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0CAN011403

January 16, 2014

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

SUBJECT: Unsatisfactory Blind Quality Assurance Drug Testing Samples
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 November 2, 2013, Arkansas Nuclear One (ANO) Fitness-for-Duty (FFD) Staff confirmed invalid test results from two blind Quality Assurance drug testing samples that were purchased from Professional Toxicology and sent to the Quest Diagnostics Laboratory in Lenexa, Kansas, for analysis.

The ANO FFD Staff completed an investigation pertaining to the blind sample errors on January 7, 2014, and pursuant to the report requirements of 10 CFR 26.719(c)(1), the investigation results and corrective actions are documented in the attachment to this letter.

This report includes no new regulatory commitments.

If you have any questions or require additional information, please contact Robert Jackson, Supervisor, ANO FFD, at 479-858-6875.

Sincerely,

***Original signed by Stephenie L. Pyle***

SLP/rwc

Attachment: Blind Quality Assurance Sample Error Investigation Report

cc: Mr. Marc L. Dapas
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**Attachment to**

**0CAN011403**

**Blind Quality Assurance Sample Error Investigation Report**

# Blind Quality Assurance Sample Error Investigation Report

## Identification of Error:

Thirty Fitness for Duty (FFD) blind Quality Assurance (QA) specimens were purchased from Professional Toxicology (Pro Tox) on October 7, 2013. Within this group were four specimens from Lot 13047N-AMP that had been certified at Substance Abuse and Mental Health Services Administration (SAMSHA) / Health and Human Services (HHS) certified laboratories to be valid human urine specimens and positive for amphetamine. The pre-certified methamphetamine level in this lot was 1800 nanograms per milliliter (ng/ml).

All of the above specimens were maintained under refrigeration and/or were kept frozen until prepared for shipment to the Quest Diagnostics Laboratory in Lenexa, Kansas. When prepared, all specimens were warmed to room temperature in manners traditionally used to prepare blind QA samples. Two of the four specimens from Lot 1307N-AMP identified as specimens 0058304 and 0058313 were shipped on October 28 and 29, 2013, respectively. Results of these specimens confirmed the presence of amphetamine at levels consistent with the Certification of Analysis obtained by Pro Tox (1742 ng/ml and 1751 ng/ml respectively); however, both specimens were determined to be invalid.

The invalid determination was based on the definition provided in 10 CFR 26.5 as:

> *result reported by an HHS-certified laboratory for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result*.

In this instance, the specimen results were reported as invalid based on inconsistent creatinine concentration and specific gravity results (10 CFR 26.161(f)(1)). Specifically, the creatinine concentrations were less than 2 milligrams per deciliter (mg/dl) (reported creatinine levels of 1.5 mg/dl and 1.4 mg/dl respectively) and the specific gravity results were greater than 1.0010 but less than 1.0200 (reported 1.0155 and 1.0150 respectively).

## Investigation:

Upon receipt of these results, the following actions were initiated:

1. The Medical Review Officer was informed of the error.

2. Pro Tox was notified and asked to initiate an investigation to determine the cause for the invalid results. When notified, the Pro Tox scientist expressed surprise and indicated no plausible explanation for the results. Pro Tox stated that the samples had originally been certified to be positive for amphetamine and valid with creatinine levels $\geq$ 75 mg/dl. Pro Tox further stated specimens from the same lot number had been distributed to other utilities and no other abnormal results had been reported. Pro Tox inquired as to the method used by the Quest Lenexa lab to quantify creatinine. Since the method used

to perform the initial certification was a colorimetric method, it was questioned whether the same method was used for this confirmation.

3. Quest Diagnostics was notified and asked to validate the creatinine levels previously reported on specimens 0058304 and 0058313 and to confirm the method used to quantify creatinine. The creatinine levels were confirmed and the method used by Quest Diagnostics in the Lenexa lab was confirmed to be the colorimetric method, which was the same method used during the lot's original certification.

4. Entergy fleet plants were notified of the event and provided the lot number of the specimens in question. While other fleet plants had obtained samples from this lot, only Waterford-3 and Vermont Yankee had processed these samples. Three specimens from this lot had been processed at the Quest Diagnostics laboratory in Norristown, Pennsylvania, by Vermont Yankee. Results of these specimens were consistent with the invalid results described above. Vermont Yankee specimens 8967960, 8967962, and 8967968 were submitted for testing on October 17 and 24, 2013. These specimen returned results that were positive for amphetamine but invalid based on creatinine levels of 1.6 mg/dl, 1.3 mg/dl, and 1.2 mg/dl. Condition Reports were written to document these errors. One specimen from lot 1307N-AMP was processed at Waterford-3. Although this specimen produced results that were positive for amphetamine and valid, the creatinine level was recorded to be 3.8 mg/dl. This value, although within acceptable validity parameters, represents a significant depletion of creatinine from the original certification level of $\geq$ 75 mg/dl reported by Pro Tox.

   Four specimens from Lot 1308-THC were also submitted by Vermont Yankee. Specimens 8968033, 8968035, 8986036, and 8986037 had been certified as positive for Tetrahydrocannabinol (THC) and valid produced results that were positive for THC but also invalid due to low creatinine levels. All four of these specimens produced creatinine levels of 1.5 mg/dl. Although these specimens were assigned a different lot number than those described above, they are included in this investigation based on the similarity of the condition, and the common clean-urine volume and process from which they were prepared. All Vermont Yankee specimens (amphetamine and THC) were processed at the Quest Diagnostics laboratory in Norristown, Pennsylvania.

Specimens from lot 1307N-AMP were also processed by non-Entergy licensees. Specifically, Nine Mile Point and Dominion received invalid results from specimens in this lot. Ongoing dialogue with personnel at these facilities indicates that a cause for the depleted creatinine was not determined. Conversations with Pro Tox over the course of the investigation failed to indicate a conclusive explanation for the depleted creatinine in the reference lot. According to Pro Tox, the anomaly was discussed with representatives from SAMSHA who were also unable to offer an acceptable explanation. The following possible causes for the depleted creatinine levels were offered by Pro Tox:

1. A residual amount of bleach solution used to rinse the shipping containers could possibly have caused a chemical breakdown of the creatinine molecules after the lot is placed in shipping containers. This possibility was ruled out when the rinse solution was changed to a non-bleach solution and subsequent testing on specimens from a new lot, lot 1312N-AMP, continued to produce results with depleted creatinine.

2. One of the drug-free urine providers used by Pro Tox had begun a drastic dietary regimen consisting of mega-vitamins, natural herbs and anti-oxidants. Pro Tox considered if possibly a constituent of their diet could be causing the creatinine to deteriorate. According to an email from Pro Tox, this scenario is still under investigation. However, two additional amphetamine specimens from lot 1312N-AMP were obtained from Pro Tox as part of the ongoing investigation. These specimens had been certified to be positive for amphetamine and valid with creatinine levels of 75 mg/dl according to Pro Tox. This lot was supposed to have been prepared with urine obtained from new providers. Results from these two specimens indicated depleted creatinine levels of 14.9 mg/dl, and 15.0 mg/dl. These results were provided to Pro Tox. Pro Tox expressed continued surprise and offered no explanation for the depleted creatinine.

**Conclusion:**

Depleting levels of creatinine in blind QA specimens manufactured by Pro Tox has been identified in multiple lots of specimens and confirmed by two independent SAMSHA/HHS certified labs since July of 2013. Despite this recurring anomaly, the toxicologist at Pro Tox has been unable to provide a plausible explanation for the unexpected results. Absent the ability of the blind QA sample vendor to provide reliable specimens to validate the integrity of the FFD testing program, the vendor in question will not be used until valid explanation(s) are provided and issues producing unreliable results are corrected.

**Immediate Actions:**

The Arkansas Nuclear One and Vermont Yankee Medical Review Officers were notified.

Fleet plants were notified of the discrepancy.

A Condition Report was initiated at all Entergy plants affected by this condition.

An investigation was conducted.

**Additional Corrective Actions:**

Based on the above findings, another provider of blind QA specimens will be utilized throughout the Entergy fleet until the issues at Pro Tox have been identified and corrected.