



GPU Nuclear Corporation
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Parsippany, New Jersey 07054
201-316-7000
TELEX 136-482
Writer's Direct Dial Number:

December 8, 1990
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C311-90-2148
C321-90-2027
4410-90-L0081

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

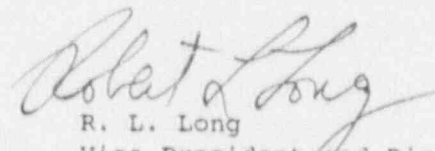
Gentlemen:

Subject: Three Mile Island Nuclear Station Unit 1 (TMI-1)
Three Mile Island Nuclear Station Unit 2 (TMI-2)
Oyster Creek Nuclear Generating Station (OC)
Operating License and Docket Nos:
DFR-50/Docket 50-289 (TMI-1)
DPR-73/Docket 50-320 (TMI-2)
DPR-16/Docket 50-219 (OC)

Fitness For Duty (FFD) Program Report on
an Unsatisfactory Performance Testing Incident

Pursuant to 10 CFR 26, Appendix A, Subpart B, Section 2.8(e)(4), GPU Nuclear Corporation (GPUN) hereby submits a FFD Program Report for an investigation involving an unsatisfactory performance test result ("false negative") by a DHHS certified laboratory under contract to GPUN to perform drug testing as required by 10 CFR Part 26 and GPUN's Fitness For Duty Program.

Very truly yours,


R. L. Long
Vice President and Director
Corporate Services

RLL/GMG/plp
cc's on next page

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PDR ADOCK 05000219
S PDR

GMG:C3112148

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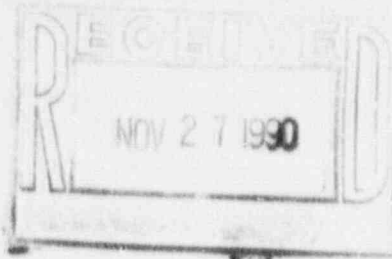
17 135

TE15

cc: Administrator, NRC Region I
NRC Resident Inspector, OCNCS
OC Project Manager

TMI-1 Project Manager
Senior NRC Resident Inspector, TMI-1

TMI-2 Project Manager, PDNP Directorate



GPU Nuclear Corporation
Post Office Box 388
Route 9 South
Forked River, New Jersey 08731-0388
609 971-4000
Writer's Direct Dial Number:

November 12, 1990

Paula Childs
1912 Alexander Drive
Burlington, North Carolina 27709

SUBJECT: Title 10 Code of Federal Regulations Part 26, Appendix A,
Subparagraph B, Step 2.8 [E] [4] Fitness for
Duty Investigations

Dear Ms. Childs,

On May 18, 1990, the GPU Nuclear (GPUN) acting Medical Director, Judy Venet, issued Quality Deficiency Report (QDR) #90-025. This report identified per 10CFR26, Appendix A, Subparagraph B, Section 2.8 [E] [4] a report of an unsatisfactory performance testing result. This resulted in an investigation to determine the cause and corrective actions for the unsatisfactory performance test. This unsatisfactory performance test was a blind sample designated A303-762 which was expected to result in a positive THC reading.

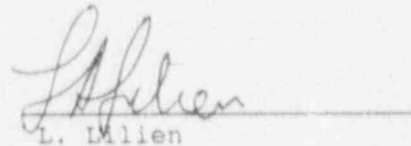
Elschly Laboratories which prepared the blind sample reported 172 ng/ml of THC. The Roche's Burlington, N. C. laboratory (the lab utilized to test the sample was contrary to GPUN instructions) showed a negative result on the initial screening of this blind sample.

Roche Labs responded to the QDR (on 6/14/90) that they performed a retest on the sample which resulted in a second negative screen and a result of 130 ng/ml on the GCMS confirmation assay at their Raritan, N. J. facility. An aliquot of this Roche sample was sent to Dr. Elshly (the blind sample preparer) for further tests. Elshly Labs retest reported a negative screen result and a result of 109 ng/ml on the GCMS confirmation assay. The Raritan lab also requested and received a aliquot of the original blind sample control batch from Elshly Labs. The Raritan analysis gave a THC value of 153 ng/ml which is within the target range of $172 \pm 20\%$ given by Elshly Labs.

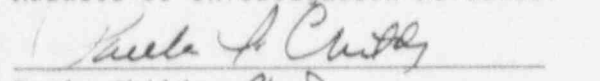
This initial response from Roche Bio Medical Laboratories on the QDR was not accepted by the GPUN Medical Department since no cause could be attributed to the problem. This resulted in a the performance of two audits. The first being O-COM-90-13 of Elshly Labs in Oxford, Miss. (Audit Report enclosed) and a second Audit of Roche Labs in Research Triangle, North Carolina (Audit Report enclosed). Note that the Burlington, N.C. Lab was moved to Research Triangle, N.C., this includes both equipment and procedures. Both audits were performed using a technical specialist familiar with similar laboratory testing. Both labs' procedures and controls were found to provide satisfactory analysis of urine samples for drugs. The audit teams could not attribute the false readings reported to either lab. Therefore no corrective action for the false negative result is required by GPU Nuclear; however each lab may wish to pursue further procedural analysis if any corrective measures could impact on the finding.

Per 10CFR26, this letter and its attachments shall be filed as the record made of the investigative findings and corrective actions. Since no process errors were detected, no corrective actions need be taken. But, as required by law, this record shall be signed and dated by the individual(s) responsible for the day to day management and operations of the DHHS certified lab. Please denote this by signing the attached page, signifying your review of the records of this investigation. This investigation will then be reported to the Nuclear Regulatory Commission as required by 10CFR26, Appendix A, Subparagraph D,2.8 [E][4] since the results achieved were not what was expected. The NRC will ensure notification of the finding to DHHS.


John Solakiewicz


L. Lilien

Results of Investigation Reviewed:

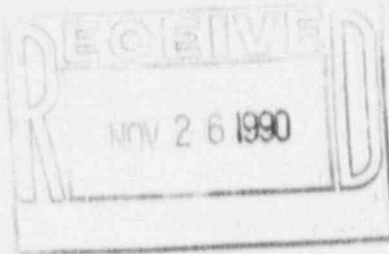

Paula Childs, Ph.D.
Director, Forensic Toxicology

(90-077)

Attachments

cc: M. Bircsak, Roche Labs
F. Fiedler, Dir. Nuclear Assurance
G. Busch, Licensing Gener. Mgr.
J. Rogers, Licensing Engineer
G. Gurican, Engineer Sr. I Licensing
J. Venet, Mgr. Medical Svcs. (acting)
S. Singleton, Mgr. Human Resources/Program Devel.
R. Markowski, Mgr. QA Prog. Devel. Audit
D. Hosking, QA Mgr., TMI
D. Corett, Tech. Anal. Sr. II QA Audit.
P. Magitz, Engr. Sr. I QA Audit.
B. Alatary, QA Audits Manager

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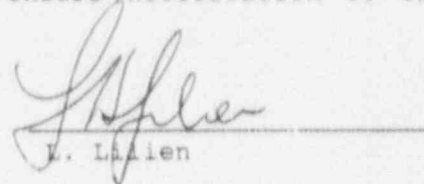
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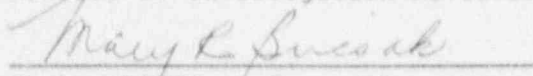
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John Solakiewicz


L. Lillian

Results of Investigation Reviewed:


Paula Childs, QA Manager
RBL - North Region

(90-377)

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P. Fiedler, Dir. Nuclear Assurance
G. Busch, Licensing Gener. Mgr.
J. Rogers, Licensing Engineer
G. Gurican, Engineer Sr. I Licensing
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D. Corett, Tech. Anal. Sr. II QA Auditor.
P. Magitz, Engr. Sr. I QA Auditor.
B. Alatary, QA Audits Manager



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609 971-4000
Writer's Direct Dial Number:

November 12, 1990

Dr. Elsohly
1215-1/2 Jackson Avenue
Oxford, Mississippi 38655

SUBJECT: Title 10 Code of Federal Regulations Part 26, Appendix A,
Subparagraph B, Step 2.8 [E] [4] Fitness for
Duty Investigations

Dear ~~Ms. Childs~~, ^{Dr. Elsohly}

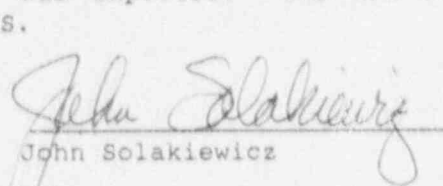
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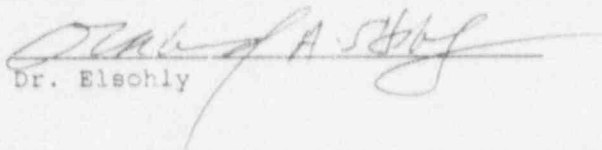
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John Solakiewicz


L. Lilien

Results of Investigation Reviewed:


Dr. Elschly

(90-078)

Attachments

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