



GULF STATES UTILITIES COMPANY

RIVER BEND STATION POST OFFICE BOX 220 ST. FRANCISVILLE, LOUISIANA 70775
AREA CODE 804 635-8094 346-8851

April 4, 1990
RBG- 32662
File Nos. G9.5, G1.51

Director, Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

Gentlemen:

River Bend Station - Unit 1
Docket No. 50-458

Pursuant 10CFR26, Appendix A Subpart B, Section 2.8(e)(4), please find enclosed Gulf States Utilities Company's (GSU) report (FFD90-F03) on an investigation involving an unsatisfactory performance test result by a DHHS certified laboratory under contract to GSU to perform drug screen testing under 10CFR Part 26 "Fitness For Duty Program".

Should you have any questions, please contact Mr. David L. Lorring at (504) 381-4157.

Sincerely,

W. H. Odell
Manager-River Bend Oversight
River Bend Nuclear Group

WMO/TCC/JHM/TWS/pg

cc: U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

NRC Resident Inspector
P.O. Box 1051
St. Francisville, LA 70775

9004260252 900404
PDR ADOCK 05000458
P PDC

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FITNESS FOR DUTY PROGRAM
Report FFD90-F03
"False Negative"

REPORTED CONDITION

On 02/08/90, Gulf States Utilities Company (GSU) fitness for duty (FFD) program supervisor forwarded a blind performance test specimen to GSU's contract laboratory, American BioTest Laboratories, Inc (ABLI), a U. S. Dept. Health and Human Services (DHHS) certified lab. The test specimen was spiked with a known 1632 nanograms per milliliter (ng/ml) amphetamines and 2283 ng/ml methamphetamines, prepared by El Sohly Laboratory, Inc. (ELI) on 12/20/89. By letter dated 02/21/90, GSU's contracted medical review officer (MRO) reported the results from ABLI for the blind performance test specimen as being negative. Cut-off levels for initial screening are 1000 ng/ml and 500 ng/ml for confirmation.

Since the blind sample was known to have a high concentration of amphetamines and methamphetamines, GSU's quality assurance representative advised ABLI that the sample should have tested positive, that they should reanalyze the sample, and should initiate their own internal investigation as to the cause of the event.

In accordance with provisions of River Bend Station FFD program procedure FFD-16-001, the FFD program supervisor issued a condition report (CR90-0137) and requested that GSU's Quality Assurance Department conduct an investigation of the event. This report is submitted in accordance with 10CFR Part 26, Appendix A, Subpart B, Section 2.8(e)(4).

INVESTIGATION

On 02/21/90, GSU's QA representative requested ABLI to conduct an internal investigation to determine the cause of the discrepancy in test results. The preliminary results of this investigation were received at GSU on 03/05/90 as ABLI's nonconforming activity report (NCAR) dated 02/22/90 (attachment 1).

The NCAR determined that the discrepancy was "a technical oversight (error) on the part of the gas chromatography/mass spectrometry (GC/MS) operator relating to the analysis of the specimen".

ABLI's NCAR was reviewed by GSU's technical specialist Dr. El Sohly on 03/16/90 who reported that the investigation was accurate. Based on this evaluation, GSU has accepted ABLI's investigation as to the cause of the incident.

ROOT CAUSE AND CORRECTIVE ACTION TO PREVENT RECURRENCE

Root cause of this incident was determined to be human error on the part of the GC/MS operator.

CORRECTIVE ACTION/RECOMMENDATIONS

GSU has required additional training for the GC/MS operators concerning this specific incident. The corrective action consisted of a formal training session given by the laboratory director on 03/02/90 to all GC/MS operators. Objective evidence of the training was recorded in their respective personnel files.

To identify any prior similar occurrences performed by the particular operator the laboratory reviewed all tests for the previous 30 days. No other similar occurrences were identified.

The laboratory has instituted a policy of requiring that two certifying scientists review all data for which a specimen is screened positive yet confirmed negative. This additional review will continue until 04/04/90.

IMPACT

This investigation was completed as required by 10CFR Part 26, Appendix A, Subpart B, Section 2.8(e)(4) and GSU's Station Support Manual Procedure FFd-16-001. There was no impact on security, plant safety, or to the safety and health of the public.

NONCONFORMING ACTIVITY REPORT

CR 90-0137
ATTACHMENT 1
page 1 of 3

Subject FALSE NEGATIVE ON BLIND QC SPECIMEN: RIVER BEND

Date 22-FEB-90

I N I T I A T O R	NONCONFORMING ACTIVITY	
	O/A 19 FEB TOM STANBERRY FROM RIVERBEND INFORMED ABTL LABORATORY DIRECTOR THAT A BLIND QC SPECIMEN (ID# 132107) SPIKED WITH AMPHETAMINE WAS INCORRECTLY REPORTED AS NEGATIVE.	
	RECOMMENDATIONS INVESTIGATE THE FOLLOWING POSSIBLE SOURCES OF ERROR: 1) INCORRECT PANEL SETUP; 2) CORRECT PANEL SETUP BUT SCREENED NEGATIVE; 3) SCREENED POSITIVE BUT CONFIRMED NEGATIVE; 4) CONFIRMED POSITIVE BUT INCORRECTLY REPORTED.	
	INITIATOR	R.K. LATVEN <i>RK Lat</i> DATE 22-FEB-90
S U P E R V I S O R	ROOT CAUSE AND EFFECTS	
	SAMPLE SCREENED POSITIVE BY I/A BUT CONFIRMED NEGATIVE. THE ROOT CAUSE WAS DETERMINED TO BE A TECHNICAL OVERSIGHT (ERROR) ON THE PART OF THE GC/MS OPERATOR RELATING TO THE ANALYSIS OF THIS SPECIMEN. SEE ATTACHMENT FOR DETAILS.	
	CORRECTIVE ACTION TRAINING TO BE PROVIDED TO ALL GC/MS OPERATORS RELATING TO AMPHETAMINE ANALYSIS; ALL AMPHETAMINE SCREENED POSITIVES/CONFIRMED NEGATIVES FOR PRECEDING 30 DAYS RE-EXAMINED; TWO CERTIFYING SCIENTISTS ARE TO REVIEW DATA FOR ALL SCREENED POSITIVES/CONFIRMED NEGATIVES FOR 30 DAYS.	
	APPROVAL BY SUPERVISOR	J.S. WIESNER <i>JW</i> DATE 5 MAR 90
Q A M G R	RESPONSE EVALUATED AND ACCEPTED DATE 5 MAR 90	
	CORRECTIVE ACTIONS VERIFIED LABORATORY DIRECTOR PROVIDED FORMAL TRAINING SESSION COVERING ANALYSIS OF AMPHETAMINES TO ALL GC/MS OPERATORS 3/2/90; RE-EXAMINATION OF DATA PENDING; VERIFICATION OF DOUBLE REEVIEW PENDING.	
	VERIFIED BY	R.K. LATVEN <i>RK Lat</i> DATE 5 MAR 90
	NCAR CLOSURE	DATE

American BioTest
Laboratories, Inc.

NCAR 22 FEB 90: FALSE NEGATIVE ON BLIND QC SPECIMEN: RIVERBEND

ROOT CAUSE AND EFFECTS

ATTACHMENT

SAMPLE SCREENED POSITIVE BY I/A BUT CONFIRMED NEGATIVE. THE ROOT CAUSE WAS DETERMINED TO BE A TECHNICAL OVERSIGHT (ERROR) ON THE PART OF THE GC/MS OPERATOR RELATING TO THE ANALYSIS OF THIS SPECIMEN.

The EXHIBIT (attached) is the operant data used in the GC/MS analysis of specimen ID# 132107 and shows the extracted ion current profiles (EICP) of the quantitating ions (Q/I) and internal standards (I/S) for amphetamine and methamphetamine. These data were used by the GC/MS operator for the specimen in question:

- Quadrant 1: EICP of m/z 116, Q/I of amphetamine;
- Quadrant 2: EICP of m/z 130, Q/I of methamphetamine;
- Quadrant 3: EICP of m/z 119, I/S of amphetamine (d3-amphetamine)
- Quadrant 4: EICP of m/z 134, I/S of methamphetamine (d5-methamphetamine)

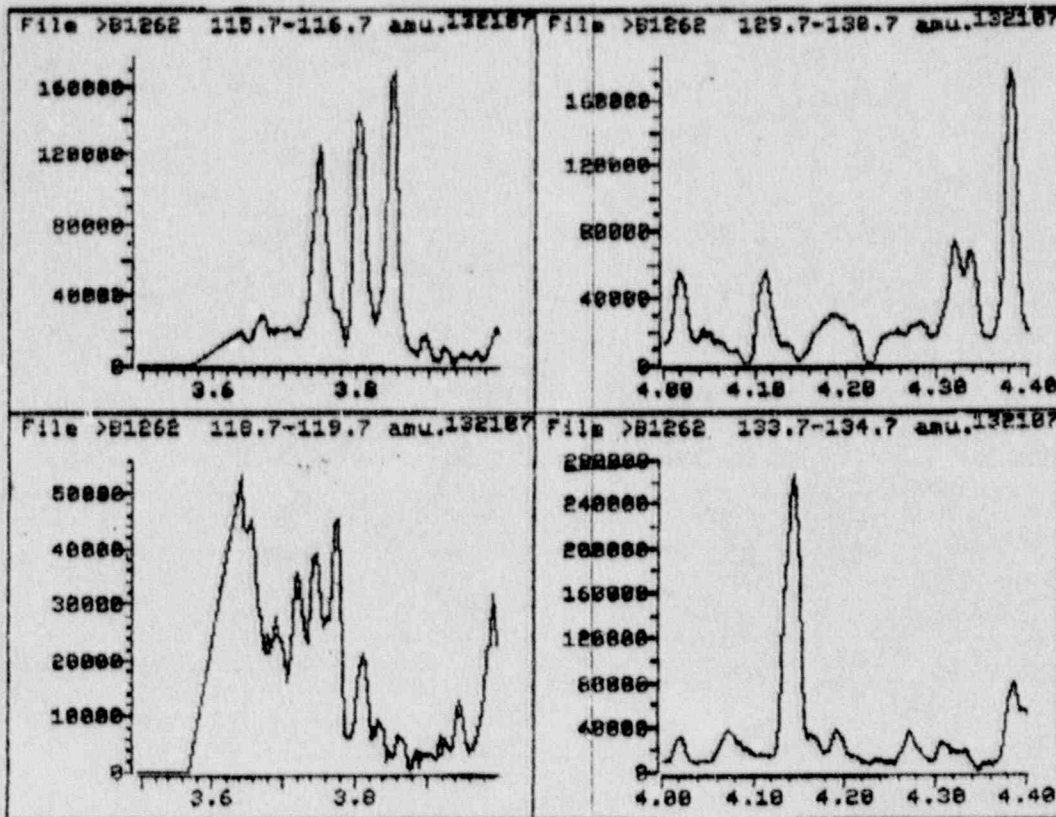
It can be seen that the I/S of methamphetamine provides a strong peak at its expected retention time, 4.14 minutes indicating the successful extraction, derivitization, and chromatography of any methamphetamine present. Lack of a peak at 4.12 min for methamphetamine m/z 130 (combined with the presence of its internal standard) indicates the absence of methamphetamine.

It is to be expected (although not assumed) in this sample that the amphetamine I/S would show a strong peak in quadrant 3, similar to that seen for methamphetamine I/S in quadrant 4. This is expected since when methamphetamine "goes" (i.e., extracts, derivitizes, etc.,) amphetamine should "go" also. In this unusual case, amphetamine I/S (and therefore any amphetamine present in the sample) did not go, probably due to inhibited derivitization.

In this analysis, the GC/MS operator did not check carefully enough for the presence of the amphetamine internal standard, and therefore did not recognize its absence. If he had recognized the absence of amphetamine I/S, he would have been required to re-extract and re-shoot the specimen on the GC/MS until the amphetamine internal standard could be detected, which would indicate that any amphetamine present would also be detectable.

However, the analyst did analyze the three peaks seen in quadrant 1 for amphetamine, and correctly determined that none met the criteria for amphetamine positive.

The net result is that due to an error on the part of the GC/MS operator in the assumption of the presence of amphetamine internal standard, the absence of amphetamine in sample ID# 132107 was incorrectly concluded.



EXHIBIT

Q-1	Q-2
Q-3	Q-4

DRUG TESTING CUSTODY AND CONTROL FORM

American BioTest Laboratories, Inc.
3350 SCOTT BLVD. • BLDG. 15 • SANTA CLARA, CA 95054 • (408) 727-5525

Step 1(a) -- Steps 1(a), (b), and (c) are to be completed by employer or collector:

Donor Social Security Number [REDACTED] (Specimen I.D. Number) **132107**

Company/Employer Name and/or Account Number **00**

Location Code: **RCS/FFD** MRO Name: **Dupont**

Step 1(b) -- Type of Test (Check Appropriate Block)

- ☐ Random ☐ Periodic ☐ Pre-employment ☐ Post Accident
☐ Reasonable Suspicion/Cause ☒ Other (Specify) **pre-access**

Step 1(c) -- Indicate which drugs specimen is to be tested for

- ☐ Only THC and Cocaine
☐ THC, Cocaine, PCP, Opiates, and Amphetamines
☒ Other (Specify) **per. RCS panel**

Step 2 -- To be completed by collector, who must read specimen temperature within four minutes of collection. Check the box below if reading is within the specified range.

- ☒ 90.5° - 99.8°F/32.5° - 37.7°C or record actual temperature here _____

Step 3 -- (See Below on Copy Number 3 -- To be completed by donor)

Step 4 -- To be completed by collector:

Collector's Name **Edwards, Margaret M.** Date of Collection **02/15/90**

Collection Site **RCS/FFD**

Facility Name and Location

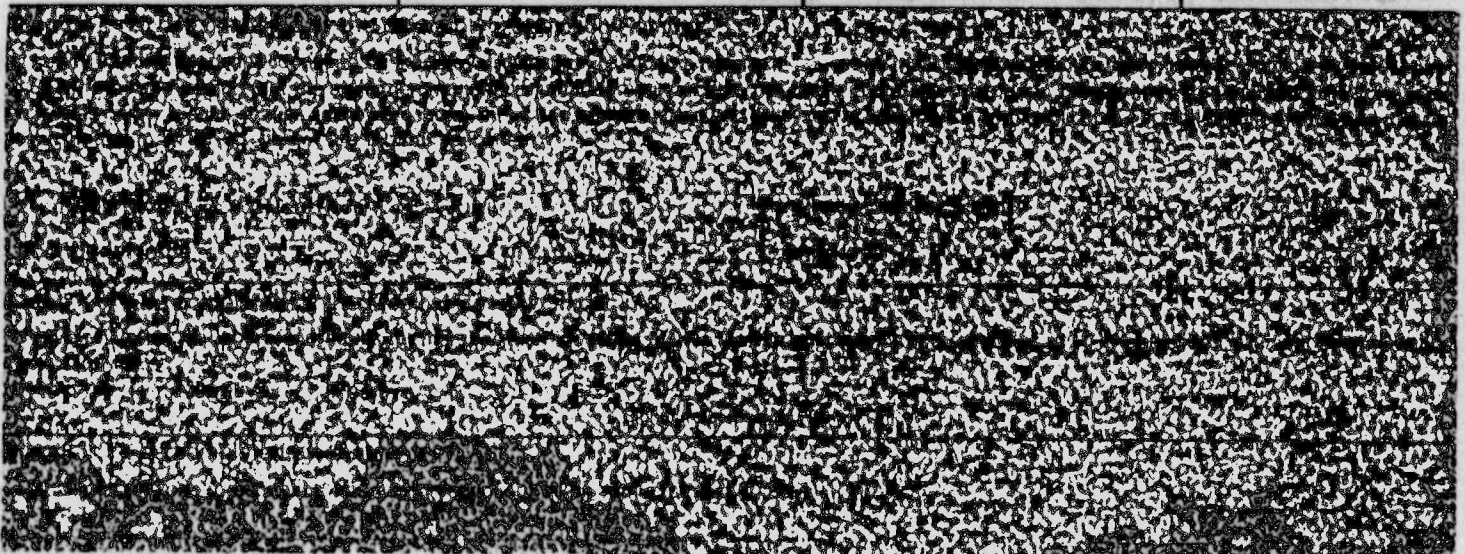
Collector's Remarks/Observations: **N/A**

I certify that the specimen identified on this form is the specimen presented to me by the employee signing the certification on Copy Number 3 of this form, and that the specimen bears an identification number identical to the number in STEP 1(a) above, and that it has been collected, labeled, and sealed in the donor's presence, as required by the instructions provided.

Margaret M. Edwards
Signature of Collector

Step 5 -- To be initiated by the collector and completed as necessary thereafter:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR	M. M. Edwards	02/15/90
To Courier	[REDACTED]	Federal Express	02/15/90



Name **Blind Sample**
(print) Last, First, M.I.

Date of Birth **N/A**

I certify I provided my urine specimen to the collector, and that specimen is in the shipping bottle marked with an identification number identical to the number in STEP 1(a) of this form. The bottle was sealed with a tamper-proof seal in my presence, and the identification label was affixed to the bottle.

N/A
Signature of Donor

N/A
Date

BENSINGER, DuPONT & ASSOCIATES, INC.

Tel: (301) 881-8210

6191 EXECUTIVE BOULEVARD
ROCKVILLE, MARYLAND 20852

Fax: (301) 816-1085

February 21, 1990

Mr. Robert P. Carter
Fitness for Duty Supervisor
Gulf States Utilities
Riverbend Station
P. O. Box 220
St. Francisville, LA 70775

BY FAX

Dear Mr. Carter:

This is to inform you that drug testing results were negative for the following specimen(s) submitted to American BioTest Laboratories, Inc.:

SPECIMEN(S) IDENTIFICATION #

900208-0008

The chain of custody was intact. The drugs for which American BioTest tested were:

T.H.C.
Cocaine
Phencyclidine
Amphetamine
Methamphetamine
Morphine
Codine
Methadone
Ambarbital
Secobarbital
Pentobarbital
Phenobarbital
Benzodiazepines
Methaqualone

Specimens received by ABT: 02/09/90
Results reviewed by BDA: 02/20/90

Sincerely,

CONFIDENTIAL

THIS DOCUMENT CONTAINS INFORMATION
PROTECTED BY THE CONFIDENTIALITY
PROVISIONS OF CURRENT FEDERAL LAW.

Robert L. DuPont
Robert L. DuPont, M.D.
Medical Review Officer

CERTIFICATE OF ANALYSIS

This is to certify that the lot numbers listed below have been certified
by immunoassay and gas chromatography/mass spectrometry to contain
the concentration of drugs specified.

Mahmoud A. Elsohly
Mahmoud A. Elsohly, Ph.D., Laboratory Director

QC SPECIMEN CONTROL LOG

Lab: 03U Date Shipped: 02/07/90

BATCH#	NAME	SSN Number	DRUG ng/ml	ACCESS#	LABORATORY RESULTS
122089B	[REDACTED]	[REDACTED]	AMP 1632 MEAMP2283	<i>Sub. # 2-8-90</i>	<i>90 02 03-0008</i>

*Name and SSN Number intentionally
deleted to protect privacy.*

*same
2/18/90*

Shawna
Shipment Prepared By

D. A. Bluff
Reviewed By

Date	Received By	Received By	Purpose of Change of Custody
FEB 07 1990	<i>Shawna</i>	Federal Express	Shipping
2/8/90	<i>T. Tolan</i>	<i>C. M. Corbin</i>	