PSE&G

Public Service Electric and Gas Company P.O. Box 236 Hancocks Bridge, New Jersey 08038-0236

Nuclear Business Unit

JUN 06 1996

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

Gentlemen:

**REPORT OF AN AMPHETAMINE "FALSE NEGATIVE"
USING MONOCLONAL ANTI-BODY REAGENT
SALEM AND HOPE CREEK GENERATING STATIONS
DOCKET NOS. 50-272, 50-311, AND 50-354**

In accordance with the requirements of 10CFR26, Appendix A, Public Service Electric and Gas Company (PSE&G), hereby informs the NRC of an unsatisfactory performance testing result by its Health and Human Services (HHS) certified laboratory. PSE&G has investigated the occurrence, found no programmatic quality control problem at the laboratory, and suggests that the matter does not require further investigation by the Department of Health and Human Services. The results of the technical evaluation performed and corrective actions taken by the HHS laboratory are attached for your review.

Should you have any further questions regarding this report we will be pleased to discuss them with you.

Sincerely,

D. R. Powell

D. R. Powell
Manager -
Licensing and Regulation

Attachments (6)

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C Mr. T. T. Martin, Administrator
USNRC Region I

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PSE&G

Public Service Electric and Gas Company P.O. Box 236 Hancocks Bridge, New Jersey 08038

Medical Department - Nuclear

TO: Richard W. Beckwith
Nuclear Licensing & Regulation

FROM: R. J. Mack, M.D.
Medical Director - Nuclear

M. T. Samuels
Medical Administrator - Nuclear

SUBJECT: **REPORT OF AN AMPHETAMINE "FALSE-NEGATIVE" UTILIZING MONOCLONAL ANTI-BODY REAGENT**

DATE: 5/22/96

On April 3, 1996, a blind performance test urine sample containing an amphetamine level of 2,899 ng/ml was reported as negative by the HHS laboratory.

We requested that Drugscan, Inc., perform a technical evaluation so that we could determine the cause of this problem. They reported that upon initial screening, using the Syva EMIT d.a.u. Monoclonal Amphetamine/Methamphetamine Assay, the sample tested just below the cut-off. GC/MS analysis of the sample showed approximately 3,000 ng/ml. of amphetamine; no methamphetamine was detected. This false negative appears to have been caused by the "poor" cross-reactivity of the Syva EMIT d.a.u. Monoclonal Amphetamine/Methamphetamine Assay to amphetamine alone, without the presence of methamphetamine in the sample. The Syva EMIT Monoclonal Amphetamine/Methamphetamine Assay is more sensitive to the illegal methamphetamine than to amphetamine alone. Syva **Polyclonal** Amphetamine/Methamphetamine Assay is more sensitive to the presence of amphetamine alone and also cross-reacts with a large variety of widely used legal substances such as decongestants and cold remedies. This results in large numbers of screen positives later determined to be negative by expensive GC/MS and d/I testing. These findings are documented in correspondence from Pennsylvania's Bureau of Laboratories (see enclosed letters). The use of Monoclonal Agents was intended to eliminate the expense of further expensive testing.

Drugscan states that the monoclonal reagent was designed to detect mixtures of amphetamine and methamphetamine and to identify illegal use at the screening stage. This blind sample contained amphetamine only.

On May 8, 1996, we received a Corrective Action Plan from Drugscan Inc., which states that they will research new screening immunoassays that demonstrate better sensitivity to amphetamines (see enclosed letter). In the future, we will purchase blind samples which include mixtures of both amphetamine and methamphetamine for submission to our **HHS** laboratory.

Based on the above explanation, I feel that this was a reagent issue (monoclonal vs. polyclonal reagents), and does not indicate a quality control problem in the laboratory. Laboratory scientists are well aware of this issue and are currently trying to resolve it and strike a balance between an excessive number of non-confirming screens and the ability to detect the use of legally manufactured amphetamine. This is not a laboratory performance or quality issue. Therefore, we suggest that this matter does not warrant further investigation by DHHS.

If you have any questions please contact me at (609)339-5600.