



Cynthia R. Hafenstine  
Manager Nuclear and Regulatory Affairs

RA 18-0006  
January 18, 2018

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

Subject: Docket No. 50-482, "Blind Sample Error Investigation Report"

To Whom It May Concern:

Pursuant to 10 CFR 26.719, "Reporting Requirements," part (c), "Drug and Alcohol Testing Errors," Wolf Creek Nuclear Operating Corporation (WCNOC) is submitting the following report of an investigation into a testing error associated with the WCNOC Fitness for Duty (FFD) Program.

On November 18, 2017, Wolf Creek Nuclear Operating Corporation was provided test results on a blind sample that were inconsistent with the expected results. After a confirmatory analysis substantiated the initial test results, an investigation was conducted to determine why the results were not consistent with the blind sample vendor's projected results. The results of that investigation are attached.

This letter contains no commitments. If you have any questions concerning this matter, please contact me at (620) 364-4204.

Sincerely,

A handwritten signature in black ink that reads "Cynthia R. Hafenstine".

Cynthia R. Hafenstine

CRH/rlt

Attachment

cc: K. M. Kennedy (NRC), w/a  
B. K. Singal (NRC), w/a  
N. H. Taylor (NRC), w/a  
Senior Resident Inspector (NRC), w/a

ADZZ  
NSIR

## Blind Sample Error Investigation Report

### Identification of Error:

Blind samples are purchased from the vendor to meet the various results required for blind specimens. A Fitness For Duty (FFD) blind specimen, formulated to test positive for Opiates, with confirmatory testing positive for Morphine, Codeine and 6-Acetylmorphine (6-AM), by a Health and Human Services (HHS) certified laboratory, was sent for testing on November 14, 2017. The specimen tested positive for Morphine and Codeine but did not test positive for 6-AM. A retest of the specimen also did not test positive for 6-AM.

### Investigation:

The November 14, 2017 blind specimen (Blind Specimen, Custody and Control (CofC) number 2040531139) is from Lot Number 1708OPTAM, manufactured on August 18, 2017 with an expiration date of February 18, 2018. The Certificate of Analysis stated the target value for 6-AM is 16 ng/mL. 10 CFR 26 requires recertification of blind specimen lots every 60 days and the lot was recertified by a HHS certified lab on October 24, 2017, with a result for 6-AM of 18 ng/mL. 10 CFR 26 requires positive blinds be between 150 and 200 percent of the initial cutoff values. The cutoff value for 6-AM is 10 ng/mL.

The specimen was sent for laboratory testing on November 14, 2017. The specimen was tested on November 15, 2017 and the results were reported to the Medical Review Officer on November 18, 2017. The specimen was positive for Codeine and Morphine but negative for 6-AM. A review of the data revealed that the specimen did contain the presence of 6-AM with a value of 8 ng/mL, below the cutoff of 10 ng/mL. A retest was performed with the results reported on November 27, 2017. On retest, the 6-AM concentration was 7.1 ng/mL, below the cutoff of 10 ng/mL. The sample Specimen Validity Testing (SVT) was performed upon receipts and the pH was 8.5 with a creatinine of 89.2 mg/dl and a negative General Oxidant test.

On November 30, 2017, the vendor of the blind specimens was contacted and an additional blind specimen from Lot number 1708OPTAM was requested for processing.

On December 2, 2017, a letter from the laboratory documented that the testing methodologies were adequately performed. The screening and confirmation tests were properly performed with acceptable instrument performance and quality control.

Another scheduled blind specimen was sent to the laboratory with a CofC number 2040531146. This specimen was also from the original Lot Number 1708OPTAM, manufactured on August 18, 2017. This specimen was one of the set of December blinds that had already been scheduled to be submitted as positive for Opiates. This specimen results was reported to Wolf Creek on December 11, 2017 as positive for Codeine, Morphine, and for 6-AM.

The specimen ordered from the vendor of the blind specimens on November 30, 2017 was received and sent for processing with a CofC 2043159898. This specimen results was reported to Wolf Creek on December 12, 2017 as positive for Codeine, Morphine, and for 6-AM.

The cause for the November 14, 2017 blind sample not testing positive for 6-AM was indeterminate.

Cause:

Degradation of specimen CofC number 2040531139 occurred prior to testing at the laboratory on November 15, 2017, causing a negative result for 6-AM (below 10 ng/mL.)

Corrective Action:

The vendor of the blind specimens was changed to a new vendor. The new vendor provides a Certificate of Analysis performed the day prior to shipping the specimens.