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

March 24, 2000

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

Gentlemen:

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

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 two 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 May 1, 1999. Numerous samples were reviewed, and no other errors of this type were identified during the audit.

A022

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,

Ralph H. Shell

for Mark J. Burzynski
Manager
Nuclear Licensing

Enclosures
cc (Enclosures):
Mr. Luis Reyes, Regional Administrator
U.S. Nuclear Regulatory Commission
Region II
Atlanta Federal Center
61 Forsyth Street, SW, Suite 23T85
Atlanta, Georgia 30303-8931

Mr. William O. Long, Senior Project Manager
U.S. Nuclear Regulatory Commission
One White Flint, North
11555 Rockville Pike
Rockville, Maryland 20852-2739

Mr. Ronald W. Hernan, Senior Project Manager
U.S. Nuclear Regulatory Commission
One White Flint, North
11555 Rockville Pike
Rockville, Maryland 20852-2739

Mr. Robert E. Martin, Senior Project Manager
U.S. Nuclear Regulatory Commission
One White Flint, North
11555 Rockville Pike
Rockville, Maryland 20852-2739

cc: Continued on page 3

cc (Enclosures):
Mr. M. C. Thadani, Project Manager
U.S. Nuclear Regulatory Commission
One White Flint, North
11555 Rockville Pike
Rockville, Maryland 20852-2739

NRC Senior Resident Inspector
Browns Ferry Nuclear Plant
10833 Shaw Road
Athens, Alabama 35611

NRC Resident Inspector
Sequoyah Nuclear Plant
2600 Igou Ferry Road
Soddy Daisy, Tennessee 37379-3624

NRC Resident Inspector
Watts Bar Nuclear Plant
1260 Nuclear Plant Road
Spring City, Tennessee 37381

CLINICAL REFERENCE LABORATORY

March 21, 2000

Monica Smith
Via Fax and Mail

RE: False Negative Opiate Report

Dear Monica:

The reporting (preliminary) of a morphine result, accession number 41854543, of 545 ng/ml as negative occurred as a result of two people failing to follow written S.O.P. As you know, most opiate cutoff values are set at 2000 ng/ml, and the confirmation aliquotter, even though receiving a preliminary screen of 592—POS, proceeded to include this confirmation specimen with a batch of 2000 – cutoff opiates. The certifying scientist then neglected to check the cutoff value, which is on the Certifier Review Screen, before electronically releasing the result as negative.

The people involved have been counseled, however, a computer 'fix' has been implemented to prevent the possibility of this happening again. The fix consists of the computer checking the numerical value of the confirmation result against the client specific cutoff for the drug being tested and flagging any attempt at associating the wrong status (POS or NEG) with that value. The implementation of this fix is complete and our QA/QC department is testing for side effects for the rest of this week.

Sincerely,

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

/nw