918, Laboratory accession number 973188640, received at PharmChem November 26, 1997 and reported negative for Benzodiazepines.

Our investigation found that above specimen was in fact screened positive for Benzodiazepines, cutoff rate 158, specimen rate 242.

However, the controls for Barbiturates 300 failed and were rerun. The reviewing scientist accidentally made a manual entry of the barbiturate 300 result for the benzodiazepine 300, thus making sample 023982918 below the cutoff or negative ( see enclosure 1,2,3,4, &5).

The employee has been counseled and PharmChem is initiating training starting immediately. We regret the inconvenience this has caused.

Sincerely,

  
Ted Xenakis  
Senior Technical Advisor

CC:  
Dr. Robert Willette

PCL

# Initial Test Tray Quality Control Record

Workplace

PCL

NOV 26 1997

1081 W

1P971

Batch Date

Batch Number

Group No.

LAN No.



0973188633



0973188642

Analyzer No.

2

Handwritten notes: 1081 W, 1P971, and other illegible scribbles.

Handwritten notes: Box 300, Box 202, 20

EMIT												
QC #	Amph	Barb	BNZO	THC	COC	MD	MTQ	OP	PCP	Prop	THC100	THC20
				50								
QC: 20	337	377	317	346	138	47	62	62	78	66	223	333
QC: 21	360	423	1353	387	204	90	137	109	106	114	244	349
Cutoff:	402	442	353	404	205	111	155	114	113	120	253	366
QC: 22	446	255	360	428	214	115	159	118	120	120	279	344
QC: 23	455	450	362	473	217	115	156	178	121	124	281	365

Note: QCs for THC 100, THC 20, Barbiturate 300, Benzodiazepine 300, Tricyclics, Phenytoin, LSD, Alcohols or adulteration screens do not show on the downloads or tray reports.

### TARGET RANGE

### OBSERVED

ALCOHOL

LOW	MEAN	HIGH
4	0	4
18	20	22
67	74	81
4	0	4
25	31	37
4.5	5	5.5
7.5	8	8.5

QC 1	QC 2
0	0
17	18
75	73
0	0
32	32
5.19	5.18
7.91	7.91

EMIT Analyst:

PRITI DESAI  
P. Desai

DATE:

112797

1



0973188635 0483 483 0006-03	446H 159H	455H 118H	-- 120H	360H 126H	-- --	428H --	-- --	214H --	115H --
0973188636 0484 484 0006-04	322 5.57	-- 59 150	-- 72	-- --	-- --	340 --	-- --	135 --	-- --
0973188637 0485 485 0006-05	335 --	-- 61 31	369H 76	-- --	116 281	-- --	223 --	143 --	-- --
0973188638 0486 486 0006-06	336 62	366 61	-- 79	400H 85	-- --	349 --	219 --	135 --	47 --
0973188639 0487 487 0006-07	328 --	-- 60 76	332 73	-- --	111 274	-- --	221 --	136 --	-- --
→ 0973188640 0488 488 0006-08	333 --	-- 60 61	336 76	→ 242H 280	-- --	-- --	224 --	139 --	-- --
0973188641 0489 489 0006-09	332 --	-- 67 80	-- 80	-- --	-- --	341 --	-- --	140 --	-- --
0973188642 0490 490 0006-10	455H 156H	450H 118H	-- 121H	362H 124H	-- --	423H --	-- --	217H --	115H --
< 0000000083 E016 67 0002-01	-- --	-- --	365	-- --	162H --	-- --	281H --	-- --	-- --
< 0000000033 E020 68 0002-02	-- --	-- --	-- --	-- --	344H --	-- --	-- --	-- --	-- --
1 0013	-- 5.18	-- 0-	-- --	-- --	-- --	0- --	-- --	-- --	-- --

DATE 11/27/1997 13:48  
OPERATOR

S.ID ANALYSIS NO	S.NO. RACK NO. CUP POS.	LIH	KAMPH NTQ pH	BARB2 OP CREAT	BARB3 PCP	BENZ2 PROP	BENZ3 THC20	THC50 ETOH	THC	AFN	COC DILAN	MD LSD
	0016		7.91	32				73				
								18				

2

1081W

11/27/97 16:01:03

POSITIVE RESULTS ONLY

PAGE: 1

PHARMCHEM LABORATORIES, INC.  
(415)328-6207

LOC: MP

ACCESSION# RANGE: 973188633 - 973188642

ACCESSION	SAMPLE ID	DATE	ASSAY	CALIBRATOR RATE/ADDR	SAMPLE RATE	RESULT
973188637	24072392	11/27/97	<del>Barbiturates 30</del>	<del>00366/2</del>	<del>00367</del>	POSITIVE <i>SA 11/27/97</i>
973188638	10820863	11/27/97	Benzodiazepines	00353/2	00400	POSITIVE
973188640	23982918	11/27/97	<del>Benzodiazepines</del>	<del>00158/2</del>	<del>00242</del>	POSITIVE <i>SA 11/27/97</i>

\*\*\* END OF REPORT \*\*\*



RUN: 18971

RESULTS REVIEW FOR ANALYZER: 2

97/11/

ACCESSION #		TEST		RESULT CUTOFF		TEST		RESULT CUTOFF	
TEST	RESULT	CUTOFF	TEST	RESULT	CUTOFF	TEST	RESULT	CUTOFF	
GC20									
017 Amp	337	00402	015 THC50	346	00404	006 CDC	138	00205	
009 OPIAT	62	00114	010 PCP	78	00113	002 BARB	377	00442	
003 BENZO	317	00353	008 MTG	62	00155	007 METH	47	00111	
011 PROP	66	00120							
* GC21									
017 Amp	360	00402	015 THC50	387	00404	006 CDC	204	00205	
009 OPIAT	109	00114	010 PCP	106	00113	002 BARB	423	00442	
003 BENZO	353#	00353	008 MTG	137	00155	007 METH	90	00111	
011 PROP	114	00120							
>>>>>> C O N T R O L (#) IS POSITIVE									
GC22									
017 Amp	446	00402	015 THC50	428	00404	006 CDC	214	00205	
009 OPIAT	118	00114	010 PCP	120	00113	002 BARB	455	00442	
003 BENZO	360	00353	008 MTG	159	00155	007 METH	115	00111	
011 PROP	126	00120							
973188636									
017 Amp	322	00402	015 THC50	340	00404	006 CDC	135	00205	
630 CRDUT	150	00019	009 OPIAT	59	00114	010 PCP	72	00113	
628 phDOT	5.57	4.99							
* 973188637									
017 Amp	335	00402	006 CDC	143	00205	099 Crea2	31	00020	
009 OPIAT	61	00114	010 PCP	76	00113	004 THCO1	223	00253	
005 THCO2	281	00322	702 BARB3	369*	00366	703 BENZ3	116	00158	
* 973188638									
017 Amp	336	00402	015 THC50	349	00404	006 CDC	135	00205	
009 OPIAT	61	00114	010 PCP	79	00113	004 THCO1	219	00253	
002 BARB	366	00442	003 BENZO	400*	00353	008 MTG	62	00155	
007 METH	47	00111	011 PROP	65	00120				
973188639									
017 Amp	328	00402	006 CDC	136	00205	099 Crea2	76	00020	
009 OPIAT	60	00114	010 PCP	73	00113	004 THCO1	221	00253	
005 THCO2	274	00322	702 BARB3	332	00366	703 BENZ3	111	00158	
* 973188640									
017 Amp	333	00402	006 CDC	139	00205	099 Crea2	61	00020	
009 OPIAT	60	00114	010 PCP	76	00113	004 THCO1	224	00253	
005 THCO2	280	00322	702 BARB3	336	00366	703 BENZ3	242*	00158	
973188641									
017 Amp	332	00402	015 THC50	341	00404	006 CDC	140	00205	
099 Crea2	80	00020	009 OPIAT	67	00114	010 PCP	80	00113	
GC23									
017 Amp	455	00402	015 THC50	423	00404	006 CDC	217	00205	

(4)

PCL

# Memorandum for Record PCL

Test Date

112697

Batch No

1081W

Accession No. (if appropriate)

### Description of Problem

- 1) AC 21 is positive for Benzo
- 2) AC 73 failed for Barb 300

### Resolutions:

- 1) Positive samples were seen for Benzo
- 2) Seen samples for Barb 300

Prepared By PRITI DESAI

PVDesai

Title

EMIT ANALYST

Date Prepared

112797

Approved By

BRYAN KERNS

Title

CCO

Date Approved

112897

5