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SOUTHERN NUCLEAR
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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 and 2
10 CFR 26.719(c) 30-Day Report
False Negative Results for a Blind Performance Test Sample

Ladies and Gentlemen:

On April 12, 2016 a drug screening was performed on a blind performance test sample. On April 18, 2016 a false negative result from the blind sample was reported to the Medical Services Supervisor at Farley Nuclear Plant and an investigation was started. The results of the investigation were received and accepted by Southern Nuclear Operating Company (SNC) on June 27, 2016. 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 Julie Collier at (334) 814-4639.

Sincerely,

Ms. C. A. Gayheart
Vice President – Farley

CAG/JAC

Enclosures: 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
Ms. C. A. Gayheart, Vice President – Farley
Mr. M. D. Meier, Vice President – Regulatory Affairs
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U. S. Nuclear Regulatory Commission
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Mr. S. A. Williams, NRR Project Manager - Farley
Mr. P. K. Niebaum, Senior Resident Inspector - Farley

Joseph M. Farley Nuclear Plant – Units 1 & 2

Enclosure

10 CFR 26.719(c) Report

False Negative Results for a Blind Performance Test Sample

Description of Incident

On 4/12/2016, Alere toxicology (Alere), a Department of Health and Human Services certified laboratory, conducted urine drug screening on Specimen ID 508696849 and reported an invalid result. On 4/18/2016, the invalid blind performance result was received by Farley Nuclear Plant's Medical Services Supervisor. Alere was contacted by the Medical Services Supervisor and informed that specimen 508696849 was a blind quality control that was adulterated with nitrite. An investigation was consequently initiated by Alere to re-analyze the specimen and determine the reason for the inaccurate test result.

Specimen ID 508696849 had been prepared by El Sohly Laboratories with a designed concentration of 886 mcg/mL. Initial reference laboratory testing by Alere for this specimen contained a presumptive positive result for nitrites, resulting in the specimen being forwarded for confirmation testing for nitrites. The specimen was prepped and aliquoted for confirmation testing. The specimen was released by Alere on 4/18/2016 as an invalid specimen with a quantitative result of 490 mcg/mL. Alere repeated the confirmation testing on 4/19/2016 for the blind performance specimen and returned the correct result of adulterated; however, the quantitation of the specimen of 527 mcg/mL was still well below the target concentration of 886 mcg/mL.

Cause

An investigation initiated by Alere discovered that the specimen was aliquoted for testing on 4/15/2016 late in the day and was placed in the testing area for the nitrite technician to perform the testing. However, due to the late hour the nitrite technician had left for the day. The specimen remained in a secure area of the lab for testing, but was left at room temperature until the next day, 4/16/2016, when testing was performed. Due to this issue Alere determined that the specimen had degraded which caused the invalid results.

The main cause identified by Alere was as follows:

> Failure of the aliquoting technician to recognize the nitrite technician had left for the day and not placing the specimen in refrigerated storage pending the confirmation test. This caused the nitrite to degrade far enough to cause the error in testing.

Southern Nuclear Operating Company (SNC) obtained the services of an independent toxicology consultant who reviewed the original laboratory report with the incorrect result. The consultant also reviewed:

- The repeat test report with correct results, including discussion of the error with the laboratory director and responsible person
- Correspondence between Alere and SNC
- The National Laboratory Certification Program (NLCP) audit and inspection reports for 2015 and 2016, including proficiency testing cycles for 2015 and 2016.
- NEI audit report of Alere from April 5-7 2016
- Documentation for training conducted as Corrective Action for the event

Following review of the documentation and discussions held with laboratory personnel on the error and the postulated sample deterioration cause, the independent toxicologist recommended a deterioration study of nitrites at the laboratory to confirm the laboratory's findings.

Four nitrite specimens having a designed concentration of 886 mcg/mL were sent to Alere for testing. The protocols for the testing were as follows:

- Immediately test all specimens for nitrites and report the results.
- Test all specimens after they had been allowed to sit out for 24 hours at room temperature.

Results from the deterioration study:

Specimen ID	1st Test Result	2nd Test Result
508328982	832 mcg/mL	609 mcg/mL
508328985	757 mcg/mL	556 mcg/mL
508328983	836 mcg/mL	630 mcg/mL
508328984	786 mcg/mL	582 mcg/mL

The results of the study indicate as much as a 25 percent deterioration of nitrites as a result of the specimen being allowed to sit out at room temperature for 24 hours. The study confirmed the laboratory's initial report of specimen deterioration.

Corrective Actions

- Alere toxicology implemented a change to the storage protocols for specimens requiring nitrite testing. All specimens that are awaiting testing will be stored in secure refrigerator storage until testing is commenced.
- Alere retrained all aliquoting technicians and nitrite technicians on the new storage protocols.
- SNC will be terminating the contract with this laboratory due to the number of errors experienced over the last 12 months.