



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

R. M. Krich
Vice President
Nuclear Licensing

February 25, 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

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, 2008

In accordance with 10 CFR 26.719(c), "Drug and alcohol testing errors," Tennessee Valley Authority (TVA) submits the following report regarding the unsatisfactory laboratory results of blind performance test samples tested at a Department of Health

A022
NRR

and Human Services (HHS) certified laboratory, including a false negative result for a positive (i.e., a false negative challenge) blind performance test sample.

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.

Enclosures 1 and 2 to this letter provide information and details concerning unsatisfactory HHS-certified laboratory performance tests 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

- Enclosures: 1) 10 CFR 26.719(c) Report Summary of Unsatisfactory Laboratory Performance Test Sample No. 2003389418
- 2) 10 CFR 26.719(c) Report Summary of Unsatisfactory Laboratory Performance Test Sample No. 2002190118

cc (Enclosures):

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 1

TENNESSEE VALLEY AUTHORITY

10 CFR 26.719(c) REPORT SUMMARY OF UNSATISFACTORY LABORATORY PERFORMANCE TEST SAMPLE NO. 2003389418

Description of Incident

The requirements of 10 CFR 26.168, "Blind performance testing," state that each licensee shall submit blind performance test samples to the Department of Health and Human Services (HHS)-certified laboratory and shall use only blind performance test samples that have been certified by the supplier.

Tennessee Valley Authority (TVA) completed an investigation on January 26, 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 November 13, 2010, HHS-certified laboratory Clinical Reference Laboratory (CRL) received blind performance test sample 2003389418 from TVA. After testing and review of the test results, CRL released test sample 2003389418 as negative on November 18, 2010, in accordance with their procedures. CRL subsequently notified TVA's Medical Review Officer (MRO) and Fitness for Duty (FFD) Coordinator that sample number 2003389418 had been classified as negative. However, since sample number 2003389418 was a blind performance test sample containing the drug propoxyphene and the metabolite norpropoxyphene, this negative classification was a false negative result for a positive (i.e., a false negative challenge).

Therefore, on November 23, 2010, TVA's MRO notified CRL that test sample number 2003389418 was an external blind that had failed to meet the expected target of positive for propoxyphene. CRL initiated an investigation on December 7, 2010.

In an investigative report dated January 18, 2011, CRL indicated that the initial propoxyphene screening value of sample number 2003389418 was 381 ng/mL. Gas chromatography-mass spectrometry (GC-MS) analysis determined a value of 291 ng/mL of norpropoxyphene (propoxyphene metabolite). After notification that sample number 2003389418 was an external blind performance test sample that had failed to meet the expected target, CRL re-screened the subject sample and re-submitted for GC-MS testing to confirm propoxyphene metabolite. The values obtained confirmed the initial results.

On November 23, 2010, at the request of TVA's MRO, CRL sent the balance of the split sample to Quest Diagnostics, an HHS-certified laboratory, for an independent split sample test. Quest Diagnostics confirmed the propoxyphene metabolite on November 30, 2010.

On December 21, 2010, TVA requested that Quest Diagnostics perform a quantitative level determination on the analyte propoxyphene. The value obtained by Quest Diagnostics was 343 ng/ml. Although the value of 343 ng/ml indicates positive for analyte propoxyphene, it does not meet the expected value provided by the blind sample manufacturer of 415 ng/ml.

In the March 31, 2008, Federal Register (FR 17104, Vol. 73, No. 62, Section 26.168) statement of consideration for the final rule of 10 CFR Part 26, "Fitness for Duty Programs," the NRC recognized that blind performance test samples containing drugs or drug metabolites at a concentration 20 percent about the cutoff levels frequently yield false negative test results. Since the analyte propoxyphene test results for blind performance sample number 2003389418 (343 ng/ml) were within 20 percent of the cutoff level (300 ng/ml), TVA's MRO identified that the lower level of analyte in the sample was a factor in the unsatisfactory laboratory performance result.

From the above referenced statement of consideration:

"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."

However, the other discrepancies identified in the testing of this sample were independent of the above false negative error. The failed sample exhibited lower creatinine quantitative results but no corresponding significant statistical pH difference. This quantitative result, in combination with Quest Diagnostic's lower than expected drug level quantitative testing results, reveal a second issue related to pre-submission sample preparation.

In April 2010, TVA's pre-submission sample preparation method was modified to reflect that the immediate processing of false negative challenges could eliminate potential possible reductions in the test cutoff level of a drug. However, since the recent sample failures indicate that TVA's pre-submittal sample preparation remains an issue, TVA's MRO contacted the lab director of the blind sample company for insight into industry operational experience that could be impacting TVA's handling of samples prior to submittal to CRL.

TVA's procedure for pre-submission sample preparation was developed prior to the use of the current lower levels of analyte in the nuclear testing program and before TVA began using the current blind sample provider. Current pre-submission sample preparation best practices no longer require samples be frozen and refrozen during storage for subsequent testing. If the samples are refrigerated, rather than frozen, mixing the samples prior to their separation into the A and B testing bottles reduces

errors in both the handling and in the determination of subsequent analyte concentration levels.

Additionally, gently inverting the samples several times rather than agitating them prevents the formation of froth and sequestration of a percentage of the analyte, also reducing the overall concentration of analyte in the liquid decanted into the testing bottles. Finally, the sample handling has been revised to ensure that after several gentle inversions to mix, the sample is immediately poured into the A and B testing bottles. This prevents an entire gradient of analyte concentration sediment from settling top to bottom, which results in a decrease in analyte concentration at the top and an increase in analyte concentration at the bottom than provided in the blind sample company's actual batch sample analyte concentration.

Immediately upon notification to the MRO of the results of this investigation, TVA revised its internal policy of preparing blind samples.

This event has been entered in TVA's Corrective Action Program.

Corrective Actions Taken or Planned

The investigation identified the false negative occurrence when positive drug levels close to the initial drug test cutoff level may be reported as negative, as noted in the NRC's statement of consideration in the final rule of 10 CFR Part 26, "Fitness for Duty Programs," dated March 31, 2008. Since this is a known industry issue in the FFD testing program, no further action needs to be taken by TVA to address this unsatisfactory test result.

This investigation also identified an issue associated with TVA's internal process involving the freezing and the subsequent mixing and handling of the blind performance test samples prior to their use in the blind testing program. An immediate corrective action resulting from this investigation was TVA's revision of its methods of preparing blind samples.

ENCLOSURE 2

TENNESSEE VALLEY AUTHORITY

10 CFR 26.719(c) REPORT SUMMARY OF UNSATISFACTORY LABORATORY PERFORMANCE TEST SAMPLE NO. 2002190118

Description of Incident

The requirements of 10 CFR 26.168, "Blind performance testing," state that each licensee shall submit blind performance test samples to the Department of Health and Human Services (HHS)-certified laboratory and shall use only blind performance test samples that have been certified by the supplier.

Tennessee Valley Authority (TVA) completed an investigation on January 26, 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 December 3, 2010, HHS-certified laboratory Clinical Reference Laboratory (CRL) received blind performance test sample 2002190118 from TVA. CRL's initial analysis measured a cocaine screening value of 271 ng/mL and a creatinine value of 27.1 mg/dL for sample 2002190118. After testing and review of the test results, CRL released test sample 2002190118 as negative on December 3, 2010, in accordance with their procedures.

On December 13, 2010, TVA requested CRL perform an investigation on this failed positive cocaine blind performance test sample. Subsequently, on December 14, 2010, TVA requested CRL perform split testing and that the split bottle be sent to Quest Diagnostics for testing of the analyte cocaine.

Per CRL's investigation, CRL received a request on December 14, 2010, to perform a split test sample retest for cocaine on test sample 2002190118. TVA's request for retesting did not indicate that test sample 2002190118, initially classified by CRL as a drug negative sample, was an external blind performance test sample. According to CRL, since performing reconfirmation testing on a negative sample would be inappropriate, CRL personnel were uncertain how to process TVA's request for retesting. Although CRL requested clarification via email from TVA on December 16, 2010, CRL had already discarded the sample bottles by the time clarification was received.

Corrective Actions Taken or Planned

CRL has now implemented a corrective action regarding processing of retests. When CRL personnel receive a request for a split sample retest that cannot be immediately processed, it will be transferred to a short-term storage area so it will not be discarded.

This event has been entered in TVA's Corrective Action Program and immediate corrective actions have been performed.



CLINICAL REFERENCE
LABORATORY

Memorandum for the Record

Date: 2/24/11
From: D. Kolbow
RE: TVA Specimen 2002190118

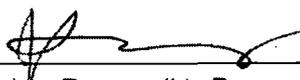
CRL received specimen 2002190118 on December 03, 2010. The specimen was accessioned and tested. The initial cocaine screening value was 271 ng/mL, which is below the 300 ng/mL screening cutoff. The data was reviewed and the sample was released as negative on 12/03/10.

On December 14, 2010, CRL personnel received a request for a split specimen retest for this specimen. The specimen was identified by CRL personnel as drug negative specimen. CRL personnel did not immediately understand how to process this request. By the time the specimen was identified as an external blind the bottles had been discarded.

Internal memoranda for the record dated 1/5/11 and 1/19/11 were prepared and forwarded to Dr Sowter to provide an explanation for these events. These memoranda are attached.

 2/24/11

Daniel Kolbow, Alternate Responsible Person Date

 2/24/11

John Irving, Responsible Person Date

Memorandum for the Record

Date: 1/19/11
From: D. Kolbow
RE: Failed Cocaine Blind Specimen 2002190118

Source: Phone Conversation with Dr. Sowter

Issue: Explanation for Failed External Blind Specimen 2002190118

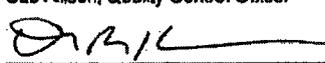
Dr. Sowter (MRO) in a phone conversation with D. Kolbow on January 18, 2011, requested a written explanation for Failed External Blind Specimen 2002190118.

Explanation: CRL received specimen 2002190118 on December 03, 2010. It was accessioned and processed in accordance with SOP. The initial cocaine screening value was 271 ng/mL. The specimen had a creatinine value of 27.1 mg/dL. The data was reviewed and the sample was released as negative in accordance with SOP on 12/03/10.

We suspect that this blind failed for the same reason as the other blind failures that have occurred recently with external blinds received from TVA. The specimen may have been diluted or improperly prepared prior to submission to CRL. The observed cocaine screening value of 271 ng/mL is slightly below the screening cutoff value of 300 ng/mL. The target value provided by the blind manufacturer was 583 ng/mL. The screening value obtained by CRL is 46% of the target value. The creatinine target value provided by the manufacturer was 72 mg/dL. The observed creatinine value of 27.1 mg/dL is 38% of the target value. The values obtained by CRL are consistent with a specimen that has been improperly diluted prior to submission.

Conclusion:

We have concluded that this blind failure is likely to have the same underlying issue that has resulted in the other recently encountered blind failures. We suspect that this blind failure is also the result of a pre-submission error and not an analysis error on the part of the laboratory.

 Sue Allison, Quality Control Officer	1-19-11 Date
 Daniel Kolbow, Alternate Responsible Person	1/19/11 Date
 John Irving, Responsible Person	1/19/11 Date
 David J. Kuntz, Responsible Person	1-19-11 Date

Memorandum for the Record

Date: 1/05/11
From: D. Kolbow
RE: Discard of Failed Blind Specimen 2002190118

Source: Email Message from Carol Pulliam, Tennessee Valley Authority

Issue: Discard of Failed External Blind Specimen 2002190118

Message: "Dr. Sowter (MRO) received the above attachment from CRL on 12/28/10 stating that a blind specimen done on 12/2/10 tested as negative and was discarded. We requested split testing on 12/14/10 and the specimen shouldn't have been discarded till 12/16/10. Can you provide further information regarding this issue?"

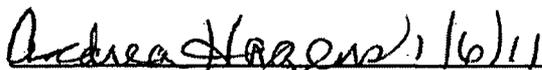
Explanation: CRL personnel received a request on December 14, 2010 for a split specimen retest for Cocaine for specimen 2002190118. The specimen was identified by CRL personnel as drug negative specimen. The specimen was not identified as an external blind in Dr. Sowter's request. As it is inappropriate to request reconfirmation testing on a negative specimen, CRL personnel did not immediately know how to process this request. CRL personnel sent a message to Dr. Sowter on December 16th requesting clarification and indicating that the specimen could be processed that same day upon receipt of revised documentation. Dr. Sowter did not respond to this message until December 21. Unfortunately, by the time the nature of the request was fully identified and understood – that a failed external blind required an investigation – the specimen bottles had been discarded.

Corrective Action:

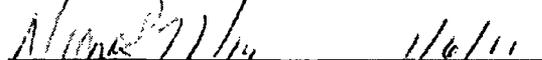
If CRL personnel receive a request for a split specimen retest that cannot be immediately processed, workflow personnel should arrange to have the relevant specimen transferred to a short-term storage area where the specimen will not be discarded.

Conclusion:

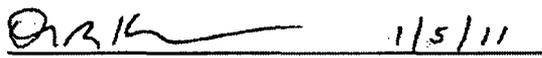
CRL personnel must make arrangements to prevent a specimen that has been requested for a split specimen retest from being discarded when a request is received prior to the specimen's scheduled discard date.

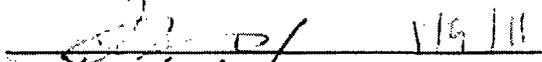

Andrea Hagens, Workflow Specialist Date

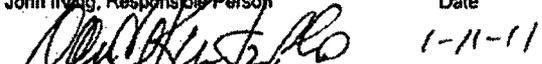

Stacy Reddick, Workflow Specialist Date


Diane Moore, Mgr of Toxicology Admin. Date


Sue Allison, Quality Control Officer Date


Daniel Kolbow, Alternate Responsible Person Date


John Irving, Responsible Person Date


David J. Kuntz, Responsible Person Date