



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

June 23, 1999

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555-0001

Gentlemen:

In the Matter of )  
Tennessee Valley Authority ) 10 CFR 26, Appendix A

**UNSATISFACTORY LABORATORY RESULT ON A BLIND PERFORMANCE TEST SPECIMEN**

In accordance with 10 CFR 26, Appendix A, 2.8 (e) 4, enclosed are the investigative findings of Clinical Reference Laboratory (CRL) which serves as TVA's contract laboratory. CRL's investigation was initiated due to a false negative result on a blind performance test sample. This blind performance sample contained opiates and should have tested positive for opiates.

TVA's Fitness for Duty (FFD) Program management met with CRL's management and determined that this incident occurred due to three CRL employees failing to follow CRL's standard operating procedures. As indicated in the enclosed report, CRL counseled each individual involved in the incident. The aforementioned investigation determined that the underlying cause of the false negative resulted from human error. Specifically, CRL personnel used the 2000 ng/ml opiate cutoff limit that was established for Department of Transportation (DOT) clients on December 1, 1998. Utilization of the DOT opiate cutoff level of 2000 ng/ml instead of the NRC opiate cutoff level of 300 ng/ml lead to the erroneous report. Following the detection of the error, TVA's FFD Program management conducted an onsite review of every TVA opiate screen positive sample since December 1, 1998 (date of the DOT opiate cutoff change). Numerous samples were reviewed, and no other errors of this type were identified during the audit.

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Due to the fact that no other incidents were uncovered and because of CRL's previous excellent record on blind performance testing, this incident was determined to be an isolated occurrence. As part of TVA's FFD Program, TVA plans to continue monitoring CRL's performance through blind performance testing to prevent reoccurrence of this type error.

If you have any questions concerning this information, please telephone Terry Knuettel at (423) 751-6673.

Sincerely,

  
Mark V. Burzynski  
Manager  
Nuclear Licensing

Enclosures

cc (Enclosures):

Mr. Luis Reyes, Regional Administrator  
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cc: Continued on page 3

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cc (Enclosures):

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Watts Bar Nuclear Plant  
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Spring City, Tennessee 37381

CLINICAL REFERENCE  
LABORATORY

June 18, 1999

Monica Smith  
TVA -Central Med Lab  
1101 Market St  
EB 10B-C  
Chattanooga, TN 37402

Dear Monica:

This letter can serve as a follow-up to the written Incident Report Form that CRL completed concerning blind specimen #41119873.

The specimen contains 535 ng/mL Morphine, as correctly analyzed by the laboratory. However, the specimen was reported "negative" due to our comparing that value to the DOT cutoff of 2000 ng/mL instead of the NRC cutoff of 300 ng/mL. Our protocol requires that specimens subject to the 300 ng/mL cutoff be prepped for GC/MS analysis separately from those specimens subject to the 2000 ng/mL cutoff, but the prepper overlooked the designated "300 ng/mL cutoff" marked on that specimen's chain of custody.

The GC/MS operator failed to catch the error when he entered the correct value into the computer and marked the test status negative.

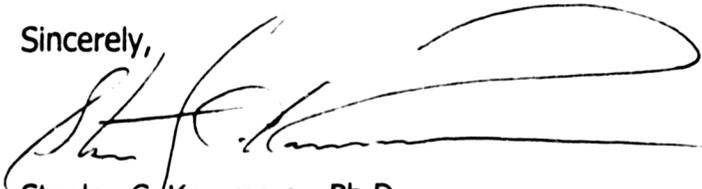
The Certifying Scientist failed to catch either of these errors, which were plainly discoverable during her routine certifying process, and reported the result negative.

The fact that a survey of every opiate positive from TVA since the 2000 ng/mL cutoff rule went into effect on December 1, 1998, shows that this was the only incident of error, supports the argument that our protocol is reliable in preventing and/or catching this error, and that only an extraordinary set of coincidences of not following S.O.P by three individuals permitted its occurrence. The individuals have been counseled, and I am confident that this error cannot be repeated.

# CLINICAL REFERENCE LABORATORY

The effect of the error on a "real" sample is debatable. Typically, a Medical Review Officer will not report the presence of 535 ng/mL Morphine in the urine as evidence of drug abuse, and low level morphine samples were the only possible source of this error. If I can further explain anything concerning this matter, please do not hesitate to call me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stanley C. Kammerer', with a large, sweeping flourish at the end.

Stanley C. Kammerer, Ph.D  
VP and Director of Toxicology

/nw