



Tennessee Valley Authority, 1101 Market Street, Chattanooga, Tennessee 37402-2801

September 15, 2009

10 CFR 26.719(c)

U.S. Nuclear Regulatory Commission
ATTN: NRC Document Control Desk
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-78
NRC Docket Nos. 50-327 and 50-328

Watts Bar Nuclear Plant, Units 1 and 2
Facility Operating License No. NPF-90
NRC Docket Nos. 50-390 and 50-391

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

Reference: Federal Register Volume 73, No. 62, Section VI, "Section-by-Section
Analysis of Substantive Changes, Subpart G - Laboratories Certified
by the Department of Health and Human Services, Subsection 26.168,
Blind Performance Testing," dated March 31, 2009

In accordance with 10 CFR 26.719(c)(1), the Tennessee Valley Authority (TVA) submits the following report regarding a drug testing error at a Health and Human Services (HHS) certified laboratory. The error was a false-negative result for a positive (i.e, a false negative challenge) blind specimen submitted to TVA's HHS-certified laboratory. This report is due within 30 days of completing the investigation. The investigation was completed on August 17, 2009. The report due date is September 16, 2009.

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Description of Incident

On June 17, 2009, TVA's Medical Review Officer (MRO) and Fitness for Duty (FFD) Program Manager, received notification of a false-negative result for a positive (i.e., a false negative challenge) blind specimen containing the barbiturate analyte. This notification was made by TVA's HHS-certified laboratory, Clinical Reference Laboratory (CRL).

Corrective Actions Taken or Planned

An investigation was immediately launched and on June 18, 2009, an independent split specimen confirmation was requested to be performed by Quest Diagnostics, also a HHS-certified laboratory. On June 25, 2009, Quest Diagnostics confirmed the barbiturate analyte with a quantitative level of 501 ng/ml. The drug test cutoff for barbiturate analyte is 300 ng/ml. On June 26, 2009, TVA requested CRL to perform a second complete immunoassay of the specimen and again a negative result was obtained. CRL was then asked to perform specific confirmatory testing for the barbiturate analyte on July 1, 2009; and on July 8, 2009, CRL returned a positive result for butabital with a quantitative result of 503 ng/ml.

The Enclosure to this report provides the formal response from CRL. The recommendations to prevent this issue from reoccurring as provided in the enclosed formal response from CRL were evaluated. However, implementing these recommendations would not conform to the testing requirements and therefore cannot be implemented.

After extensive review of this information and upon completion of the associated investigation, it is the opinion of TVA's MRO that it can reasonably be concluded that the drug-testing program with the current immunoassay techniques, may render false negative results. While there is no current remedy for this potential problem in the drug testing program, it is a recognized issue as documented in the referenced Federal Register Volume which states:

"False negatives occur when drug levels that are positive but close to the initial drug test cutoff level may actually be reported as negative. ...The NRC recognizes that false negatives will occur within its drug testing guidelines, but intends to minimize them as much as is reasonably possible within scientific constraints and practical limitations of resources...."

TVA currently performs the maximum number of 100 blind specimens per quarter. It is believed that by performing the maximum number of blind specimens each quarter, the susceptibility of false negatives occurring is increased as discussed in the referenced Federal Register Volume. TVA will continue to perform and monitor blind

U.S. Nuclear Regulatory Commission
Page 3
September 15, 2009

specimen testing in accordance with TVA's drug/blind specimen testing program. No other corrective action is planned to be taken.

This event was entered in TVA's Corrective Action Program. If you have any questions concerning this report, please contact Kevin Casey at (423) 751-8523.

Respectfully,



R. M. Krich
Vice President
Nuclear Licensing

Enclosure

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

ENCLOSURE



CLINICAL REFERENCE LABORATORY

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

Dear Dr. Sowter:

This letter is regarding specimen ID number 6401748061 which was submitted to this laboratory as a False Negative specimen challenge. The following is the summary report.

Clinical Reference Laboratory, Inc. (CRL) performed a full drug screen on specimen 6401748061. After reporting the results to the MRO office, the laboratory was informed that there was a concern because the specimen had not been reported as positive for barbiturates. The initial screening results were reviewed and were found to have been reported in accordance with CRL's standard operating procedures. Specifically, the barbiturate immunoassay result of 276 ng/mL was less than the industry standard cutoff of 300 ng/mL and consequently reported as negative.

Subsequently, it was requested that the lab perform a repeat of the full drug screen. Again, the specimen screened negative and the barbiturates result was just shy of the cutoff. The barbiturate immunoassay result of this second analysis was 280 ng/mL. Following the receipt of these results Dr. Sowter requested that a barbiturate confirmation analysis be performed. The quantitative result of this confirmation analysis was 503 ng/mL of Butalbital.

The performance data of this immunoassay supplied by Microgenics indicate that there is approximately 66% cross-reactivity of Butalbital with the antibodies designed for Secobarbital. This is a known limitation of such immunoassays. When calculating the expected result, this is very near the screening decision point.

It is my recommendation that the either two events occur to prevent this from re-occurring: One, the cross-reactivity is determined for the spiked analyte and then add the corresponding amount of the target analyte to cause it to screen a minimum of 20% above the cutoff. Two, only use the immunoassay targeted analyte. In the case of barbiturates that analyte is Secobarbital. The laboratory also has the possibility of having false-negative results with opiates and benzodiazepines since the screening assays are for a class of compounds and the cross-reactivity between compounds within the drug category vary greatly.

If you have additional questions, please call me at 913-693-5406 or email at www.kuntzd@crlcorp.com.

Best regards,

David J. Kuntz, PhD, DABFT
Executive Director of Analytical Toxicology
Clinical Reference Laboratory