GPU Nuclear

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

January 4, 1991
C000-91-1167
C311-90-2157
C321-90-2039
4410-90-L0089

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:
DPR-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 a 2nd
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 ("false negative") performance test result 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.

Sincerely,

Robert L Long

R. L. Long
Vice President and Director
Corporate Services

RLL/GMG/plp
cc's on next page

GMG:C3112157

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

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

TMI-2 Project Manager, PDNP Directorat

GMG:C3112157

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One Upper Pond Road
Parsippany, New Jersey 07054
201-316-7000
TELEX 136-482
Writer's Direct Dial Number:

November 29, 1990

Roche Biomedical Laboratories
Donald W. Long Ph.D.
6370 Wilcox Road
Dublin, Ohio 43017

SUBJECT: Title 10 Code of Federal Regulations Part 26, Appendix A, Section 2.8 (e) (4) Fitness-For-Duty Investigations

Dear Dr. Long,

On September 14, 1990, the GPU Nuclear (GPUN) acting Medical Director, Judy Venet, contacted you regarding the processing of specimen # 228-488-5027 which was a spiked sample from Elsolay Laboratory and reported back to GPUN by Roche as "negative". 10CFR26 requires an investigation to determine the cause and corrective actions for the unsatisfactory performance test.

Roche Biomedical Laboratories responded to Judy Venet on September 17, 1990 indicating a clerical error and not a testing error caused this incident.

Roche Biomedical Laboratories further responded in the November 17, 1990 letter with corrective action as follows:

> "In this case the reviewer did perform the task but failed to find and correct the initial error. We have met with the staff to reemphasize the critical nature of the review process. In addition we are now performing random audits of the data by a third reviewer to insure that the process is being completed properly.
>
> In 1991 we will introduce an on line computer system which will eliminate the clerical function."

Based upon this response GPU Nuclear accepts this corrective action.

Per 10CFR26, this letter and its attachments shall be filed as a record made of the investigative findings and corrective actions. 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 laboratory.

Please countersign this page, signifying your review of the records of this investigation and your commitment to implement the corrective actions as in your November 17, 1990 letter. This investigation will then be reported to the Nuclear Regulatory Commission (NRC) as required by 10CFR26, Appendix A, Section 2.8 (e) (4) since the results achieved were not what was expected. The NRC will ensure notification of the finding to DHHS.

S. S. Singleton

D. L. Herfel

Results of Investigation Reviewed and Concurrence by:

Donald W. Long 12-7-90

Donald W. Long, Ph.D.
Director of Toxicology

AI90075C

GB

attachments

cc: B. W. Alatary - QA Audits Manager
G. B. Brandt - Administrator, FFD
R. D. Fenton - Director, Human Resources
P. B. Fiedler - Director, Nuclear Assurance
G. M. Gurican - Engineer Sr. I Licensing
D. L. Hosking - QA Manager, Three Mile Island
R. L. Long - Director, Corporate Services
J. K. Venet - Acting Medical Director
J. F. Wilson - Legal Services Director

Roche Biomedical Laboratories
a subsidiary of Hoffmann-La Roche Inc.

Roche Biomedical Laboratories, Inc.
6370 Wilcox Road
Dublin, Ohio 43017

Telephone (614) 889-1061

November 17, 1990

Judy Venet
GPU Nuclear
P. O. Box 308
Forked River, NJ 08731

Dear Ms. Venet,

In my letter of September 17, 1990 I stated that the processing of specimen # 228-488-5027 resulted in the false negative report that was generated. In this response I summarized that testing data and indicated that the mistake resulted from a clerical error and not from a testing error.

Clerical errors of this nature should have been resolved by our dual technologist review process prior to release of the data. In this case the reviewer did perform the task but failed to find and correct the initial error. We have met with the staff to reemphasize the critical nature of the review process. In addition we are now performing random audits of the data by a third reviewer to insure that the process is being completed properly.

In 1991 we will introduce an on line computer system which will eliminate the clerical function of results entry.

Respectfully,

Donald W Long

Donald W. Long, Ph.D.
Director of Toxicology

DWL/pr

GPU Nuclear

Memorandum

Subject: FALSE NEGATIVE RESULT
REFERENCE 10 CFR PART 26(e)4
"LICENSEE BLIND PERFORMANCE TEST PROCEDURES"

Date: September 27, 1990

From: Judy Venet
Medical Director (Acting)

Location: Oyster Creek
6330-M90-097

To: Cortney Smyth
Licensing Manager

TMI-1

On September 14, 1990 the licensee MRO was notified that an aberrancy between a blind sample with a known quantity of secobarbital and the testing laboratory (Roche) results occurred on August 17, 1990. The licensee notified the following:

Donald W. Long, Ph.D.
Director of Toxicology
Roche Biomedical Laboratories, Inc.
Dublin, Ohio

Mahmoud A. ElSohly, Ph.D.
President/Laboratory Director
ElSohly Laboratories, Inc.
Oxford, Mississippi

Also notified were the following:

QA Engineering Manager, Parsippany
Manager, Human Resources Program Development
Nuclear Assurance Division Director

Dr. Long and Dr. ElSohly conducted investigations within their own organizations and the results are attached. Roche identified the root cause as human error at their facility. Please make appropriate NRC notification of this event.

If I may be of any further assistance, please contact me.

Judy Venet

Judy Venet
(ext. 4890)

Attachments

JV/plc

cc: B. W. Alatary - QA Engineering Manager
M. A. ElSohly, Ph.D. - ElSohly Laboratories
P. B. Fiedler - Director, Nuclear Assurance
D. W. Long, Ph.D. - Roche Biomedical Laboratories, Inc.
S. S. Singleton - Manager, Human Resources Program Development
Writer's file

Roche Biomedical Laboratories

a subsidiary of Hoffmann-La Roche Inc

Roche Biomedical Laboratories, Inc.
6370 W. Cox Road
Dublin, Ohio 43017

Telephone (614) 889-1061

September 17, 1990

Judy Venet
GPU Nuclear
P. O. Box 388
Forked River, NJ 08731

Dear Ms. Venet,

I have reviewed the original screening results for specimen # 228-488-5027. This specimen screened positive by Emit and by Radioimmunoassay screen methods for barbiturates. However, the data was recorded incorrectly and the results were entered as a negative rather than as the positive which it truly was.

Because the results were entered as negative the sample never reflexed to GC/MS for final testing. This was clearly a clerical error and not a testing error. I hope that this is adequate response to cover your investigation into this sample.

Respectfully,

Donald W. Long

Donald W. Long, Ph.D.
Director of Toxicology

DWL/pr

SEP 2 4 1990

ElSohly Laboratories, Incorporated
1215½ Jackson Avenue
Oxford, Mississippi 38655
(601) 236-2609

September 17, 1990

Ms. Judy Venet, RN
Occupational Medical Manager
GPU Nuclear Corporation
P.O. Box 480
Route 441 South
Middletown, PA 17057-0191

Dear Ms. Venet:

RE: Batch 020990C, SS #289-16-7885, Secobarbital @ 628 ng/mL

As you requested, I am providing for your records the following information on our blind quality control batch #020990C which contains secobarbital at 628 ng/mL.

This batch was prepared on February 9, 1990, and certified in our laboratory by GC/MS triplicate analysis at 628 ng/mL on February 14, 1990. At the same time, the material was submitted to Northwest Toxicology for reanalysis. Their certification showed 641 ng/mL secobarbital on February 21, 1990. On May 15, 1990, a reanalysis in our laboratory showed secobarbital at 625 ng/mL, and still another reanalysis on September 10, 1990, showed secobarbital at 586 ng/mL.

As you are aware, we take an aliquot of the batch on the day each shipment is made. The aliquot taken when specimen SS #289-16-7885 was shipped indicates no problems whatsoever with the specimen. Raw data supporting all the above information are available, of course, should you desire copies.

Please let me know if we may provide you with additional information or be of assistance to you at any time.

With best regards.

Sincerely,

Mahmoud A. ElSohly, Ph.D.
President
Laboratory Director