



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

R. M. Krich
Vice President
Nuclear Licensing

July 1, 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: **Submission 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), 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.

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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 June 3, 2011, this report is required to be submitted by July 3, 2011. Since July 3 is a Sunday and July 4, 2011 is a federal holiday, this report is required to be submitted by July 5, 2011.

The Enclosure to this letter provides information and details concerning the unsatisfactory HHS-certified laboratory performance test conducted for TVA by an 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 2004982763

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 2004982763

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 June 3, 2011, regarding a potential testing discrepancy concerning a blind performance test sample submitted to TVA's HHS-certified laboratory. The details of this investigation are summarized below:

On March 3, 2011, HHS-certified laboratory Clinical Reference Laboratory (CRL) received blind performance test sample number 2004982763 from TVA. After testing and review of the test results, CRL released test sample number 2004982763 as negative on March 5, 2011, in accordance with their procedures. CRL subsequently notified TVA's Medical Review Officer (MRO) and Fitness for Duty (FFD) Coordinator that sample number 2004982763 had been classified as negative.

However, sample number 2004982763 was a blind performance test sample, containing manufacturer stated nominal target values of 3500 nanograms per milliliter (ng/mL) Morphine, 3500 ng/mL Codeine, and 20 ng/mL 6-Acetylmorphine (6-MAM).

On March 7, 2011, TVA's MRO notified CRL that test sample number 2004982763 was an external blind that had failed to meet the expected target of positive for Opiates. CRL initiated an investigation on March 7, 2011.

In an investigative report dated April 4, 2011 (Attachment), CRL indicated that the sample screened positive for Opiates, with an initial screened Opiate value of 3414 ng/mL. Specimen validity testing of the initial aliquot yielded a Creatinine value of 31.9 milligrams per deciliter (mg/dL). CRL then provided a separate aliquot of the specimen to their confirmation department for Morphine and Codeine confirmation testing. The Morphine value obtained was 1712 ng/mL and the Codeine value was 1733 ng/mL. Since these results were below the confirmation cutoff levels of 2000 ng/mL for Morphine and 2000 ng/mL for Codeine, the sample was reported as negative in accordance with the CRL standard operating procedures and FFD program guidelines.

The original confirmation data was reviewed by CRL and an additional aliquot of the sample was obtained for supplemental gas chromatography–mass spectrometry (GC-MS) testing. The results obtained by GC-MS analysis were 1772 ng/mL for Morphine, 1885 ng/mL for Codeine, and 9 ng/mL for 6-MAM.

On March 9, 2011, the split (bottle B) specimen and an aliquot of bottle A were sent to Quest Diagnostics, also an HHS-certified laboratory, to be retested for Morphine, Codeine, and Creatinine. Quest Diagnostics reported values on the aliquot from bottle A of 1693 ng/mL for Morphine, 1902 ng/mL for Codeine, and a Creatinine value of 36.5 mg/dL. Quest quantitative results for the bottle B specimen were 1689 ng/mL for Morphine, 1883 ng/mL for Codeine, and a Creatinine value of 36.9 mg/dL. The quantitative results obtained by Quest on both the aliquot from bottle A and the bottle B specimen were consistent with CRL's bottle A results, as indicated in the following chart:

HHS-certified laboratory	Bottle A				Bottle B			
	Morphine (ng/mL)	Codeine (ng/mL)	6-MAM (ng/mL)	Creatinine (mg/dL)	Morphine (ng/mL)	Codeine (ng/mL)	6-MAM (ng/mL)	Creatinine (mg/dL)
CRL	1712	1733		31.9				
CRL GC-MS	1772	1885	9					
Quest	1693	1902		36.5	1689	1883		36.9
Manufacturer	3500	3500	20	73.4	3500	3500	20	73.4

Prior to this current incidence, on February 25, 2011, TVA submitted a 10 CFR 26.719(c)(1) report to the NRC concerning unsatisfactory laboratory results of blind performance test samples tested at an HHS-certified laboratory. In that February 25, 2011 report, TVA concluded that the cause of the event was due to the preparation process (mixing, freezing, reconstituting) of the blind specimen samples. The corrective action taken was to revise the internal policy of freezing and subsequent mixing and handling of blind performance test samples.

However, the batch of blind sample specimens involved in the testing errors described in the February 25, 2011, report to the NRC were not discarded at that time. The corrective action program investigation for the March 5, 2011, test result determined that the specimen involved originated from the same batch of blind test specimens as the specimen discussed in the February 25, 2011, submittal. Therefore, the March 5, 2011, event was due to the same cause identified in the February 25, 2011, submittal.

This event has been entered in TVA's Corrective Action Program and an Apparent Cause Evaluation (ACE) was completed on June 3, 2011.

Corrective Actions Taken or Planned

In accordance with the ACE, the following corrective action has been completed:

- Discard the previously frozen blind specimens and order new blind samples.
Completion date: March 10, 2011 (interim or immediate action).

In accordance with the ACE, the following corrective actions will be completed:

- Revise NPG Standard Department Procedure, NSDP-36, Rev. 0001, "Fitness-for-Duty - Administrative Duties (Blind Testing Requirements, Drug Screen Results including Notifications of Confirmed Positive Alcohol and Drug Screens Results, and Computer Data Entry of Drug Screen Results)," to add steps to be taken when a potential compromise of specimens is identified via unexpected blind specimen results, including handling of any remaining samples.

An effectiveness review of this corrective action will be conducted upon completion of corrective actions.



Dr. Brenda K. Sowter
Senior Physician, MRO
Nuclear Medical Services
TVA
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4/4/11

FAX: (423) 751-3660

Dear Dr. Sowter,

On March 5, 2011, Clinical Reference Laboratory issued a report of "negative" for urine specimen number 2004982763 identified by CRL accession number 49353410. 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 March 3, 2011. The sample screened positive for Opiates. The SVT analysis of the initial aliquot yielded a creatinine value of 31.9 mg/dL. A separate aliquot of the specimen was provided to our confirmation department for Morphine and Codeine confirmation testing. The result obtained for Morphine was 1712 ng/mL. The result obtained for Codeine was 1733 ng/mL. Because these results were below the confirmation cutoff level of 2000 ng/mL for Morphine and Codeine, the sample was reported as negative in accordance with CRL SOP and FFD program guidelines.

On March 7, 2011, the laboratory received notification from you that the sample was an external blind which had failed to meet the expected result of positive for Opiates. The stated nominal target values provided by the manufacturer for the blind sample are 3500 ng/mL Morphine, 3500 ng/mL Codeine, and 20 ng/mL 6-Acetylmorphine. The value for creatinine provided by the manufacturer was 73.4 mg/dL.

An investigation was initiated by CRL on March 7, 2011. The initial screening data was reviewed. The initial screening value for Opiates was 3414 ng/mL. The initial creatinine test had a result of 31.9 mg/dL.

The original confirmation data was reviewed. Additional aliquots of the sample were obtained for supplemental GC/MS testing. The results obtained by GCMS analysis were 1772 ng/mL for Morphine, 1885 ng/mL for Codeine and 9 ng/mL for 6-Acetylmorphine.

On March 9, 2011, the split (bottle B) specimen and an aliquot of bottle A were sent to Quest to be retested for Morphine, Codeine, and creatinine. Quest reported to you that their quantitative results for the bottle B specimen were 1689 ng/mL for Morphine, 1883 ng/mL for Codeine, and 36.9 mg/dL for creatinine. Quest reported levels of 1693 ng/mL for Morphine, 1902 ng/mL for Codeine, and 36.5 mg/dL for creatinine on the aliquot from bottle A.

The quantitative results obtained by Quest for these tests are consistent with the values obtained by CRL.

The repeat testing performed by CRL yielded results consistent with the initially obtained values. The quantitative results obtained by Quest on the aliquot from bottle A are also consistent with CRL's original values. The quantitative results obtained by Quest on bottle B are also consistent with CRL's results for the specimen contained in Bottle A.

CRL's test methods are re-verified for accuracy internally on an annual basis. The accuracy of each test method has also been consistently reconfirmed on a quarterly basis through our participation in external Proficiency Testing programs.

These findings indicate that the material originally supplied by the manufacturer was compromised (diluted or improperly mixed) prior to submission to CRL, resulting in a lower concentration of all analytes within the specimen.

Over the last two years, CRL has experienced multiple occurrences of "false negative" blind reporting with the external blinds supplied by TVA. We have not experienced this type of recurring problem with any other agency or supplier of external blinds. Upon investigation, the failed specimens received by CRL from TVA have repeatedly been shown to be sub-potent when compared to the manufacturer's expected values. The materials supplied by the manufacturer, if properly stored, are expected to be stable for an extended period of time.

To avoid future occurrences of this problem, we recommend that the procedures for storing, mixing, and transferring the blind material into specimen bottles at TVA be thoroughly investigated. The root cause of this recurring problem must be identified. At no time should additional water, negative urine, or any other liquid be added to the material supplied by the manufacturer before or after transfer to the final specimen bottles. If the blind material is frozen, it must be completely thawed and thoroughly mixed prior to dispensing.

The appropriate procedures for preparing these blinds must be clarified and the proper training for carrying out these procedures must be provided to prevent further occurrences of this type of failure.

Sincerely,



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