Northern States Power Company

414 Nicollet Mall
Minneapolis, Minnesota 55401-1927
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January 13, 1992

10 CFR Part 26
Appendix A
Section 2.8.e.4

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

MONTICELLO NUCLEAR GENERATING PLANT
Docket No. 50-263 License No. DPR-22

PRAIRIE ISLAND NUCLEAR GENERATING PLANT
Docket Nos. 50-282 License Nos. DPR-42
50-306 DPR-60

Blind Sample Performance Testing False Negative

On December 11, 1991 our Medical Review Officer discovered that a blind performance specimen spiked positive for opiates had been reported negative by MEDTOX Laboratories, Inc. According to the blind specimen supplier, Bio-Rad, the specimen should have been positive for opiate metabolites greater than 300 nanogram per milliliter. In accordance with 10 CFR Part 26, Appendix A, Section 2.8.e.4, an investigation signed and dated by the individuals responsible for the day-to-day operation and management of the HHS-certified laboratory is attached.

Results of NSP's investigation indicate that possible explanations for the negative test result on blind performance specimen G152593 are:

1) source dilution or

2) use of an expired specimen.

MEDTOX urinary creatinine testing indicated the specimen was slightly dilute. NSP's investigation concluded that the cause of the dilution in specimen G152593 is unknown and may likely represent source dilution.

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Specimen G152593 had an expiration date of November 30, 1991. The specimen was submitted on December 4, 1991. However, another blind performance specimen from the same batch, submitted on December 19, 1991, was confirmed positive by MEDTOX Laboratories. This would suggest the sample didn't deteriorate with time and reduces the likelihood of specimen expiration as a cause of the false negative.

The absolute cause for this false negative is unknown. In response to our investigation, we will ensure more rapid cross checking to identify blind specimen negative reports within 24 hours of receipt. This will give NSP an opportunity to retest the samples at our backup laboratory. Additionally, procedures will be revised to prohibit the use of expired Bio-Rad specimens.

Please contact us if you have any questions related to this matter.

Thomas M Parker
Manager
Nuclear Support Services

c: Regional Administrator III, NRC
Monticello Senior Resident Inspector, NRC
Monticello NRR Project Manager, NRC
Prairie Island Senior Resident Inspector, NRC
Prairie Island NRR Project Manager, NRC
J E Silberg

Attachment: MEDTOX Laboratories Inc. Report on Specimen G152593

MEDTOX LABORATORIES, INC.
402 West County Road D • St. Paul, Minnesota 55112 • 612-636-7466

12 December 1991

Constance N. Pries, M.D.
Medical Review Officer
Northern States Power
414 Nicollet Mall
Minneapolis, MN 55401

RE: Specimen G152593, Blind

Dear Dr. Pries:

I am responding to your written request for information regarding the processing and analysis of specimen G152593, which you have now informed me to be a blinded proficiency specimen. This specimen was logged into MEDTOX on December 4, 1991 at 6:19 pm by Ethyl J. Nelson, MLT. The screening analysis by immunoassay was also performed on the evening of December 4, by Becky Laaksonen, MT (ASCP). That screening analysis was verified on the evening of December 4 by Gwen Williams, MT (ASCP).

This specimen was tested for amphetamines, cocaine metabolite, opiates, phencyclidine, and marijuana metabolite following federal guidelines for urine drug screening. The immunoassay results were negative for each drug.

Following our standard operating procedures, this specimen was also tested for urinary creatinine. The measured urinary creatinine concentration in this specimen was 19 mg/dl, which is below our acceptable threshold of 20 mg/dl. Therefore, an adulteration profile was run on this specimen as well. This profile revealed a specific gravity of 1.004, sodium of 30 meq/L, potassium 6.4 meq/L, chloride 22 meq/L, and pH 7.0. Each of the adulteration parameters, other than the creatinine, were within the acceptable ranges. Therefore this specimen was not invalidated, nor did it require a message describing its low creatinine concentration. This is again our standard operating procedure and is following federal guidelines.

The negative result was certified by Cynthia K. Veit, MT (ASCP), our Chief Medical Technologist on December 5 at 7:57 am, and was reported to your office on December 5, 1991 at 8:33 am.

Following your notification on December 11, I discovered that this negative urine specimen has been destroyed following our standard protocol. I have reviewed all documentation regarding the handling and analysis of this specimen. I find that all of our procedures were followed correctly, all quality control specimens were within range, and that the reported result was the correct result according to our analysis. A review of the raw data of the immunoassay shows that the opiates were slightly elevated, compared to negative specimens and controls, but the opiates were still clearly below the threshold of 300 ng/ml.

In conclusion, the analysis of specimen G152593 was performed correctly by MEDTOX Laboratories. The specimen was slightly dilute, as indicated by the low creatinine result. The opiates were slightly elevated, but clearly negative. The negative result reported on December 5 appears to be the correct result for this specimen.

Sincerely,

Harry G. McCoy, Pharm.D.
Clinical Director