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JAFP-96-0029

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Mail Station P1-137
Washington D.C. 20555

Subject: James A. FitzPatrick Nuclear Power Plant (JAFNPP)
Docket No. 50-333
10 CFR 26, Appendix A, "Guidelines For Drug And Alcohol Testing Programs"

Gentlemen:

This report is written in accordance with 10 CFR 26, Appendix A, Section 2.8, "Quality Assurance and Quality Control" requirements.

On December 15, 1995, New York Power Authority (NYPA) identified a urine blind test specimen (BTS) test result that had been incorrectly reported (Positive Amphetamines BTS reported as negative) by the facilities Department of Health and Human Services (H.H.S.) testing laboratory, Corning MetPath Clinical Laboratories. Due to the presence of an interfering agent found in the BTS during sample analysis, and because of the laboratory's reporting standards and regulations, the urine BTS was reported as negative. A recent similar event involving the reporting of a false negative BTS by this H.H.S. (reference letter JAFP-95-0549 dated 12/14/95 to the NRC), prompted the Power Authority to immediately contact MetPath and request an aliquot of the Test Specimen T21922 be forwarded to an alternate testing laboratory for analysis.

The subject test specimen Number T21922 was prepared by Forensic Control Company. Forensic Control Company laboratory prepared the test specimen for Bensinger, DuPont and Associates (BDA), the company contracted by JAFNPP to supply BTS samples.

TEST SPECIMEN NUMBER T21922 SAMPLE COMPOSITION AS PREPARED BY FORENSIC CONTROL COMPANY:

Matrix - Human urine
Identity and Concentration of Amphetamines -
Amphetamines - 310 ng/ml
Methamphetamines - 1600 ng/ml

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The Specimen Lot was confirmed using gas chromatography/mass spectrometry (GC/MS) technique at three H.H.S. certified laboratories prior to its being placed in service on September 5, 1995. Laboratories confirmed their specimens within ±20% of the target levels with no indications of interfering agents within the test specimens.

Specimen Number T21922 was entered into normal specimen shipment by JAFNPP and received by Corning MetPath Clinical Laboratories on December 7, 1995. On December 7, 1995, Specimen Number T21922 was screened positive for Amphetamines by Enzyme Multiplied Immunoassay Technique (EMIT) testing. A confirmation test by GC/MS was performed on December 7, 1995 with results indicating the presence of Amphetamine at a concentration of 300 ng/ml and Methamphetamine at a concentration of 1614 ng/ml. However, due to the presence of an interfering substance with qualifying ions, the specimen could not be reported as positive. On December 8, 1995, the GC/MS test was repeated with the same concentration results. The interfering agent was still present and could not be eliminated. Laboratory criteria could not be met, and due to procedural guidelines, Corning MetPath Clinical Laboratories was required to report test results for Test Specimen T21922 as negative.

CORRECTIVE ACTIONS:

On November 15, 1995, NYPA identified a similar finding involving the incorrect reporting (Positive Amphetamines BTS reported as negative) of a test specimen by the same H.H.S. testing laboratory. This incident also involved the presence of an interfering agent found in the urine specimen which resulted in the BTS being reported as negative.

On December 15, 1995, upon identifying this reported false negative, NYPA informed Corning MetPath of the condition, requested that any remaining test sample of Test Specimen T21922 be retained, and that an investigation be started into the analysis of specimen. On December 18, 1995, NYPA requested that an aliquot of Test Specimen T21922 be sent from Corning MetPath to an alternate H.H.S. testing laboratory, Laboratory Corporation of America (LabCorp), for analysis. The results obtained by LabCorp, using GC/MS, were positive for amphetamine and methamphetamine, within target levels and without indication of the presence of an interfering agent.

The JAFNPP's Medical Review Officer has scheduled a conference with clinical officers from MetPath and BDA to review details associated with the false negative reportings, and recommend that MetPath laboratory identify the interferant which might help to identify the source of contamination.

Corrective action taken by JAFNPP as a result of the November 15, 1995 reported false negative included initiating new contracts with an alternate BTS supplier and H.H.S. testing laboratory. Full implementation of this initiative is scheduled for completion by the end of January 1996.

If you have questions concerning this issue, please contact Mr. Gordon Brownell of my staff at (315) 349-6360.

Very truly yours,

HARRY P. SALMON, JR.

HPS:GJB:las

cc: USNRC, Region I
USNRC Resident Inspector
USNRC Project Directorate