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SOUTHERN COMPANY

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U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D. C. 20555-0001

Joseph M. Farley Nuclear Plant – Units 1 & 2
10 CFR 26.719(c) 30-day Report
False Negative Results for a Blind Performance Test Sample

Ladies and Gentlemen:

On April 22, 2015, a drug screening was performed on a blind performance test sample. On April 23, 2015, a false negative result from the blind sample was reported to the Medical Services Supervisor at Farley Nuclear Plant (FNP) and an investigation was started. The results of the investigation were received and accepted by Southern Nuclear Operating Company (SNC) on Monday, May 18, 2015. Therefore, in accordance with the requirements of 10 CFR 26.719(c), SNC hereby submits the enclosed Report.

This letter contains no NRC commitments. If you have any questions, please contact Greg Bell at (334) 814-4765.

Sincerely,

Ms. C. A. Gayheart
Vice President – Farley Nuclear Plant

CAG/JMC

Enclosure: 10 CFR 26.719(c) Report

cc: Southern Nuclear Operating Company
Mr. S. E. Kuczynski, Chairman, President & CEO
Mr. D. G. Bost, Executive Vice President & Chief Nuclear Officer
Mr. M. D. Meier, Vice President – Regulatory Affairs
Mr. D. R. Madison, Vice President – Fleet Operations
Mr. B. J. Adams, Vice President – Engineering
Mr. C. R. Pierce, Regulatory Affairs Director
Ms. B.L. Taylor, Regulatory Affairs Manager - Farley
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U. S. Nuclear Regulatory Commission
Mr. V. M. McCree, Regional Administrator
Mr. S. A. Williams, NRR Project Manager - Farley
Mr. P. K. Niebaum, Senior Resident Inspector - Farley

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Enclosure
10 CFR 26.719(c) Report

Description of the Incident:

On April 22, 2015 Alere Toxicology, a Department of Health and Human Services certified laboratory, conducted a urine drug screening on Specimen ID number 507496385 and reported a negative result. On April 23, 2015 the negative blind performance test result was received by Farley Nuclear Plant's (FNP) Medical Services Supervisor. Alere was then contacted and informed by the Medical Services Supervisor that Specimen 507496385 was a blind quality control sample of Codeine, Morphine and 6-Acetylmorphine (6-AM) targeted at 3000 ng/mL for Codeine, 3000 ng/mL for Morphine and 15 ng/mL for 6-AM. An investigation was consequently initiated by Alere to re-analyze the specimen and determine the reason for the inaccurate result.

Per 10 CFR 26.31(d)(1), at a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol.

Initial reference laboratory screenings for Specimen 507496385 contained a presumptive positive result for opiates, negative results for any other drug, and normal for specimen validity testing. During initial testing the drug analyzer displayed a message (an "F" flag) that indicated the specimen exceeded the linearity of the instrument. Due to the linearity issue, the laboratory technician decided to perform a manual one to five (1:5) dilution of the specimen. The specimen was re-analyzed having been diluted, but the technician failed to multiply by the dilution factor when determining the results. This was not noticed by the certifying scientist upon review. Based on this information the specimen was reported to FNP as negative. After being informed by FNP that the specimen was a blind quality control sample it was re-analyzed on April 23, 2015 with positive results for codeine, morphine and 6-AM being obtained by Gas Chromatography/ Mass Spectrometry (GC/MS).

Cause:

An investigation initiated by Alere discovered that the dilution protocol and error with the application of the dilution factor was the primary cause of the false negative test results. The initial screening resulted in presumptive positive results for opiates with a result of 6480 ng/mL, however an "F" flag was present, indicating that the result was outside of the linear range of the assay. Although the initial screening results are not considered quantitative, Alere does use the results to determine appropriate dilutions for the subsequent GC/MS confirmation testing.

In this instance, the technician noted that the instrument controls had been set up for another batch of samples for the Department of Transportation (DOT). DOT samples have different cutoff values for amphetamines and cocaine metabolite when compared to Nuclear Regulatory Commission (NRC) samples. The technician scheduled all of the NRC samples to be re-analyzed with the proper controls while "masking out" the other tests that were run correctly (including opiates) so that they would not be repeated.

For Specimen 50749638, a 1:5 dilution was needed based on the presumptive positive result for opiates. The technician thought that the automatic dilution protocol could not be used because opiates were masked out, therefore the technician performed a manual dilution on that particular sample. The technician noted on the data sheet that the dilution was 1:5. The result obtained

on the diluted sample was 1845 ng/mL, which when multiplied by the dilution factor would be 9225 ng/mL. 9225 ng/mL is well above the 2000 ng/mL cutoff for opiates. However, the technician processing the data failed to multiply by the dilution factor of five and the result of 1845 ng/ml was transmitted into the computer Laboratory Information Management Software (LIMS) system. Contributing to the error, the certifying scientist reviewing the results also failed to apply the dilution factor. Because 1845 ng/mL was below the opiate cutoff, the result was reported as negative. In addition, the 6-AM result can only be reported if the morphine concentration is above 2000 ng/mL; therefore the presumptive positive 6-AM was also not confirmed.

The two main causes identified by Alere are as follows:

1. Failure of the laboratory technician to re-run the sample using the automatic instrument dilution protocol due to the belief that the instrument was not capable because opiates were masked out.
2. Failure of the laboratory technician and the certifying scientist to multiply the dilution factor of five to the results, although the dilution was manually written on the data print out.

SNC obtained the services of an independent toxicology consultant who reviewed the data from the screening, dilution and confirmation testing of the opiate specimen. Additionally, the signed counseling sessions and training were reviewed along with the changes in the LIMS software and found to be acceptable. Chain of custody and other documentation were all in accordance with the standard operating procedure.

Corrective Actions:

Alere Toxicology demonstrated that the instrument can successfully perform the automatic dilution with specimens masked out. The laboratory technician was counseled on the error and training was conducted with all laboratory technicians and certifying scientists on the scenario.

Alere Toxicology also requested a change in their LIMS system to require a review by the certifying scientist and supervisory personnel for specimens with an "F" flag for exceeding linearity. The software change was implemented in the LIMS system on May, 6 2015.

SNC will submit double the number of blind specimens, or 2% of specimens submitted, for no less than 30 days to ensure the corrective actions taken by the laboratory are effective.