Entergy

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Mark A. Giles
Manager, Licensing
Arkansas Nuclear One

10 CFR 26.719(c)(1)

0CAN081001

August 19, 2010

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

SUBJECT: Unsatisfactory Laboratory Testing 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 June 15, 2010, Arkansas Nuclear One (ANO) Fitness for Duty (FFD) Staff received inaccurate drug testing results from a Health and Human Services (HHS)-Certified Laboratory. A blind performance drug test sample containing a pre-determined amount of cocaine metabolite was submitted to the Lexana, Kansas Quest Diagnostics Laboratory for analysis. The Quest-Lexana Laboratory reported the sample test results to be negative.

The ANO FFD Staff completed an investigation on July 28, 2010 pertaining to the blind sample testing error, and pursuant to the reporting requirements of 10CFR 26.719(c)(1), provided the investigation report documented in Attachment 1. An explanatory report from the Quest-Lexana Laboratory is contained in Attachment 2, with a follow-up explanatory letter from the Quest-Lexana Laboratory contained in Attachment 3.

There are no commitments contained in this submittal. Should you have any questions concerning this issue, please contact Robert Jackson, ANO FFD, at 479-858-6875.

Sincerely,

MAG/slc

Attachment: 1. Arkansas Nuclear One - Blind QA Sample Error Investigation Report
Attachment: 2. Quest Diagnostics Report Dated July 14, 2010
Attachment: 3. Quest Diagnostics Report Dated July 22, 2010

A022
NRC

cc: Mr. Elmo Collins
Regional Administrator
U. S. Nuclear Regulatory Commission
Region IV
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011-4125

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

U. S. Nuclear Regulatory Commission
Attn: Mr. Kaly Kalyanam
MS O-8 B1
Washington, DC 20555-0001

Attachment 1

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Arkansas Nuclear One - Blind QA Sample Error Investigation Report

Arkansas Nuclear One
Blind QA Sample Error Investigation Report
CR-ANO-C-2010-01526-CA-1

Identification of Error:

A blind QA sample purchased from Professional Toxicology on 6/9/2010 was submitted to the Quest Diagnostics Laboratory in Lenexa, Kansas (Quest – Lenexa) as a "false negative challenge" on 6/14/2010. This sample, lot number 1004 COCLO, had previously been certified by the Quest - Lenexa laboratory, and re-verified by the Clinical Reference Laboratory as positive for cocaine with a pre-determined value for the cocaine metabolite benzoylecgonine of 435 ng/ml, meeting the requirement found in 10 CFR 26.168(g)(3) that a false negative challenge must contain a measurable amount of the target drug or analyte in concentrations ranging between 130 and 155 percent of the initial cutoff values. The regulatory cutoff for this metabolite is 300ng/ml; therefore the pre-determined value of the sample was 145 percent of the cutoff value. On 6/15/2010 results were received from the Quest - Lenexa lab indicating that the sample was negative for all substances.

Investigation:

Upon receipt of the lab result, the remaining aliquot from this sample was submitted in the typical blind fashion to the Quest Diagnostics Laboratory in Atlanta, Georgia. This laboratory identified the sample as positive for cocaine with a quantified value of 432 ng/ml.

Entergy fleet plants were notified of the error to determine if other samples from this lot number had been submitted. Grand Gulf Nuclear Station indicated that they had processed a sample from this lot number (sample #8998936) and that a positive result was obtained from the Quest – Lenexa facility quantifying the cocaine metabolite at 426 ng/ml.

The Quest – Lenexa facility was advised of the conflicting results and a re-test of the sample using limit-of-detection methodology was requested. Based on this request the Lenexa facility re-processed the sample using the same immunoassay methodology as was used on the first sample. The re-test produced a positive immunoassay screening result for cocaine, and confirmatory testing quantified the cocaine metabolite at 427 ng/ml.

Based on inconsistencies between the expected results and the actual results, and the difference between the first and second test results of the same sample, Quest – Lenexa was asked to conduct an investigation. The results of their investigation indicate that, during preliminary testing, the absorbance ratio of the initial sample was 0.966. The absorbance ratio required for a sample to be considered positive and confirmation testing to be performed is 1.00. On retest, the sample produced an absorbance ratio of 1.15. This represents a difference in the two immunoassay results of 0.18. According to Quest – Lenexa, this variation in immunoassay response is considered acceptable. They concluded that the event was a random error, since all internal quality control specimens were within acceptable limits. Further, they attested that all proficiency testing for cocaine for the previous year had been reviewed and no systematic bias was evident.

Conclusion:

Based on the investigation conducted by Quest – Lenexa, the discrepancy represents a random error caused by the sample initially being screened just below the cutoff, eliminating the need for additional confirmatory testing. No systematic bias was identified in the testing procedures. Arkansas Nuclear One Fitness for Duty Staff conducted an aggregate review of Entergy Fleet blind performance testing errors that have been documented since January, 2007 to determine if previously reported testing errors were similar. Based on this aggregate review, the identified probable causes for previous events were not determined to be similar to this subject event. No further corrective actions are planned by Entergy in this matter.

Immediate Actions:

Entergy Fleet plants were notified of the discrepancy.
An investigation was conducted.

Corrective Actions:

Based on the above conclusions, no additional corrective actions for this event are anticipated at this time.

Attachment 2

0CAN081001

Quest Diagnostics Report Dated July 14, 2010

Quest Diagnostics Incorporated

10101 Renner Blvd.
Lenexa, KS66219
800.873.8845
www.questdiagnostics.com

Quest Diagnostics

July 14, 2010

Jerry D. Woods
Sr. Coordinator, Security
Access Authorization / Fitness for Duty / Medical
Entergy Operations, Inc. / Arkansas Nuclear One
1448 SR 333
Russellville, AR 72802

RE: **Specimen ID:** 7765920
Accession No: 050669R

Dear Mr. Woods:

Per your request, the laboratory has completed our investigation into the analysis of the above referenced specimen identified by you as a blind specimen. The specimen was received in the laboratory on June 15, 2010 and reported as negative the same day.

Upon investigation, the specimen screened negative, just below the cutoff for cocaine. The absorbance reading for the calibrator and donor specimens were 1199.5 and 1159, respectively, resulting in a ratio of 0.966. Specimens must have a ratio of 1.0 or greater to be considered presumptively positive and have confirmation testing performed. All controls met the acceptance criteria.

As part of the investigation, the specimen was tested for cocaine metabolite (benzoylecgonine) by gas chromatography/mass spectrometry (GC/MS). The concentration of benzoylecgonine in the blind specimen was 427 ng/mL. The specimen was re-screened and the ratio was 1.15. The results from this repeat screening analysis indicated that the specimen screened presumptively positive, just above the cutoff.

The initial testing reagent used at the laboratory is the Microgenics DRI Cocaine immunoassay. This reagent has a cross-reactivity of 100% with benzoylecgonine. Results from laboratory proficiency test challenges indicate no deficiencies in the laboratory's ability to detect cocaine metabolite in urine.

In summary our investigation indicates there is no systematic bias in our testing procedures. The NRC blind screened just below the cutoff and therefore was not sent for confirmation.

If you have any additional questions or concerns, please call me at 913-577-1828.

Sincerely,

Barbara Rowland
Director, Laboratory Operations
Employer Solutions
Quest Diagnostics Incorporated

Attachment 3

0CAN081001

Quest Diagnostics Report Dated July 22, 2010

Quest Diagnostics Incorporated

10101 Renner Blvd.
Lenexa, KS66219
800.873.8845
www.questdiagnostics.com

Quest Diagnostics

July 22, 2010

Jerry D. Woods
Sr. Coordinator, Security
Access Authorization / Fitness for Duty / Medical
Entergy Operations, Inc. / Arkansas Nuclear One
1448 SR 333
Russellville, AR 72802

RE: **Specimen ID:** 7765920
Accession No: 050669R

Dear Mr. Woods:

Per your request, this letter is sent for the purpose of clarifying information concerning the blind quality control specimen received into the laboratory on June 15, 2010.

The initial testing ratio was 0.966 and the re-screen ratio during the investigation process was 1.15. The mean of the two ratio results is 1.058. A +/- 20% range from this mean is 0.85 – 1.27 and both results were within +/- 10%. This variation in immunoassay response is considered acceptable. I would also like to clarify that the testing technology and testing procedure for both the first and second immunoassay analyses were identical and that "limit of detection methodology", which is typically applicable to GC/MS testing, was not utilized or needed for this investigation.

I believe this to be a random error since all quality control specimens were within acceptable limits. All proficiency testing specimens for the previous year have been reviewed for cocaine. These results confirm our belief there is no systematic bias in our testing procedures. None of the proficiency results were outside +/- 20% of the group mean. The NRC blind screened just below the cutoff and therefore was not sent for confirmation.

If you have any additional questions or concerns, please call me at 913-577-1828.

Sincerely,

Barbara Rowland
Director, Laboratory Operations
Employer Solutions
Quest Diagnostics Incorporated