Dominion Nuclear Connecticut, Inc. Millstone Power Station Rope Ferry Road Waterford, CT 06385



DEC 16 2003

Docket Nos. 50-245 50-336 50-423 B19014

RE: 10 CFR 26, Appendix A

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

Millstone Power Station, Unit Nos. 1, 2 and 3
10 CFR 26, Appendix A, Subpart B, Section 2.8(e)(4) Report
Unsatisfactory Laboratory Performance Test

Pursuant to 10 CFR 26, Appendix A, "Guidelines For Drug And Alcohol Testing Programs," Subpart B, "Scientific And Technical Requirements," Section 2.8, "Quality Assurance and Quality Control," Item (e)(4), "Licensee Blind Performance Test Procedures," Dominion Nuclear Connecticut, Inc. (DNC) submits the findings and corrective action taken by our primary testing laboratory, Quest Diagnostics, (see Enclosure 1), based upon their investigation of an unsatisfactory performance test. This performance test result is from a Department of Health and Human Services (DHHS) certified laboratory under contract to DNC to perform drug testing as required by 10 CFR Part 26 in support of the DNC Fitness-For-Duty (FFD) Program.

On October 16, 2002, Quest Diagnostics processed, and reported as negative, blind specimen #7812624 (DNC number 021615007M). Quest Diagnostics was advised that this specimen was a blind quality control sample supplied by DUO Research, Inc. that was spiked with a controlled substance. Enclosure 1 provides the Quest Diagnostics report of its investigation and corrective actions taken, dated December 16, 2002, as required by 10 CFR 26, Appendix A, Subpart B, Section 2.8(e)(4). DNC acknowledges that this letter exceeds the 30-day submittal schedule delineated in 10 CFR 26, Appendix A, Subpart B, Section 2.8(e)(4). The cause of this condition is being investigated in accordance with the requirements of the Millstone corrective action program (CR-03-10560).

There are no regulatory commitments contained within this letter.

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If you have any questions regarding this submittal, please contact Mr. David Dodson at (860) 447-1791 x2346.

Very truly yours,

DOMINION NUCLEAR CONNECTICUT, INC.

J. Alan Price

Site Vice President - Millstone

Enclosure 1) Re: Specimen #7812624, Investigation Report on Blind Performance Test Sample Prepared by Quest Diagnostics, dated December 16, 2002

cc: H. J. Miller, Region I Administrator

D. G. Holland, NRC Project Manager, Millstone Unit No. 1 R. Prince, NRC Inspector, Region I, Millstone Unit No. 1 R. M. Pulsifer, NRC Project Manager, Millstone Unit No. 2

V. Nerses, NRC Senior Project Manager, Millstone Unit No. 3

Millstone Senior Resident Inspector

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## Enclosure 1

Millstone Power Station, Unit Nos. 1, 2 and 3

Re: Specimen #7812624, Investigation Report on Blind Performance Test Sample Prepared by Quest Diagnostics, dated December 16, 2002 December 16, 2002

Dr. Jonathan Mittelman Medical Review Officer Millstone Power Station 156 Rope Ferry Road Bldg 532/1 Fitness for Duty Waterford, CT 06305

## Dear Dr. Mittelman:

A NRC drug screen was received from Millstone Station by Quest Diagnostics in Norristown, Pennsylvania on October 16, 2002 on a specimen identified as:

Specimen Number:

7812624

Donor ID:

021015007M

Collection Date:

October 15, 2002

Laboratory Number:

1070451

The specimen was reported as Negative on October 16, 2002. We were advised that this was a blind quality control sample supplied by Duo Research, Inc. that was spiked with 1500 ng/mL of D-Amphetamine.

An investigation was conducted by our laboratory that included the following:

- 1. The original immunoassay data was reviewed. The amphetamine result from 10/16/02 was found to be a borderline negative value. Reanalysis of the specimen by immunoassay on 10/18/02 gave a borderline positive result.
- 2. A GC/MS analysis was performed to check the quantitative level of the D-Amphetamine. The result was 1434 ng/mL.
- 3. The cross reactivity of the screening reagent was evaluated for Methamphetamine and Amphetamine. It was found that the reagent in use tested positive at a concentration of 1000 ng/mL of D-Methamphetamine but a concentration of approximately 1500 ng/mL of D-Amphetamine was required to trigger a positive response.
- 4. The reagent manufacturer, Dade Behring, was notified of the issue on 10/22/02. Spiked standards of different concentrations of D-Amphetamine were exchanged between Quest Diagnostics and Dade Behring for evaluation on multiple lots of reagents.
- 5. On 11/5/02 Dade Behring spent the day in our laboratory along with the instrument manufacturer, Olympus America, to help troubleshoot the cross reactivity issue. At that time, different cross reactivity to Amphetamine, but not Methamphetamine, was found between reagent bottles. The explanation for this was not clear.
- 6. On 11/9/02 an evaluation was performed in the laboratory of various reagent bottles from the same lot number of the Amphetamines screening reagent. It was noted that those bottles that had a small amount of surfactant added to the reagent to prevent the build-up of bubbles in the reagent exhibited decreased cross reactivity to D-Amphetamine with no impact of D-Methamphetamine.
- 7. On 11/10/02, we had a discussion with other Quest Diagnostics sites to determine how formation of micro-bubbles in the Amphetamines screening reagent could be eliminated without the addition of surfactant. At that time, we were informed of the availability of special sized tubing to prevent this.

8. New tubing was ordered and installed on one of our Olympus analyzers for the Amphetamines channel. Surfactant was not added to the reagent and the channel was evaluated for micro-bubble formation. This was found to be an effective solution.

The corrective action for this incident was the installation of special sized tubing on all of the analyzers used for the Dade Behring Amphetamines screening reagent. The reagents were evaluated for cross reactivity and were found to meet reagent specification.

If you have any additional questions or concerns, please call me at (877) 642-2216 x 4502.

Sincerely,

Susan Mills

Susan Mills Operations Director, Forensic Toxicology CHW, Norristown, Pa.