



Entergy

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W. K. Hughey
Director
Nuclear Safety & Regulatory
Affairs

September 3, 1998

U.S. Nuclear Regulatory Commission
Mail Station P1-37
Washington, D.C. 20555

Attention: Document Control Desk

Subject: Grand Gulf Nuclear Station
Unit 1
Docket No. 50-416
License No. NPF-29
Fitness for Duty Unsatisfactory Performance Testing

GNRO-98/00072

Gentlemen:

On August 5, 1998 the Fitness For Duty (FFD) section at Grand Gulf Nuclear Station (GGNS) received a laboratory report from their confirmation laboratory, Smithkline Beecham Clinical Laboratory (SBCL) in Leesburg, Florida, showing that a positive spiked blind performance specimen was declared negative. GGNS's test of the aliquot indicated 76.42 ng/ml on the first run and 73.92 on the second run.

In accordance with 10CFR26, Appendix A, Paragraph 2.8e(4), an investigation was conducted into the unsatisfactory performance testing result from SBCL. On August 5, 1998, Dr. Randy Easterling (MRO Officer) requested SBCL to rerun for PCP only by Gas Chromatography/Mass Spectrometry (GC/MS) with a quantitative level by GC/MS. This reanalysis indicated a concentration level of 21.5 ng/ml which is directly below the threshold (cutoff) level of 25 ng/ml for PCP. On August 10, 1998, Dr. Randy Easterling requested an investigation into this incident since this was a blind performance sample which was certified to be positive. A week's response time was given to Dr. Schaffer of SBCL to investigate.

On August 7, 1998, GGNS FFD Section submitted a split sample of the same sample for analysis. Final results from the split sample indicated a concentration level of 65 ng/ml. GGNS tested the aliquot twice also. The first result was 62.54 ng/ml and the second result was 60.09 ng/ml. On August 13, 1998, Dr. Easterling requested that the investigation also include the disparity between SBCL's analytical results of the aliquots of the sample.

Other drug testing facilities operated by Entergy have not had any unsatisfactory performance testing results from this particular lot number.

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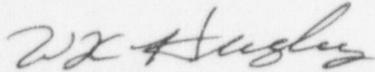
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Dr. Schaffer, with the SBCL, could give no explanation to the disparity between the two tests. After SBCL's and GGNS's investigations, no apparent cause for the discrepancy could be found. GGNS will continue its blind performance testing program with the laboratory and carefully monitor its performance. However, we believe at this time, this event is an isolated anomaly and no further action is planned.

The investigation report from SBCL was submitted to GGNS on August 19, 1998, and is being transmitted to the NRC within 30 days as required by 10CFR26, Appendix A, paragraph 2.8e(4). Attached are the summary of events, requests for investigation, and the investigation response.

If you have any questions regarding this matter please contact Mr. Harold Reed, Supervisor, Investigations and FFD, at(601) 437-2751.

Yours truly,



WKH/rrj
attachments

cc: (See Next Page)

September 3, 1998

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cc:

Ms. J. L. Dixon-Herrity, GGNS Senior Resident (w/a)
Mr. L. J. Smith (Wise Carter) (w/a)
Mr. N. S. Reynolds (w/a)
Mr. H. L. Thomas (w/o)

Mr. E. W. Merschoff (w/a)
Regional Administrator
U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Mr. J. N. Donohew, Project Manager (w/2)
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Mail Stop 13H3
Washington, D.C. 20555

Summary of Events

- August 5, 1998 Blind Performance specimen Partial SSN#06-6953 SID#1373E was reported to GGNS as negative by GGNS's confirmation laboratory, Smithkline Beecham Clinical Laboratory. Dr. Randy Easterling (MRO Officer) requested re-analysis of the sample by GC/MS for PCP only with a quantitative level. A memo from Dr. Easterling was faxed to Dr. Schaffer from SBCL with this request.
- August 6, 1998 A memo from Dr. Easterling to Dr. Schaffer was faxed requesting all information concerning the initial testing.
- August 6, 1998 Donna Williams, GGNS FFD, received a call from Dr. Schaffer concerning the retest of the sample. The quantitative level was 21.5ng/ml which is directly below the cutoff of 25ng/ml.
- August 7, 1998 James Collins, Lab Technician at GGNS, sent the Split Sample to SBCL for testing. This sample was sent individually.
- August 10, 1998 Dr. Easterling faxed a letter to SBCL (GEO98-00070) requesting an investigation of sample Partial#06-6953 SID#1373E. A week was given to SBCL to complete the investigation.
- August 10, 1998 Harold Reed, Supervisor of Fitness For Duty, requested that the aliquot sample be rerun at GGNS. Results were showing a reading on the 1st run 62.54ng/ml and a 2nd run of 60.09ng/ml. These results were again showing a positive reading for PCP. Cutoff for PCP is 25ng/ml.
- August 10, 1998 Donna Williams talked with Mr. Charles Rushing with Consolidated Technologies concerning their certified samples. He stated that their samples were only guaranteed for three months. This sample was from lot# 1745609. This sample was ordered from them in June 1997. But, he also said it also depended on how the sample was preserved. It was stated that they have never had any problem with lots of PCP, only THC. He checked with two labs because they had used sample from this same lot number. Their results were ranging from 47ng/ml to 52ng/ml. He stated that they had tested samples they had for three years and never had any problems with lots.

- August 12, 1998 Donna Williams called ANO to talk to the lab concerning lot #1745609. Steve Kaufman checked their records to see if they had received any certified samples from Consolidated Technologies. He was not able to find the lot number among the ones they had used.
- August 12, 1998 Charles Rushing from Consolidated Technologies faxed a copy of two results from the same lot number. Scott & White Lab results gave a result of 47ng/ml and the Associated Regional and University Pathologists, Inc., result was 52ng/ml. Each lab received a positive test result of PCP from the same lot number.
- August 13, 1998 Received final results from the second split sample sent to SBCL Accession #469590H. Results by GC/MS showed positive for PCP with a quantitative level of 65ng/ml. Dr. Randy Easterling (MRO) sent a letter to SBCL requesting further investigation into the disparity in the test results.
- August 20, 1998 Donna Williams called Dr. Schaffer at 13:48p.m. and left message on voice mail. Requested that he return call no later than August 21, 1998. Dr. Schaffer returned call at 14:45p.m. He stated that he does not understand what happened. He has no explanation for the results. But, he faxed a copy of his investigation of this matter and also sent the original investigation by overnight mail.

Date: August 5, 1998
To: Dr. M. Schaeffer
DPL/Smithkline
From: Dr. Randy Easterling 
MRO Review Officer
Subject: Discrepancy in Test Results

Dr. Schaeffer, we received test results for the specimen listed below. Our test show different results and we are requesting a quantatative level by GC/MS on this sample. Please rerun sample for PCP only by GC/MS.

Partial SSN# 06-6953 Coll: 7-29-98
SID# 1373E
Coll Time: 10:00 Accession # 458374H

Your immediate response to this matter will be greatly appreciated. If you have any problems please call me at (601) 437-2481.

Date: August 6, 1998
To: Dr. M. Schaeffer
DPL/Smithkline
From: Dr. Randy Easterling 
MRO Review Officer
Subject: Discrepancy in Test Results

Dr. Schaeffer, concerning the memo received from me August 5, 1998 on a discrepancy in test results. After discussing this with the Supervisor of Fitness For Duty this problem may be a violation and result in a CR. All information concerning the initial testing must be sent to us for documenting. The discrepancy was very wide range in test results that the probability of a negative result is very unlikely. Listed below is the information on the specimen.

Partial SSN#06-6953 Coll: 7-29-98
SID#1373E
Coll Time: 10:00 Accession # 458374H

Please answer this request immediately. Also, do rerun this sample with a quantatative level for PCP by GC/MS. If there is any problem with honoring this request please call at (601) 437-2481.

**Entergy
Operations**

Entergy Operations, Inc.

August 10, 1998

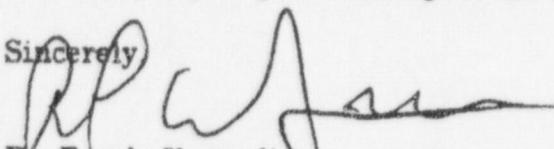
Dr. Michael Schaffer
Doctors and Physicians Laboratory
801 East Dixie Avenue
Post Office Box 491100
Leesburg, Florida 34749-1100

GEO98-00070

Dear Dr. Schaffer:

On July 30, 1998, the Fitness for Duty Section (FFD) sent a urine specimen to Doctors and Physicians Laboratory (DPL) for drug screening. The sample was a BioRad blind performance sample that was certified to be positive for PCP (Phencyclidine) metabolites at our threshold level. On August 5, 1998, DPL sent results back to the FFD section stating the sample was negative for any drug metabolites (See Attachment). Because this is an unsatisfactory performance testing result, the Nuclear Regulatory Commission's 10CFR 26 requires that we ask DPL to conduct an investigation into how this occurred and how DPL will take action to prevent future events from occurring. Doctors and Physicians Laboratory shall furnish the FFD section with a record of the investigative findings and the corrective actions taken by your laboratory. This record shall be signed by the individual(s) responsible for the day-to-day management and operation of the laboratory. We ask that you complete your investigation within one week of receipt of this letter so we may report your findings to the NRC.

Sincerely,


Dr. Randy Easterling
Medical Review Officer

RE./dw
attachment/enclosure
cc: H. Cooper
H. L. Reed
W. Eaton
Central File
Corporate File



August 13, 1998

Dr. Michael Schaffer
Doctors and Physicians Laboratory
801 East Dixie Avenue
Post Office Box 491100
Leesburg, Florida 34749-1100

Dear Dr. Schaffer:

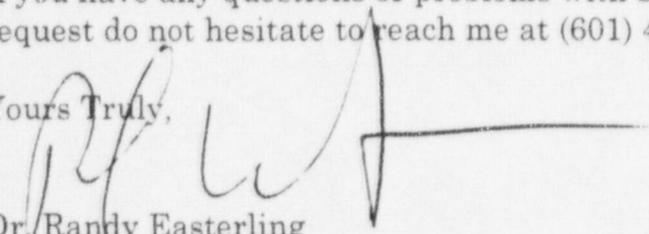
Fitness For Duty received test results that show a large discrepancy in the final results by GC/MS. As you are aware of the problem we had with the first results on the sample listed below. DPL first split sample results were negative. Requested a rerun by GC/MS for PCP only and received a 21.5ng/ml. GGNS shipped the second split sample to DPL on August 7, 1998 and final results were positive on PCP with a quantatative level of 65ng/ml. GGNS received on the first run of the aliquot a 76.42ng/ml and the second run 73.92 ng/ml. Again, the aliquot was tested on August 10, 1998 and the first run was 62.54ng/ml and the second run was 60.09ng/ml. As you can see the disparity between DPL's results and GGNS. We need all information from the first initial test to the final of both test listed below. An investigation into this matter must be completed and returned to GGNS within a week of the date of this letter.

1st Split sample: Partial#06-6953 SID#1373E
Coll Time: 10:00 Coll Date: 7-29-98
Accession #458374H

2nd Split sample: Partial#06-6953 SID#1373E
Coll Time: 10:00 Coll Date: 7-29-98
Accession #469590H

If you have any questions or problems with being able to fulfill this request do not hesitate to reach me at (601) 437-2481.

Yours Truly,


Dr. Randy Easterling
Medical Review Officer

SKB
SmithKline Beecham
Clinical Laboratories

Michael I. Schaffer, Ph.D.

August 19, 1998

Randy Easterling, M.D., Medical Review Officer
Entergy Operations, Corporate Security
Fitness for Duty
Grand Gulf Nuclear Station
P.O. Box 756
Port Gibson, MS 39150

RE: Partial SS# 06-6953
SID# 1373E

Dear Dr. Easterling:

Pursuant to your request we have instituted an investigation into the above mentioned matter and the results follow.

1. Specimen 06-6953, SID # 1373E was received into the laboratory, and logged into the computer system by K. Stack on 08/05/98.

The specimen was aliquotted and placed into a NRC batch for initial immunoassay screening. The specimen did not screen positive for any of the five analytes, and was therefore signed out as negative on 08/05/98. A review of the PCP channel showed some activity, but less than what would be required for a presumptive positive.

2. On 08/05/98, we received a correspondence from Dr. Easterling noting a different result, and requesting a quantitative level by GC/MS for PCP only.
3. The sample was re-aliquotted and submitted for analysis by GC/MS for PCP, and was determined to have 21.5 ng/mL of PCP.
4. Subsequently, a second sample was submitted to the laboratory, and received on 08/10/98. It had a partial SS # on the chain of custody form of 06-6753, and a partial SS # on the bottle of 06-6953. The sample was deemed test in question, and the facility was called, to obtain an affidavit that the correct number should be 06-6953.

The specimen was then processed, and it did in fact screen positive for PCP, and then went onto confirmation, and confirmed at a concentration of 65 ng/mL.

801 E. Dixie Avenue, Leesburg, FL 34748 • 800-342-9520

5. Obviously, there is a discrepancy here, since the first specimen submitted did not meet the calibration cutoff for the PCP immunoassay, and therefore did not go onto confirmation. The result of the GC/MS analysis of that specimen, did in fact show the presence of PCP, but at a concentration below the cutoff level of the assay. This was consistent with the first analysis.
6. The second analysis proved the presence of the analyte at a concentration of 65 ng/mL.

The matter is somewhat unresolved, as I cannot determine why or how the two samples gave differing results.

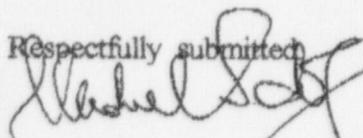
I would be glad to forward the first sample to the laboratory of your choice for a second GC/MS analysis for the presence of PCP.

At the present time I am completely baffled, and can find no answer for this occurrence. We of course, will maintain both samples frozen for one years time, and if so desired will comply with any additional requests that you could make, that we could comply with.

I am sorry for the problem and issues that it has created, and of course would be happy to discuss the matter with you at your earliest convenience.

At this time, I can think of no other issues left pending here in Leesburg, but am open to any suggestions that you may have.

Respectfully submitted,



Michael I. Schaffer, Ph.D., D.A.B.F.T.
Director of Toxicology/Manager
Responsible Person

XC: Documentation of two tests