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Joseph Pechacek
Licensing Manager

June 18, 2009
JAFP-09-0077

United States Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

SUBJECT: James A. FitzPatrick Blind Sample Error Investigation Report
James A. FitzPatrick Nuclear Power Plant
Docket No. 50-333
License No. DPR-59

Dear Sir or Madam:

This report is submitted in accordance with 10 CFR 26.719(c), "Drug and alcohol testing errors". On May 19, 2009, the James A. FitzPatrick Nuclear Power Plant was provided test results on a blind sample that were inconsistent with the expected results. After a confirmatory analysis substantiated the initial test results, an investigation was conducted to determine why the results were not consistent with blind sample vendor's projected results. The results of that investigation are contained in Enclosure 1.

There are no commitments contained in this report.

Questions concerning this report may be addressed to Mr. Larry Kelley, Sr. Coordinator Security/Access/FFD, at (315) 349-6493.

Sincerely,

Joseph Pechacek
Licensing Manager

JP/ed

Enclosure(s): 1. James A. FitzPatrick Blind Sample Error Investigation Report

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NRR

cc:

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ENCLOSURE 1

James A. FitzPatrick
Blind Sample Error Investigation Report

JAFP-09-0077 Enclosure 1
James A. FitzPatrick Blind Sample Error Investigation Report

Identification of Error:

Blind samples are purchased from the vendor to meet the various sample results required for blind specimens. Six blind performance samples were sent to the confirmatory laboratory on May 12, 2009 for testing. Confirmatory results were received between May 13, 2009 and May 19, 2009. Five of the samples were returned with the expected results. One sample identified by the vendor as an "invalid – dilute" with "negative" drug results, returned results from the confirmatory laboratory on May 18th, 2009 as "invalid" with no further results. The confirmatory lab indicated this sample was invalid due to creatinine levels that were below the acceptable range.

Investigation:

The confirmatory lab and the blind sample vendor were contacted in reference to the error reported for sample specimen ID# 7620392. The certified analysis of sample specimen ID# 7620392 provided by the blind sample vendor classified the sample as dilute with the following values: Specific Gravity 1.002 mg/dL, pH 6.000, and creatinine 10. The expiration date for the vendor samples tested was 09/30/2009. For a sample to be classified as dilute, the creatinine reading should be ≥ 2 and < 20 with a specific gravity of > 1.0010 and < 1.0030 mg/dL. The confirmatory lab results returned were: Specific Gravity 1.002 mg/dL, pH 6.3, and creatinine 0.9. The lab classified the results as invalid due to creatinine levels less than 2mg/dL. In cooperation with the Medical Review Officer, the aliquot was reanalyzed at the confirmatory laboratory to confirm the results. The results were confirmed and sent to the MRO. The results again indicated an invalid test and had the same analysis values as the initial test. The blind sample vendor identified similar results in the batch / lot #SAC3352 which produced the sample error. Tests were conducted on the suspect batch / lot #SAC3352 by the vendor and they found an increase in pH which could be the result of bacterial contamination. A rise in pH is known to cause hydrolysis of creatinine. This hydrolysis can cause creatinine degradation in the sample which would yield results causing the sample to be classified as invalid as opposed to dilute.
No errors were determined to have occurred in the confirmatory laboratories processing and reporting of the sample.

Cause:

The confirmatory labs analysis of subject specimen ID# 7620392 from batch / lot # SAC3352 and classification of the sample as invalid and not dilute is believed to be a result of bacterial contamination. The contamination can cause a rise in pH as indicated on the initial confirmatory labs analysis, due to the hydrolysis of creatinine. Test results indicate that creatinine degradation had taken place. Samples tested from batch / lot#SAC3352 at the blind sample provider's facilities confirmed the degradation of creatinine.

Corrective Action:

The blind sample provider has removed the batch from service and provided a replacement batch. The blind sample provider has now incorporated "bacteria stat" to prohibit growth of any bacteria that may be introduced during the bottling process.