



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

March 30, 2005

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 amphetamine/methamphetamine and should have tested positive for amphetamine/methamphetamine.

Management from TVA's Fitness for Duty (FFD) Program consulted CRL's management and determined that this occurred due to:

- (1) The original data was entered incorrectly by the confirmation analyst, who failed to multiply the on-column result by the dilution factor.
- (2) The error of the confirmation analyst was overlooked by the certifying scientist.

Both individuals were counseled on the error and retraining was initiated for certifying scientists and gas chromatography/mass spectrometry analysts during the laboratory's March 25, 2005, continuing education session. Retraining documentation will be maintained on file in the Quality Assurance office of the laboratory.

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.

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

Sincerely,



Fredrick C. Mashburn
Senior Program Manager
Nuclear Licensing

Enclosures

cc (Enclosures):

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ENCLOSURE

Investigative Findings
Of
Clinical Reference Laboratory

**Corrective & Preventative Action
Report Form**

43556043

CPARF #: 050303.01

Recipient: W. Akinmoladun
M. Eckstein

Originator: Stan Kammerer Phone#/Ext: 5045

Facility: CLS

Problem/Complaint: Dr. Kammerer was contacted by TVA and informed that specimen 43556043 was a positive blind. Upon review it was determined that the specimen's on-column concentration was not multiplied by its dilution factor and the specimen was reported as negative.

Corrective Action: 43556043 was reprep'd undiluted in BID MAR2005015. The undiluted reprep amphetamine value was 1957 ng/ml and the methamphetamine value was 2081 ng/ml. Correct specimen results were entered into LIMS, Corrected Report comment added and SID was retransmitted. The CCF was forensically corrected and re-imaged for reporting to Dr. Enriquez. The programmed LOQ for amphetamine and methamphetamine was changed from 200 ng/ml to 100 ng/ml in the primary and backup instrument software.

Supervisor Comments:

Name:

Date:

QA/QC Comments:

This was an isolated incident. No other specimens were affected in BID FEB2005432. Dilution factors are checked as required by SOP when preparing specimens for analysis and by the certifying scientist prior to reporting of all results. The reporting certifying scientist was counseled regarding the uncalculated dilution as evidence by the signature at the bottom of this report form. Retraining for all non-negative and negative certifying scientists is scheduled for 08:00 on 03/25/05. Documentation of retraining will be attached to this report and filed for future review.

Name: Trevor Proctor/tsp

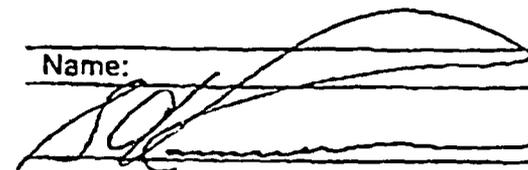
Date: 03-07-05/ 03-24-05

**Lab/Project/Department
Manager Comments:**

Name:

Date:

V.P. Review:



Date: 3/22/05

Recipient Review:

Whitty Akinmoladun

Date:

Mary Eckstein MECKSTEIN

Date: 3/10/05 and 3/24/05

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.