Nuclear Operating Company

South Texas Project Electric Generating Station P.O. Box 289 Wadsworth, Texas 77483

April 17, 2017
NOC-AE-17003458
10 CFR 26

Attention: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

South Texas Project
Units 1 and 2
Docket Nos. STN 50-498, STN 50-499
Report of Unsatisfactory Blind Testing Results in Fitness for Duty Program

In accordance with 10 CFR Part 26, Subpart N, Recordkeeping and Reporting Requirements, Section 26.719 (c)(1), STP Nuclear Operating Company (STPNOC) is reporting unsatisfactory blind performance testing results from Quest Diagnostics Laboratories for the STPNOC Fitness for Duty (FFD) Program.

On March 21, 2017, Quest Diagnostics Laboratories reported a false negative blind test result on two (2) specimens to STPNOC. The cause was determined to be a human performance error – failure to properly follow standard operating procedures. A summary of the Quest Diagnostics Laboratories investigation report submitted to STPNOC is attached. Corrective actions associated with this issue are being tracked in the STP Corrective Action Program.

This letter contains no regulatory commitments.

If you have any questions, please contact Marilyn Kistler at (361) 972-8385.

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Manager, Plant Protection/
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Attachment: Summary of Unsatisfactory Blind Testing Results Investigation Report

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NSIR

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Summary of Unsatisfactory Blind Testing Results Investigation Report

DESCRIPTION OF INCIDENT:

On March 21, 2017, Quest Diagnostics Laboratories, a Department of Health and Human Services certified laboratory, conducted a urine drug screening on two (2) blind specimens #0774410 and #0774411 and reported a negative result. On March 21, 2017, the negative blind performance test results were received by the South Texas Project (STP) Fitness for Duty (FFD) Coordinator for Specimens #0774410 and #0774411. Quest was then contacted and informed by the Fitness for Duty Coordinator and the Access and FFD Supervisor that Specimens #0774410 and #0774411 were blind quality control samples of Marijuana targeted at 95 ng/ml.

An investigation was consequently initiated by Quest at the request of the Medical Review Officer (MRO) to re-analyze the specimens and determine the reason for the inaccurate results.

INVESTIGATION:

As a result of the investigation, it was determined that all THC quality control results were acceptable and the analysts and certifying scientists reviewing the data followed standard operating procedure. However, further investigation revealed that the THC screening reagent on one of the initial testing instruments was improperly prepared. The initial testing supervisor directed the staff to discard the reagent but they inadvertently missed discarding reagent from Olympus #9. The improperly prepared reagent was no longer in use after March 21, 2017. All data tested on Olympus #9 on March 21, 2017 was reviewed. This review was completed on March 22, 2017. It appeared that specimens with absorbance readings that were fifty percent of the cutoff absorbance might potentially be affected. To ensure all specimens needing to be re-tested were identified, the laboratory pulled any specimens with absorbance readings ten percent or greater of the calibrator absorbance. All STP specimens received on March 21, 2017 were re-tested. All repeated specimens with the exception of two (Specimens #0774410 and #0774411) remained negative. The re-testing was completed on March 24, 2017. The two (2) specimens (Specimens #0774410 and #0774411) were re-tested and were presumptive positive on the initial testing. The specimens were tested using the laboratory confirmation method and corrected reports were issued to the Medical Review Officer on March 24, 2017.

CAUSE:

The laboratory's standard operating procedures were not followed. The THC screening reagent from Olympus #9 on one of the initial testing instruments was improperly prepared.

IMMEDIATE ACTIONS:

All specimens (including fifty-three specimens submitted by STP) tested on Olympus #9 on March 21, 2017 were reviewed and the specimens needing to be re-tested were identified and retested. Retesting was completed on March 24, 2017. The specimens were tested using the laboratory confirmation method and corrected drug reports were issued to the Medical Review Officer on March 24, 2017.

All STP specimens are being sent to the backup lab (Alere) until this issue has been resolved and the corrective actions performed by Quest have been completed.

CORRECTIVE ACTIONS:

Quest Diagnostics Laboratories verbally discussed the issue with key personnel during the initial investigation and retrained the personnel directly involved in the improper reagent preparation. Completed on March 29, 2017.

The acceptance criteria for evaluation of initial testing instrument calibration was revised. Completed on March 28, 2017.

Formal in-service training was provided to other appropriate personnel to include a review of the standard operating procedures, calibration protocols, the proper handling of potential reagent issues and the results of the incident investigation. Completed on March 29th and 30th, 2017.