

Mark J. Ajluni, P.E.
Nuclear Licensing Director

**Southern Nuclear
Operating Company, Inc.**
40 Inverness Center Parkway
Post Office Box 1295
Birmingham, Alabama 35201
Tel 205.992.7673
Fax 205.992.7885

April 25, 2012



Docket Nos.: 50-348
50-364

NL-12-0869

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

Joseph M. Farley Nuclear Plant
Fitness for Duty 30-Day Report
Blind Performance Testing Error

Ladies and Gentlemen:

As required by 10 CFR 26.719(c)(1), Southern Nuclear Operating Company (SNC) hereby submits the enclosed 30-day report concerning a blind performance testing error that occurred at a Department of Health and Human Resources-certified laboratory used by the SNC Fitness For Duty Program

This letter contains no NRC commitments. If you have any questions, please contact Doug McKinney at (205) 992-5982.

Sincerely,

A handwritten signature in black ink that reads "Mark J. Ajluni". The signature is written in a cursive style with a prominent initial "M".

M. J. Ajluni
Nuclear Licensing Director

MJA/TMM

Enclosure: Fitness for Duty 30-Day Report Blind Performance Testing Error

U. S. Nuclear Regulatory Commission

NL-12-0869

Page 2

cc: Southern Nuclear Operating Company

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

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

Mr. T. A. Lynch, Vice President – Farley

Mr. B. L. Ivey, Vice President – Regulatory Affairs

Mr. B. J. Adams, Vice President – Fleet Operations

RTYPE: CFA04.054

U. S. Nuclear Regulatory Commission

Mr. V. M. McCree, Regional Administrator

Mr. R. E. Martin, NRR Project Manager – Farley

Mr. E. L. Crowe, Senior Resident Inspector – Farley

Joseph M. Farley Nuclear Plant

Enclosure to NL-12-0869

**Fitness for Duty 30-Day Report
Blind Performance Testing Error**

Enclosure to NL-12-0869

Fitness for Duty 30-Day Report Blind Performance Testing Error

Introduction

10 CFR 26.168, "Blind performance testing," and Southern Nuclear (SNC) Procedure MS-FFD-007, "Blind Performance Test/Quality Control," describe the requirements and procedures for blind performance testing to insure that the Department of Health and Human Resources (HHS)-certified laboratories used by the SNC Fitness For Duty (FFD) Program are performing effectively and are providing accurate drug/validity test results.

On March 22, 2012, the SNC Medical/FFD Services Coordinator at Farley Nuclear Plant (FNP) notified the SNC FFD Coordinator of a potential error on a blind performance specimen drug/validity test conducted by Alere Toxicology Services. Alere Toxicology Services is one of two HHS-certified laboratories utilized by SNC to run analytical drug/validity tests according to the requirements of NRC regulations. On March 23, 2012, Alere Toxicology Services confirmed to SNC that an error in testing and reporting of results for the blind performance specimen had occurred. A formal investigation was initiated by the Laboratory Director of Alere Toxicology Services at the request of the SNC FFD Coordinator.

Background

NRC regulations have specific requirements regarding the submission of blind performance test specimens to each HHS-certified laboratory utilized by the SNC Medical/FFD Services Department for analysis and confirmation of drug/validity test results. SNC procedures include these requirements. On March 19, 2012, a blind performance test specimen was analyzed on-site at FNP using the Siemens V-Twin Analyzer. Initial results obtained from the on-site analysis indicated the specimen was positive for Nitrites, an indicator that the specimen was "adulterated." Per procedure, the Medical/FFD Services Coordinator compared the initial test results of the blind performance specimen with the Certificate of Analysis (COA) provided by EISOHLY Laboratories, supplier of blind performance test specimens for the SNC FFD Program. The COA indicated the blind performance specimen was positive for Nitrites and that the specimen was "adulterated." The Medical/FFD Services Coordinator and the SNC FFD Coordinator verified the initial blind specimen results correlated with the COA and the run was accepted. Per SNC procedure, the blind performance specimen was then sent to Alere Toxicology Services in order to confirm the initial test results.

On March 22, 2012, the SNC Medical/FFD Services Coordinator at FNP received a final report of test results from Alere Toxicology Services. According to the report, the blind performance test specimen was "negative." The presence of Nitrites was not indicated and the specimen was not reported out as "adulterated." The Medical/FFD Services Coordinator consulted the SNC FFD Coordinator and confirmed that the results reported out by Alere Toxicology Services did not correlate with on-site test results and the results reported by the EISOHLY Laboratories' COA. The SNC FFD Coordinator contacted the Alere Toxicology Services Laboratory Director and notified him of the potential error and requested a formal investigation.

On March 26, 2012, the SNC FFD Coordinator received a formal report of the investigation. Alere Toxicology Services reported that the negative test results reported out on March 22, 2012, were incorrect due to an administrative error on the part of Alere laboratory personnel. It was determined that the testing technician and certifying scientist failed to apply a dilution factor to the test results. As a result, negative test results for Nitrites were reported. If the laboratory

Enclosure to NL-12-0869

Fitness for Duty 30-Day Report Blind Performance Testing Error

personnel had applied the dilution factor and multiplied the Nitrites result accordingly, a very high level of Nitrites (positive) would have been reported instead of the negative results reported. Alere laboratory personnel failed to follow procedure for applying dilution factors during analysis of the blind performance specimen.

The specimen was tested a second time by Alere following the correct technical procedure (application of dilution factors), and the test results were confirmed as positive for Nitrites and were reported out as an adulterated specimen. This second confirmatory test correlated with initial results obtained during on-site analysis of the specimen at FNP Medical Services on the Siemens V-Twin Analyzer and as verified by the EISohly COA. The incorrect drug/validity test results reported out by Alere Toxicology Services were due entirely to the administrative/performance error by laboratory personnel. Corrective actions were taken by the laboratory to address the error.

Corrective Actions

On March 22, 2012, the SNC Medical/FFD Services Coordinator at FNP followed SNC procedure and notified the SNC FFD Coordinator as soon as the potential error was identified. The SNC FFD Coordinator immediately contacted Alere Toxicology Services and notified the Lab Director of the potential error and requested an immediate formal investigation. When the blind performance specimen was reanalyzed at SNC's request, the blind performance specimen was positive for Nitrites and the specimen was reported out as adulterated. As required by Alere procedure, a second confirmatory test specific for Nitrites was performed on the blind performance specimen. Confirmatory test results for Nitrites were positive and correlated with results from the on-site initial testing conducted at FNP Medical Services and with the EISohly Laboratories COA.

Technical Evaluation No. 340636 was entered by SNC into the corporate corrective action program database and reads, "On 03/26/12 FNP received a final report from the HHS-certified lab, ALERE, that contained incorrect results for a blind performance specimen submitted for test. The blind performance specimen had tested as initial positive for nitrite on-site at FNP. A final report of NEGATIVE was issued by ALERE. Licensing was consulted & it was determined that a 30-day written report to the NRC is required."

Alere Toxicology Services provided a written statement that indicated the testing technician and certifying scientist were counseled regarding the "severity" of the laboratory test error. According to the statement, both individuals were required to sign an internal memorandum which was reviewed by the laboratory Quality Assurance/Quality Control officer, supervisor of the individuals, production manager, laboratory-responsible person, and laboratory director. Alere Toxicology Services further documented that all testing technicians and certifying scientists were retrained regarding performance of dilutions on the initial/confirmatory test results, and the importance and implications of failure to correctly apply dilution factors to the data results from instruments that do not automatically calculate results. Alere further indicated they would implement use of a time stamp for data in which dilutions have been performed to ensure it is clear to both testing technicians and laboratory scientists.

Enclosure to NL-12-0869

**Fitness for Duty 30-Day Report
Blind Performance Testing Error**

Summary

During the ensuing investigation of this error, SNC determined that SNC procedures used for blind performance testing are accurate as evidenced by immediate identification and investigation of the error. This also confirmed that the skills, training, and qualifications of SNC site Medical/FFD Coordinators in the area of FFD drug/validity testing are effective. It was determined that this was a human performance/administrative error by Alere Toxicology Services personnel and an isolated incident. Alere Toxicology Services assured SNC FFD Program Management that steps were taken to address the error with involved personnel. In addition, Alere Toxicology Services notified SNC FFD Program Management that new instruments have been purchased and the potential for this type of error will be eliminated with installation of the new equipment. The new instrumentation automatically multiplies and calculates the numerical test results prior to the reporting of results when dilution factors have been utilized and applied to specimens during the testing process. Because Alere has addressed this issue with updated instrumentation that will automate the necessary processes, SNC did not choose to increase blind performance testing by Alere at this time.

SNC continues to utilize Alere Toxicology Services as the HHS-certified laboratory for two of the four SNC sites. LabCorp is utilized as the HHS-certified laboratory for the other two SNC sites. Maintenance of a contractual relationship with these two reputable HHS-certified laboratories offers SNC the opportunity to quickly utilize the services of either of the laboratories in the event of a serious/catastrophic test error.