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Jeffrey S. Forbes Vice President Operations ANO

0CAN030701

March 6, 2007

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

Subject:

Drug Testing Laboratory Performance Report

Arkansas Nuclear One – Units 1 and 2

Docket Nos. 50-313 and 50-368 License Nos. DPR-51 and NPF-6

## Dear Sir or Madam:

On January 11, 2007, the Arkansas Nuclear One (ANO) Fitness for Duty (FFD) testing laboratory, Quest Diagnostics, reported negative results for a blind Quality Assurance sample that should have tested positive for marijuana metabolites. Upon receipt of this information, ANO began an investigation of the incident.

On January 12, 2007, Quest Diagnostics was notified of the discrepancy and was requested to conduct an investigation into the cause of the error. The laboratory retested a sample from the subject sample and again obtained negative results.

During the investigation of the incident, the manufacturer of the certified samples, Professional Toxicology Services, Inc. (PTS), was contacted and reported that they had experienced similar problems with samples from the same lot number as ANO's problem sample. The manager of PTS acknowledged that they had neglected to inform ANO of the recall of the subject sample lot.

On February 5, 2007, ANO received the completed investigative report from Quest Diagnostics which concluded that the subject sample lot repeatedly screened below the 50 ng/ml cutoff level, thereby documenting that the sample lot supplied by PTS was defective.

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In accordance with paragraph 2.8(e)(4) of Appendix "A" to 10CFR26, enclosed is the investigation report provided to ANO by Quest Diagnostics concerning the unsatisfactory performance test result.

There are no commitments contained in this submittal.

Sincerely,

Dale E. James Manager, Licensing

DEJ//s

cc: Dr. Bruce S. Mallett
Regional Administrator
U. S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

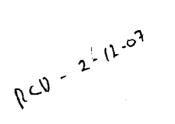
NRC Senior Resident Inspector Arkansas Nuclear One P.O. Box 310 London, AR 72847

U. S. Nuclear Regulatory Commission Attn: Ms. Farideh Saba Mail Stop 0-8 B1 Washington, DC 20555-0001

## Attachment to 0CAN110501

**Vendor Quality Assurance Report** 

3175 Presidential Drive Atlanta, Georgia 30340 770.452.1590 www.questdiagnostics.com





February 5, 2007

Stephen A. Kaufmann AA/FFD Entergy-ANO 1448 SR 333 Russellville, AR 72802

Re: Lab Accession Number 899414A

## Dear Mr. Kaufmann:

Upon your request, the laboratory has investigated a discrepancy in results that were reported on a blind quality control sample that was submitted for testing. The sample (899414A) was reported by the laboratory as Negative on January 11, 2007. Following notification from your office that the specimen should have contained Marijuana Metabolites at a concentration above the minimum immunoassay cutoff (50 ng/mL), the laboratory performed the following internal investigation:

- 1. The laboratory reviewed the original drug screening data from Load TXNRC0111004 to ensure all quality control results were acceptable and to ensure that the correct result was reported for specimen 899414A. A review of the results confirmed that all quality control results for the Marijuana Metabolite assay were acceptable and the specimen was correctly reported as Negative for Marijuana Metabolites. The following absorbance values were obtained for the quality control samples and the blind quality control specimen (899414A):
  - a. THC50 Cutoff Calibrator = 1058.5
  - b. THC 25% Above Cutoff Control = 1214
  - c. THC 25% Below Cutoff Control = 633
  - d. THC Negative Control = -129
  - e. 899414A = 864
    - i. Since the Marijuana Metabolites assay results of specimen 899414A (864) were below the Cutoff Calibrator (1058.5), the specimen was correctly reported as "Negative".
- 2. The laboratory obtained an aliquot of specimen 899414A and tested the specimen by Gas Chromatography/Mass Spectrometry(GC/MS) in order to identify the concentration of Carboxy-THC in the specimen. This step was performed to identify if the amount of Carboxy-THC present in the sample was sufficient to elicit a Positive response on the initial immunoassay screening procedure. The laboratory identified a concentration of Carboxy-THC equivalent to 66 ng/mL by GC/MS analysis. Since the immunoassay cutoff is

- 50 ng/mL, a concentration of Caroboxy-THC equivalent to 66 ng/mL should have elicited a response above the Cutoff Calibrator.
- 3. The laboratory repeated the immunoassay screening test for specimen 899414A on Load TXNRC0120002 to identify if a positive response could be obtained. The result of the specimen for the Marijuana Metabolite assay was still below the cutoff for the procedure:
  - a. THC50 Cutoff Calibrator = 989.5
  - b. THC 25% Above Cutoff Control = 1502
  - c. THC 25% Below Cutoff Control = 833
  - d. THC Negative Control = -34
  - e. 899414A = 956

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- i. Since the Marijuana Metabolites assay results of specimen 899414A (956) were below the Cutoff Calibrator (989.5), the specimen was still considered Negative.
- 4. Based on information provided in your correspondence of January 12, 2007, it appears that the manufacture (Professional Toxicology Services, Inc.) has had problems associated with the performance of Lot#0612THC in the past. I have obtained information from a supplier of analytical standards (Cerilliant Corporation) that indicates certain racemic mixtures of ±11-nor-9-Carboxy-Δ9-THC should not be used for immunoassay testing. I would suggest discussing this issue with Professional Toxicology Services, Inc. to identify if this is a potential explanation for the variation in performance of the THC blind quality control specimens. I am including a copy of the documentation from Cerilliant for your review.

The laboratory has completed the investigation of this matter and has been unable to identify any laboratory based root causes contributing to the inability to detect Marijuana Metabolites above the cutoff concentration. The laboratory suspects the problem may be associated with the manufacturer's process for preparation of the blind quality control specimen and has submitted additional information to support this issue. No changes in standard operating procedures were warranted as part of this investigation.

If you have any questions pertaining to the above investigation, please contact me directly at (770) 936-5009.

Sincerely

Brian A. Brunelli Laboratory Director