Southern Nuclear

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Vogtle Electric Generating Plant – Units 1 and 2
10 CFR 26.719(c)(1) 30-Day Report
Blind performance test results inconsistent with sample provided

Ladies and Gentlemen:

On October 16, 2020, a blind performance test sample was sent to Quest Employer Solution laboratory in Atlanta GA for Vogtle Electric Generating Plant. On October 19, 2020, the Medical Services Supervisor received the report and discovered that the results were inconsistent with the expected test result. An investigation was initiated and accepted by Southern Nuclear Operating Company (SNC) on November 6, 2020. Therefore, in accordance with 10 CFR 26.719(c)(1), SNC hereby submits the enclosed report.

This letter contains no NRC commitments. If you have any questions, please contact Matthew Horn at (706) 848-1544.

Respectfully submitted,

Drayton Pitts
Site Vice President
Vogtle 1&2

RDP/CSM/KCW

Enclosure: 10 CFR 26.719(c)(1) report

Cc: Regional Administrator
NRR Project Manager – Vogtle 1 & 2
Senior Resident Inspector – Vogtle 1 & 2
RType: CVC7000

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Enclosure

10 CFR 26.719(c)(1) report

10 CFR 26.719(c)(1) Report

Description of the incident

On Friday, 10/16/2020, Quest Employer Solution laboratory in Atlanta, a Department of Health and Human Services certified laboratory, reported a blind performance test result for accession 900190K to Southern Nuclear (SNC) Vogtle Nuclear Plant. On Monday, 10/19/2020, the Vogtle Medical Services Supervisor received the report and, upon review of the result against the certificate of analysis for that performance test, discovered that the result was inconsistent with the expected test result. The blind performance test result from the laboratory was reported as positive for amphetamine but should have been positive for amphetamine and methamphetamine. The Quest Account Manager was contacted to notify the laboratory of a potential testing error. This information was provided to the Responsible Person at the laboratory, who began an investigation to determine the reason for the inaccurate result. Quest released a corrected report on 10/19/2020 indicating a positive amphetamine and methamphetamine result for Specimen 900190K.

Cause

Original data for initial and confirmatory testing of this specimen was pulled from storage and reviewed. Initial testing by immunoassay indicated a presumptive positive result for the amphetamine class of drugs. Confirmatory testing data indicated a positive (i.e. greater than cutoff) result for both amphetamine and methamphetamine. Quantitative (i.e. amphetamine=1993 ng/mL, methamphetamine=2018 ng/mL) results entered into the Lab Information Management System (LIMS) by the reviewing certifying scientist matched those obtained during confirmatory testing. Qualitative (i.e. positive vs negative) results for this specimen (also entered by the certifying scientist) did not match those obtained during confirmatory testing: amphetamine was correctly marked as Positive, while methamphetamine had been incorrectly marked as Negative. Reports generated by the LIMS do not display quantitative results for analytes marked as Negative, which resulted in the inconsistent results observed by SNC. Therefore, the cause was determined to be a human performance error by the certifying scientist.

Corrective Actions

On 10/19/20, the certifying scientist was removed from the review of confirmatory data and the final reporting of amphetamines confirmatory results until retraining is completed and their competency is evaluated. Retraining consists of reviewing Standard Operating Procedures, direct observation by a trainer, and review of the trainee's work prior to reporting results until the employee demonstrates competency. The certifying scientist will be reinstated for review and reporting of amphetamines confirmatory results on satisfactory completion of retraining and competency evaluation.

To prevent similar errors in the future, the laboratory has mandated documented two-party review of all confirmation data entry: two qualified employees must independently review and sign off on any results entered manually into the LIMS. This requirement was implemented on 10/19/2020. The Quest Diagnostics Information Technology team is developing a software interface to obtain

confirmation data from the instruments and populate the quantitative fields of the LIMS. Per follow-up discussion with Quest representatives on 11/19/2020, development of the software interface has been completed.

Corrective actions developed by the laboratory were found to be acceptable by SNC.