Tennessee Valley Authority
1101 Market Street, LP 3R
Chattanooga, Tennessee 37402-2801

R. M. Krich
Vice President
Nuclear Licensing

September 2, 2011

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
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: **Submittal of Report in Accordance with 10 CFR 26.719(c)(1) for Drug and Alcohol Testing Errors**

In accordance with 10 CFR 26.719(c), the Tennessee Valley Authority (TVA) submits the following report regarding the unsatisfactory laboratory results of a blind performance test sample tested at a Department of Health and Human Services (HHS) certified laboratory.

A022
NRR

The requirements of 10 CFR 26.719(c) state, in part, that licensees shall notify the NRC within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a licensee testing facility or an HHS-certified laboratory, including in the testing of quality control or actual specimens. Since TVA completed the investigation on August 3, 2011, this report is required to be submitted by September 2, 2011.

The Enclosure to this letter provides information and details concerning the unsatisfactory HHS-certified laboratory performance test conducted for TVA by another HHS-certified laboratory and the associated corrective actions.

There are no regulatory commitments contained within this letter. If you have any questions concerning this report, please contact Kara M. Stacy at (423) 751-3489.

Respectfully,

R. M. Krich

Enclosure: 10 CFR 26.719(c) Report Summary of Unsatisfactory Laboratory Performance Test Sample Number 6402205759

cc (Enclosure):

NRC Regional Administrator - Region II
NRC Senior Resident Inspector - Browns Ferry Nuclear Plant
NRC Senior Resident Inspector - Sequoyah Nuclear Plant
NRC Senior Resident Inspector - Watts Bar Nuclear Plant, Unit 1
NRC Senior Resident Inspector - Watts Bar Nuclear Plant, Unit 2

ENCLOSURE

TENNESSEE VALLEY AUTHORITY

10 CFR 26.719(c) REPORT
SUMMARY OF UNSATISFACTORY LABORATORY PERFORMANCE TEST
SAMPLE NUMBER 6402205759

Description of Incident

The Nuclear Regulatory Commission's regulations of 10 CFR 26.168, "Blind performance testing," require that each licensee submit blind performance test samples to the Department of Health and Human Services (HHS)-certified laboratory and use only blind performance test samples that have been certified by the supplier.

The Tennessee Valley Authority (TVA) completed an investigation on August 3, 2011, regarding a potential testing discrepancy concerning a false-negative result for a positive blind performance test sample submitted to TVA's HHS-certified laboratory.

By letter dated July 1, 2011, TVA submitted the results of an investigation regarding errors with blind sample 2004982763 to the NRC. The investigation of the testing errors for blind sample 2004982763 consisted, in part, of an Apparent Cause Evaluation (ACE). During the preparation of the ACE for blind specimen sample number 2004982763, TVA identified what appeared to be an unexpected blind specimen test sample result from March 2010. TVA further identified that the results of the investigation regarding the March 2010 unexpected blind sample report had not been reported to the NRC as required by 10 CFR 26.719(c). This discrepancy was entered into TVA's Corrective Action Program (CAP) and an investigation was performed to determine if a 30-day report was required. TVA concluded that the requirement of 10 CFR 26.719(c) was not met with regard to submittal of a report to the NRC for the results of the investigation regarding the March 2010 unexpected test result. Therefore, the results of TVA's investigation of the unexpected blind sample results for March 2010 are discussed below.

In an investigative report dated April 7, 2010 (Attachment), HHS-certified laboratory Clinical Reference Laboratory (CRL) documented their receipt of blind performance test sample number 6402205759 from TVA on March 13, 2010. Sample bottle A screened positive for Opiates, although the CRL investigative report dated April 7, 2010 did not provide specific opiate (Morphine, Codeine) values. An additional screening test performed on the initial aliquot of sample bottle A yielded a presumptive positive result for 6-Acetylmorphine. CRL then forwarded two separate aliquots of the specimen bottle A to their confirmation laboratory for confirmation testing of Opiates (Morphine, Codeine) and 6-Acetylmorphine. Since the analyses results for these three aliquots of specimen sample bottle A were below the confirmation cutoff levels for Morphine, Codeine, and 6-Acetylmorphine, the sample was reported as negative in accordance with CRL procedures and Fitness for Duty (FFD) program guidelines.

Based on the test results from specimen sample bottle A, CRL subsequently notified TVA's MRO and FFD Coordinator that sample number 6402205759 had been classified as negative. On March 24, 2010, TVA's MRO and FFD Program Manager notified CRL that the sample

number 6402205759 was an external blind that had failed to meet the expected result of positive for Morphine, Codeine, and 6-Acetylmorphine.

In the investigation initiated by CRL on March 24, 2010, the initial screening and original confirmation data were reviewed. The drug screen was repeated on March 25, 2010, and additional aliquots of the specimen sample bottle A were obtained for a repeat of the confirmation testing.

The split specimen (bottle B) was provided to alternate HHS-certified laboratory Quest Diagnostics for testing, yielding positive results for Morphine, Codeine, and 6-Acetylmorphine. Additionally, retesting of an aliquot of bottle A provided to Quest confirmed the values for Morphine, Codeine, and 6-Acetylmorphine to be consistent with values obtained by CRL.

CRL's investigation indicated that the results suggested the specimen originally contained In bottle A was compromised, resulting in a lower concentration of all analytes within that specimen. Three independent test methods, each of which contained acceptable internal quality control samples, resulted in values approximately one-half of their stated target values. The repeat testing performed by CRL for each of these three independent tests yielded results consistent with their initial values. The results obtained by Quest on the aliquot from bottle A were consistent with CRL's original values. Since Quest reported significantly higher positive results for Morphine, Codeine, and 6-Acetylmorphlne in bottle B, CRL's opinion was that the specimen contained in bottle B did not closely match the specimen contained in bottle A.

Although this issue was determined to be a result of human error, TVA was unable to determine the specific error in the specimen preparation. Identified factors were TVA's historical practice of processing multiple blind specimens simultaneously and the performance of the blind specimen preparation by a new employee who was still in training on the blind specimen preparation process. None of these contributing factors raised a specific concern about the overall soundness of the TVA FFD Program.

Corrective Actions Taken or Planned

TVA's corrective actions for this unexpected test result were:

Train new employee on the blind specimen preparation process
Completion date: April 19, 2010

Revise the blind specimen processing procedure to require the blind specimen package to be complete prior to initiating of the next specimen package
Completion date: May 18, 2010

ATTACHMENT

CLINICAL REFERENCE LABORATORY

Dr. Brenda K. Sowter
Senior Physician, MRO
Nuclear Medical Services
TVA
1101 Market Street, EB 10B-C
Chattanooga, TN 37402

FAX: (423) 751-3660

4/7/10

Dear Dr. Sowter,

On March 18, 2010, Clinical Reference Laboratory (CRL) issued a report of "negative" for urine specimen number 6402205759 identified by CRL accession number 47210137. CRL was subsequently notified that this specimen was an external blind that was expected to test positive for Morphine, Codeine, and 6-Acetylmorphine.

This sample was received by CRL on 3/13/10. The sample screened positive for Opiates. The SVT analysis of the initial aliquot yielded a creatinine value of 23.8 mg/dL. An additional screening test performed on the initial aliquot yielded a presumptive positive (13.3 ng/mL) result for 6-Acetylmorphine. Two separate additional aliquots of the specimen were forwarded to our confirmation laboratory for Opiates confirmation testing and 6-Acetylmorphine confirmation testing. The results for the drug analytes in these aliquots were below the confirmation cutoff levels for Morphine, Codeine, and 6-Acetylmorphine. The sample was reported as negative in accordance with CRL SOP and FFD program guidelines.

On 3/24/10, the laboratory received notification from you that the sample was an external blind which had failed to meet the expected result of positive for Morphine, Codeine, and 6-Acetylmorphine. The stated target values for the blind sample are 3500 ng/mL Morphine, 3500 ng/mL Codeine, and 20 ng/mL 6-Acetylmorphine. The stated expected level for creatinine is 46.2 mg/dL.

An investigation was initiated by CRL on 3/24/10. The initial screening data was reviewed. The initial screening value for Opiates was 2875 ng/mL. The drug screen was repeated on 3/25/10. This repeated screening test yielded a value of 2857 ng/mL for Opiates. The initial creatinine test had a result of 23.8 mg/dL. Repeat testing yielded a result of 23.4 mg/dL.

The original confirmation data was reviewed. The results obtained were 1686 ng/mL for Morphine, 1764 ng/mL for Codeine, and 9 ng/mL for 6-Acetylmorphine. Additional aliquots of the sample were obtained for a repeat of the confirmation testing. The results obtained by GCMS analysis were 1579 ng/mL for Morphine, 1671 ng/mL for Codeine and 9 ng/mL for 6-Acetylmorphine.

On 3/24/10, the split (bottle B) specimen was sent to Quest to be retested. You indicated to us on 3/31/10 that the split specimen tested positive for Morphine, Codeine, and 6-Acetylmorphine at Quest. We have been informed by Quest that their quantitative results for the bottle B split specimen were 2705 ng/mL for Morphine, 2806 ng/mL for Codeine, 19 ng/mL for 6-Acetylmorphine, and 43.5 mg/dL for creatinine.

On 3/30/10 an aliquot of bottle A was sent to Quest for retesting. The quantitative results from these tests on bottle A are consistent with the values obtained by CRL. Quest reported levels of 1701 ng/mL for Morphine, 1705 ng/mL for Codeine, and 26.5 mg/dL for creatinine on the aliquot from bottle A.

These results suggest that the specimen originally contained in Bottle A was compromised, resulting in a lower concentration of all analytes within that specimen. Three independent test methods (Creatine, Morphine/Codeine, and 6-Acetylmorphine) each containing acceptable internal quality control samples, have yielded values at approximately one-half of their stated target values. The repeat testing performed by CRL for each of these three independent tests has yielded results consistent with their initial values. Each of these validated test methods have been re-verified through analyses of external Proficiency Test samples on a recurring basis. The quantitative results obtained by Quest on the aliquot from bottle A are also quite consistent with CRL's original values. As Quest has reported significantly higher positive results for Morphine, Codeine, and 6-Acetylmorphine in Bottle B, we believe that the specimen contained in Bottle B did not closely match the specimen contained in bottle A.

To avoid future occurrences of this nature, we recommend that the procedures for preparing, mixing, and transferring the blind material into the specimen bottles at the collection site be carefully reviewed. Additional training may be required to ensure that these procedures are performed correctly.

If we can be of further assistance in this matter, please let us know.

Sincerely,

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