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NL-15-2295

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 November 18, 2015 a drug screening was performed on a blind performance test sample. On November 19, 2015 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 December 17, 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,

A handwritten signature in black ink, appearing to read "Cheryl A. Gayheart".

Ms. C. A. Gayheart  
Vice President – Farley

CAG/JAC

Enclosures: 10 CFR 26.719(c) Report

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cc: Southern Nuclear Operating Company

Mr. S. E. Kuczynski, Chairman, President & CEO

Mr. D. G. Bost, Executive Vice President & Chief Nuclear Officer

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Mr. C. R. Pierce, Regulatory Affairs Director

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U. S. Nuclear Regulatory Commission

Mr. L. D. Wert, Regional Administrator (Acting)

Mr. S. A. Williams, NRR Project Manager - Farley

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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 the Incident:**

On November 18, 2015 Alere Toxicology (Alere), a Department of Health and Human Services certified laboratory, conducted a urine drug screening on Specimen ID number 507745407 and reported a negative result. On November 19, 2015 the negative blind performance result was received by Farley Nuclear Plant's (FNP) Medical Services Supervisor. Alere was then contacted by the Medical Services Supervisor and informed that Specimen 507745407 was a blind quality control that was diluted with Creatinine targeted at 15.9 mg/dL and specific gravity 1.0020. An investigation was consequently initiated by Alere to re-analyze the specimen and determine the reason for the inaccurate result.

Initial reference laboratory screenings for Specimen 507745407 contained a presumptive positive result for creatinine at 14.1 mg/dL. This resulted in the specimen being forwarded to another technician for specific gravity testing. During the specific gravity testing the specimen was tested by a technician using an ATAGO refractometer. The specific gravity reading that was obtained was 1.0038, thus the specimen was reported negative to the FNP Medical Services Supervisor. Alere repeated the specific gravity test on November 19, 2015 after notification that the specimen in question was a blind specimen designed to be diluted. This repeat test was conducted on the original ATAGO refractometer and a Rudolph refractometer. Both instruments recorded the same results for specific gravity. The corrected reading was reported on November 20, 2015 to the FNP Medical Services Supervisor as a negative but dilute specimen with a creatinine result of 14.1 mg/Dl and a specific gravity reading of 1.0021.

**Cause:**

An investigation initiated by Alere discovered the screening technician did not depress the read button on the refractometer resulting in the specific gravity reading from the previous specimen to be displayed. This reading was recorded on the worksheet and was included in the batch for review. This was found to be a procedure violation and a human performance event by the technician. Alere's investigation focused on this specific issue but also examined the overall laboratory policy on errors. During the investigation the laboratory reviewed their policy on errors, their review process for specimens and their policy on developing engineering controls for corrective actions.

The main cause identified by Alere is as follows:

1. Failure of the laboratory technician to follow procedure while utilizing the refractometer resulting in a reading from a previous specimen to be recorded as the result for specimen 507745407.

Southern Nuclear 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 result with correct results.
- Correspondence between the Alere laboratory and SNC.
- Documentation of counseling of the employee who made the error.
- Corrective action changes made to the Standard Operating Procedure (SOP).
- Training documentation for all affected technicians and certifying scientists on the proper process and on the procedure revision.

- Documentation of additional tests that were correctly performed using the revised procedure.

The independent toxicology consultant also reviewed two previous errors at the laboratory in an effort to determine if they were indicative of a larger issue previously not addressed. The consultant found that the laboratory had conducted root cause investigations for each incident to attempt to identify causes and solutions. In each instance a change in procedure or an Information Technology solution was implemented to address the issue and prevent future occurrences. All training corrective actions were applied to both the individuals involved in the events as well as other personnel who may run into similar issues, which is similar to Operating Experience programs implemented by nuclear licensees. The corrective actions for the three previous errors remain implemented and the documentation of the corrective actions was in good order. No additional issues were identified.

**Corrective Actions:**

Alere Toxicology has implemented a change to its SOP for specific gravity to include a water blank control in between each actual specimen to prevent a back to back reading from occurring again.

Alere Toxicology retrained all screening technicians and certifying scientists on the new procedure and the error.

SNC will submit double the number of blind specimens, or 2 % of specimens submitted, for no less than 60 days to ensure the corrective actions taken by the laboratory are effective.