BOSTON EDISON
Pilgrim Nuclear Power Station
Rocky Hill Road
Plymouth, Massachusetts 02360

10CFR26
Appendix A
Subpart B
Section 2.8(e)(4)

E. T. Boulette, PhD
Senior Vice President – Nuclear

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

November 2, 1994
BECo Ltr. #94-119

SUBJECT: REPORT OF UNSATISFACTORY PERFORMANCE TESTING INCIDENT

Attached is Boston Edison Company's Report of Unsatisfactory Performance Testing Incident required by the Fitness for Duty Regulation, 10CFR26, Appendix A, Subpart B, Section 2.8(e)(4). Portions of the attached report contain privileged, or confidential commercial information as defined by 10CFR2.790(b)(1). You are requested to withhold this information from public disclosure based on the affidavit attached to the document.

Please refer any question or comments concerning this report to Mr. J.F. Neal of my staff at (508)830-8788.

E.T. Boulette

E.T. Boulette PhD

RLC/lam/unsat

Attachment

cc: U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Sr. Resident Inspector
Pilgrim Nuclear Power Station

NOTE

PORTIONS OF ATTACHED REPORT CONTAIN PRIVILEGED/CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM PUBLIC DISCLOSURE IN ACCORDANCE WITH 10CFR2.790(b)(1)

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ATTACHMENT

Summary of Unsatisfactory Performance Testing Incident

Description of Incident

SmithKline Beecham Clinical Laboratories of Philadelphia (SBCLP) on July 13, 1994, reported a false negative result to Dr. Jacqueline Hess, Medical Review Officer (MRO) of Boston Edison Company (BECo). Dr. Hess's medical staff transferred a Quality Assurance Systems (QAS) Lot #09304 urine sample into a SBCLP sample container and included it as blind sample #3319107 in a batch of BECo samples sent 7/7/94 to SBCLP. QAS states that Lot #09304 contains morphine in a concentration of 124 nanograms per milliliter (ng/ml) and codeine at 637 ng/ml. SBCLP reported the sample negative, but a sample with 300 ng/ml or more of codeine is positive by Health and Human Services (HHS) and NRC regulation.

Investigation of Incident

On August 17, 1994, Quality Systems Incorporated (QSI) under contract to BECo performed an audit of SBCLP in response to the false negative performance test result reported to BECo for specimen #931769A that was produced from test lot #09304. The test lot was supplied to BECo by Quality Assurance Systems (QAS).

BECo's audit team technical specialist reviewed the codeine analysis reports for the specimen and several others to determine if there was a recurring problem with interferences in the testing/analysis process. Based on this review there did not appear to be a trend which would indicate the false negative was of a recurring nature but rather an isolated occurrence.

The technical specialist also reviewed the Standard Operating Procedure for performing the analysis to determine if there appeared to be a procedural problem with the opiates analysis. No procedural problems were identified by the audit team.

Lead Auditor Review

The lead auditor discussed the internal procedure followed by SBCLP for initiating corrective action. There are several procedures that address performance test "misses" but none of them apply directly to the situation encountered with the BECo test specimen. Due to the lack of a formal mechanism to report and follow up on utility performance test problems a finding was issued.

Corrective Action

Corrective action taken by SBCLP involved a review of the specimen handling, processing, test data and reporting activities. No errors or problems were identified. The review was documented in a letter sent to BECo (enclosed). The review stated that the "source of the interference in the blind specimen was unknown and represented an isolated incident".

To address the audit finding regarding the lack of a formal mechanism to report and follow up on utility performance test problems, SBCLP revised their quality assurance procedure to specifically include the handling of unacceptable blind specimens.

Conclusion

As a result of the August 17, 1994, audit, one audit finding was issued for corrective action. Corrective action taken to address the audit finding was reviewed by the audit team and found to be acceptable. The audit finding was closed. SBCLP's reasoning for not requiring further corrective action as a result of the false negative performance test was accepted by the audit team. Additional testing performed by an independent lab (Drugscan) was also unable to isolate and identify the interfering contaminant that lead to the false negative result on specimen #931769A. No further corrective action was deemed necessary.

Attachments

- SmithKline Beechman Clinical Laboratories letter to Jacqueline Hess, MD, dated July 29, 1994.
- Quality Systems Incorporated letter to Robert J. Kennedy, dated August 23, 1994.
- SmithKline Beechman Clinical Laboratories letter to Mr. Robert Mullens, dated August 23, 1994.
- Drugscan letter to Jacqueline Hess, MD, dated September 30, 1994.