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January 31, 1991 MN-91-26

SEN-91-41

UNITED STATES NUCLEAR REGULATORY COMMISSION

Attention: Document Control Desk

Washington, DC 20555

References:

(a) License No. DPR-36 (Docket No. 50-309)

(b) 10 CFR 26, Appendix A, Subpart B

Subject: Fitness for Duty Blind Performance Test Program

Gentlemen:

In accordance with Section (e)(4) of Reference (b), enclosed is a report by Dr. Robert Willette of Duo Research, Inc. concerning Maine Yankee's Blind Performance Test Program. Duo Research, Inc. is contracted by Maine Yankee to coordinate the Performance Test Program. The report concerns an investigation of two incidents associated with blind testing. As stated in the report, the incidents have been resolved; however, we continue to monitor the performance of the certified lab.

For the period January - December 1990, Duo Research, Inc. reported a cumulative accuracy score of 99.4%; a positive correct score of 97% and a percentage positives of 20%. The Blind Performance Test Program indicates that the testing lab is meeting the requirements of the Fitness for Duty Program.

Should you have any questions on the enclosed material, please contact us.

Very truly yours,

SENICOL

S. E. Nichols, Manager Nuclear Engineering & Licensing

SEN/sjj

Enclosure

c: Mr. Thomas T. Martin Mr. E. H. Trottier Mr. Charles S. Marschall

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Laboratory Inspection Report

On December 10, 1990, Dr. Robert Willette conducted an inspection and record audit of the SmithKline Beecham Clinical Laboratories in Norristown, Pennsylvania. The aAudit report was submitted previously through New Hampshire Yankee.

During the record audit, three results from blind quality control samples were investigated. A sample containing damphetamine was reported as negative, whereas a blank sample, submitted at the same time, was reported as positive for amphetamine. A review of the records at the laboratory revealed that all identifying information contained on the submitting custody forms for both samples was in complete agreement with the information on the bottle label. The test records were consistent with the reported results. It can only be concluded that the two samples were interchanged at the collection site at the time they were prepared for shipment to the laboratory.

For a result received in August, what appears to be the last example of the difficulties encountered with the screening for the THC metabolites described in the previous inspection report (see September 4, 1990 monthly report). This was a sample containing approximately 130 ng/mL of THC-9-acid, but failed to screen positive at the 100 ng/mL cutoff. As noted earlier, the laboratory has since modified the manner in which it is establishing its cutoff for its cannabinoid assay. We have not received any further examples of this since September. We did receive one further positive for a sample containing about 75 ng/mL of metabolite during September (after the previous inspection). Since September three samples containing the 75 ng/mL and submitted through New Hampshire Yankee, have been reported correctly.

We will continue to monitor this situation closely to ensure that the laboratory's performance on detecting cannabinoids does not become unsatisfactory.