

Tennessee Valley Authority, 1101 Market Street, Chattanooga, Tennessee 37402

May 22, 2013

10 CFR 26.11 10 CFR 26.719(c)

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

> Browns Ferry Nuclear Plant, Units 1, 2, and 3 Renewed Facility Operating License Nos. DPR-33, DPR-52, and DPR-68 NRC Docket Nos. 50-259, 50-260, and 50-296

Sequoyah Nuclear Plant, Units 1 and 2 Facility Operating License Nos. DPR-77 and DPR-79 NRC Docket Nos. 50-327 and 50-328

Watts Bar Nuclear Plant, Unit 1 Facility Operating License No. NPF-90 NRC Docket No. 50-390

Watts Bar Nuclear Plant, Unit 2 Construction Permit No. CPPR-92 NRC Docket No. 50-391

Subject: Report of Drug Testing Error In Accordance With 10 CFR 26.719(c)(1)

In accordance with the requirements of 10 CFR 26.719(c), Tennessee Valley Authority (TVA) is providing the details of testing errors discovered in the performance of testing at a Department of Health and Human Services (HHS) certified laboratory. TVA completed an investigation of a testing error at the HHS-certified laboratory on April 25, 2013. The Enclosure to this letter provides information concerning the unsatisfactory performance test conducted for TVA by its HHS-certified laboratory.

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There are no regulatory commitments contained in this letter. If you have any questions concerning this matter, please contact Dr. Brenda Sowter at 423-751-2599.

Respectfully,

J. W. Shea

Vice President, Nuclear Licensing

Enclosure: 10 CFR 26.719(c) Report Of Testing Errors For Specimen

Identification No. 2017260910

cc: Quest Diagnostics

Employer Solutions 1777 Montreal Circle Tucker, GA 30084

## **ENCLOSURE**

## TENNESSEE VALLEY AUTHORITY

## 10 CFR 26.719(c) Report Of Testing Errors For Specimen Identification No. 2017260910

On April 12, 2013, during the investigation of conflicting results between Tennessee Valley Authority's (TVA's) primary contract drug testing laboratory and the split specimen/retest testing laboratory (Quest Diagnostics), TVA determined that a false positive testing error had occurred by TVA's Health and Human Services (HHS)-certified split specimen testing laboratory (Quest Diagnostics) on an actual donor urine specimen obtained during the donor's follow-up drug test. This report is being made in accordance with 10 CFR 26.719(c), which requires that the licensee submit to the Nuclear Regulatory Commission (NRC) a report of the incident and corrective actions taken or planned within 30 days of completing an investigation of any testing errors. TVA completed the investigation of this testing error on April 25, 2013.

On March 20, 2013, an individual reported to Browns Ferry Nuclear Plant medical to provide a urine specimen for a follow-up drug test. The specimen provided by the individual (Specimen 1; also Specimen No. 2017260910) was out of the acceptable temperature range. In accordance with TVA procedures, medical services performed an observed/witnessed sample collection (Specimen 2). Both specimens were sent to TVA's primary testing laboratory for extended panel testing. Specimen 1 tested analytically negative. Specimen 2 tested analytically positive for amphetamines. Because the donor challenged the results of Specimen 1, TVA had the primary testing laboratory provide bottle B of Specimen 1 to Quest Diagnostics for split specimen testing. On April 7, 2013, Quest Diagnostics provided results stating that Specimen 1 contained amphetamine and methamphetamine metabolites. TVA's Medical Review Officer (MRO)/Substance Abuse Expert (SAE) requested on April 8, 2013, that Quest Diagnostics perform quantitative analyses and that TVA's primary laboratory perform a complete re-analysis to level of detection. Quest Diagnostics provided quantitative test results on April 8, 2013, indicating that Specimen 1 was positive for amphetamine and methamphetamine metabolites. Because there remained a discrepancy between the two laboratories regarding Specimen 1, TVA's MRO/SAE requested a retest by Quest Diagnostics including a specimen validity test. The primary testing laboratory's test results were provided on April 11, 2013, confirming a negative test result. This laboratory specifically analyzed for amphetamines and methamphetamines and noted that neither of these were detected. On April 11, 2013, TVA's MRO/SAE, after having received similar specimen validity results from both laboratories. contacted both laboratories to request that the specimen be sent for analysis by a third independent laboratory. Quest Diagnostics provided the requested re-test results on April 12, 2013, indicating a failure to reconfirm amphetamines and methamphetamines on Specimen 1 (i.e. they reported a negative result). Based on these results, Quest Diagnostics had provided incorrect results indicating a false positive on April 7, 2013. Furthermore, since Quest Diagnostics had now confirmed the results were negative for amphetamines, the specimen was not sent to a third independent laboratory.

As an interim corrective action, on April 12, 2013, TVA ceased requesting that the primary contract laboratory forward split specimens to Quest Diagnostics. TVA currently has alternative pathways developed for split specimen testing.

On April 25, 2013, Quest Diagnostics provided TVA the results of their internal investigation into the cause of the discrepant test results. The laboratory identified the source of the discrepant result to be related to a sample handling error during the original confirmation procedure, resulting in two consecutive samples with the same confirmatory test results. As part of the investigation, the laboratory reviewed the job performance of the individual responsible for removal of the test aliquot from the original specimen container and the job performance of the individual responsible for preparation of the test aliquot for confirmation analysis. Both individuals appeared to follow procedures as written during the evaluation period and no aberrations were identified. In order to prevent a recurrence of this issue, the laboratory has updated the standard operating procedure to require repeat analysis of any sample containing discrepant results from the primary laboratory. Based on the new standard operating procedure requirement, if any specimen is tested and has discrepant results from the original laboratory, the test will be repeated to verify the result prior to reporting. The laboratory will document retraining of each individual to ensure consistent performance.

No other samples in the batch were adversely affected by the incident and no other correction reports were required for other specimens.

This issue is being tracked in TVA's Corrective Action Program as PER 715507. As identified above in the description of the Quest Diagnostics internal investigation, the laboratory has updated their standard operating procedure and performed training of the staff on the updated procedure, and will take actions to re-train all individuals. TVA has submitted this information to the Operating Experience group for consideration in sharing this information, and has provided the information to the Quality Assurance group for consideration during future audits.