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

R. M. Krich
Vice President
Nuclear Licensing

September 26, 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. TVA completed an investigation of a testing error at the HHS-certified laboratory used by TVA on August 25, 2011. As a result, this report is required to be submitted by September 24, 2011. Since September 24, 2011, is a Saturday, this report is required to be submitted by September 26, 2011.

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

There are no regulatory commitments contained in 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 2005029037

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 2005029037

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 25, 2011, regarding a potential testing discrepancy concerning specimen number 20050029037, a false negative challenge (FNC) for opiates, submitted to TVA's HHS-certified laboratory.

In a Memorandum for the Record dated July 27, 2011 (Attachment), HHS-certified laboratory Clinical Reference Laboratory (CRL) documented their receipt of specimen number 20050029037 from TVA on July 7, 2011. CRL assigned specimen number 20050029037 a unique identification number in accordance with their standard operating procedures. The initial opiate screening value for sample bottle A was 3274 nanograms per milliliter (ng/mL), which is above the 2000 ng/mL opiate screening cutoff value. Subsequent gas chromatography–mass spectrometry (GC/MS) confirmation testing indicated sample bottle A was negative for morphine and codeine. After reviewing the results, CRL released sample bottle A as negative for opiates.

TVA Corporate FFD staff reviewed the documentation for test specimen number 20050029037 to verify it was an FNC for opiates. On July 12, 2011, TVA notified CRL that specimen number 20050029037 was a blind specimen that had failed to meet the expected target value of positive for opiates. Upon notification of the testing discrepancy, CRL initiated an immediate investigation, verifying that the extraction had occurred properly and that the specimen identification number was correct.

CRL discovered that the identification number printed on the chromatogram did not match the number provided by the barcode reader, a possible indication that the sample had been switched with another sample in the batch. CRL determined that a human error had occurred when the sample was placed in sequence for testing on the GC/MS instrument. The GC/MS instrument has a barcode reader that prints the specimen identification number (i.e., "sid") that it reads at the time of injection along with the specimen number sequenced by a human. There was a mismatch, undetected by two employees, resulting in an error in the reporting of test results for TVA test specimen number 20050029037 and a non-TVA client.

Both the TVA specimen bottle A and the non-TVA sample were re-extracted and the results confirmed that the samples had been switched. CRL issued corrected reports indicating that TVA specimen number 20050029037 tested positive for codeine, morphine and

6-Acetylmorphine. As a corrective action, CRL terminated the certifying scientist and the analyst and provided a verbal warning to the extraction chemist responsible for the error. CRL is also performing training and re-training for the toxicology chemists and analysts for vial loading and sample identification verification.

In addition to the attached report, CRL management further advised TVA's Medical Review Officer that analytical errors are usually detected through the retesting of samples upon donor request. CRL participates in four audits every year that look at over 1600 positive specimens and have never identified this type of error in the past. Additionally, CRL's Executive Director of Analytical Toxicology is not aware of any errors of the type discussed in this report being identified in litigation type procedures during the five years of his employment with CRL. TVA concludes that this isolated human performance error by CRL employees does not raise a specific concern about the overall soundness of the testing portion of TVA's FFD Program.

This event has been entered in TVA's Corrective Action Program and an Apparent Cause Evaluation (ACE) Report has been completed.

Corrective Actions Taken or Planned

TVA's corrective actions and enhancements for this unexpected test result are:

- To complete an industry benchmarking for alternate HHS-certified laboratories that:
  (1) are experienced with 10 CFR 26 requirements,
  (2) have successfully completed a Nuclear Energy Institute (NEI) audit, and
  (3) are currently used by other utilities that are required to meet the provisions of 10 CFR 26.

  In addition, TVA will determine if any computer tracking mechanisms exist that prevent specimens from inadvertently being exchanged during the testing process.
  Corrective Action Completed

- Provide benchmarking results to TVA Administrative Services/Supply Chain for utilization during the FFD testing contract re-bid process.
  Corrective Action Completed

- Issue management expectation that TVA will increase the amount of blind specimens that are submitted to CRL for FFD testing by 10% until February 29, 2012 unless TVA selects an alternate primary HHS-certified laboratory for FFD testing prior to that date. If another HHS-certified laboratory is selected, the blind specimen submittal rate will return to the 10 CFR 26 specified rate.
  Corrective Action Completed

- Provide TVA Quality Assurance (QA) with the final CRL report for specimen number 20050029037 for consideration in upcoming QA Fitness for Duty Program Audit
  Enhancement Completed

- Review QA audit of CRL.
  Corrective Action Completion date: December 02, 2011

- Review above corrective actions, QA audit findings and industry Operating Experience to ensure there have been no recurrences with CRL. If TVA selects an alternate primary HHS-certified laboratory for FFD testing prior to that date, an effectiveness review is not needed.

  Effectiveness Review Completion date: February 29, 2012

ATTACHMENT

CLINICAL REFERENCE LABORATORY

Memorandum for the Record

Date: 7/27/11

From: S. Allison

RE: TVA Specimen 2005029037

CRL received specimen 2005029037 on July 07, 2011. The specimen was accessioned and tested. The initial opiate screening value was 3274 ng/mL, which is above the 2000 ng/mL screening cutoff. The sample was sent to confirmation. Confirmation data indicated the sample was negative for morphine and codeine. The data was reviewed and the results were released as negative on 7/9/11.

Andrea Hagens, workflow specialist was notified on 7/12/11 that the blind failed to meet the expected target value of positive for "opiates". The MRO requested the sample be re-analyzed in this laboratory, bottle B sent to Lab B and the remainder of bottle A be returned to TVA. On investigation of the complaint, the RP noted that the sid printed on the chromatogram did not match the number provided by the barcode reader. It was suspected the sample was switched with another sample in the batch. On further review, it was found that another sample in the batch had a barcode "read" that matched the TVA blind.

Corrective Actions were initiated on 7/12/11.The TVA blind and the suspect samples were re-extracted. The re-extraction results prove the samples were switched. Corrected reports were issued for samples 49376370 and 37788456.

Correct reports:

- 49376370 positive for codeine, morphine and 6-AM.
- 37788456 positive for Hydrocodone and Hydromophone.

The MRO and MRO representatives were notified by the RP. Laboratory management was notified. The certifying scientist and the analyst were terminated. The chemist who made the error was given a warning. Training and re-training for the toxicology chemists and analysts for vial loading and sample identification verification is on- going.

Internal Corrective and Preventative Action Report Forms and associated documentation are attached.

7.27.11

S. Allison, QC Officer — Date

7/27/11

David Kuntz, Ph.D, Responsible Person — Date

ATTACHMENT

Corrective & Preventative Action Report Form

CPARF #: 20110719

Recipient: Confirmation Certification

Originator: Dr. Kuntz

Phone#/Ext: 5406

49376370 37788456

Problem/Complaint:

TVA external blind failed to meet target. Andrea Hagens, workflow specialist was notified on 7/12/11 that the blind failed to meet the expected target value of positive for "opiates". The MRO requested the sample be re-analyzed in this laboratory, bottle B sent to Lab B and the remainder of bottle A be returned to TVA. On investigation of the complaint, the RP noted that the sid printed on the chromatogram did not match the number provided by the barcode reader. It was suspected the sample was switched with another sample in the batch. On further review, it was found that another sample in the batch had a barcode read that matched the TVA blind.

Corrective Action:

The TVA blind and the suspect sample were re-extracted. The re-prep results prove the samples were switched. Corrected reports were issued for samples 49376370 and 37788456. Correct reports: 49376370 positive for codeine, morphine and 6-AM. 37788456 was positive for Hydrocodone and Hydromophone. The MRO and MRO representatives were notified by the RP. Laboratory management was notified. The certifying scientist and the analyst were terminated. The chemist who made the error was given a warning.

QA/QC Comments:

Additional data found in this incident report includes: Initial notification, Copies of chromatography from initial batch with sid/barcode number mis-match. The computer printout of results, the signed ccf with the originally reported results, documentation of discussion with MRO assistant. Corrective actions with term notices and written warning with supporting documentation. A copy of the entire original extraction batch. A copy of the entire re-extraction batch. A copy of the corrected reports.

Name: S. Allison 7/19/11

Confirmation Supervisor

Training, SOP review and observation of vial order is currently on-going with confirmation staff.

Name: Brett Oswald 7/27/11

R.P. Review: 7/27/11

Recipient Review:

Note: The Laboratory Director receives a quarterly CPARF report which is reviewed and signed. All individual CPARFs are stored in the QA/QC Office and are available to the director at his discretion for review.