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Exelon Nuclear

10 CFR 26.719(c)

June 23, 2009

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

Limerick Generating Station, Units 1 and 2
Facility Operating License Nos. NPF-39 and NPF-85
NRC Docket Nos. 50-352 and 50-353

SUBJECT: 10 CFR 26.719(c) Report
Unsatisfactory Laboratory Performance Tests

Pursuant to 10 CFR 26.719(c), *"Drug and alcohol testing errors,"* Exelon Generation Company, LLC (Exelon), is submitting information for Limerick Generating Station (LGS), Units 1 and 2, concerning unsatisfactory laboratory performance tests of "blind-specimen" samples tested at a Department of Health and Human Services (HHS) certified laboratory. The HHS-certified laboratory is under contract with Exelon to perform drug testing as required by 10 CFR 26 in support of implementation of the Exelon Fitness-for-Duty (FFD) Program at the LGS facility.

10CFR26.719(c) stipulates in part that licensees shall notify the NRC within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of quality control or actual specimens.

Attachments 1 and 2 to this letter provide information and details concerning unsatisfactory HHS-certified laboratory performance tests conducted for LGS by an HHS-certified laboratory and the associated corrective actions. Enclosures 1 and 2 to this letter contain reports from the HHS-certified laboratory that conducted the analysis of the "blind specimen" samples.

There are no regulatory commitments contained within this letter.

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NRR

If you have any questions or require additional information, please contact Mr. Richard Gropp at 610-765-5557.

Respectfully,

DCK

Pamela B. Cowan
Director, Licensing & Regulatory Affairs
Exelon Generation Company, LLC

Attachment 1: Summary of Unsatisfactory Laboratory Performance Test - Sample Specimen No. 19818913
Attachment 2: Summary of Unsatisfactory Laboratory Performance Test - Sample Specimen No. 19818863
Enclosure 1: Medtox Laboratories' Letter dated May 26, 2009 - Sample Specimen No. 19818913
Enclosure 2: Medtox Laboratories' Letter dated May 27, 2009 - Sample Specimen No. 19818863

cc: Regional Administrator - NRC Region I w/ attachments/enclosures
NRC Senior Resident Inspector - Limerick "

ATTACHMENT 1

Limerick Generating Station, Units 1 and 2

Docket Nos. 50-352 and 50-353

10 CFR 26.719(c) Report
Summary of Unsatisfactory Laboratory Performance Test
Sample Specimen No. 19818913

Attachment 1

Summary of Unsatisfactory Laboratory Performance Test
Sample No. 19818913

Introduction

10CFR26.168, *"Blind performance testing,"* stipulates that each licensee shall submit blind performance test samples to the HHS-certified laboratory and shall use only blind performance test samples that have been certified by the supplier.

On May 26, 2009, Exelon Generation Company, LLC (Exelon) completed an investigation concerning a potential testing discrepancy with a "blind specimen" sample submitted by Limerick Generating Station (LGS), Units 1 and 2, to the Department of Health and Human Services (HHS) certified laboratory used by LGS. The HHS-certified laboratory is under contract with Exelon to perform drug testing as required by 10 CFR 26 in support of implementation of the Exelon Fitness-for-Duty (FFD) Program at the LGS facility.

As a result of the potential testing discrepancy identified with the "blind specimen," LGS FFD personnel initiated a follow-up investigation. The details of this investigation are summarized below.

Summary

A "blind-specimen" sample (i.e., #19818913) that was considered as "dilute," was submitted from the LGS facility to *Medtox Laboratories*, Exelon's HHS-certified laboratory for testing. 10CFR26.168(g) specifies several parameters for blind performance test samples. A "dilute" sample must be certified by the supplier and the test sample must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030.

The "blind-specimen" was purchased from *Professional Toxicology Services (PTS)*, an HHS-certified laboratory. The Certificate of Analysis (COA) from PTS verified the specimen to be "dilute" with a specific gravity target value of 1.0011 – 1.0029, which is within the range specified by 10CFR26.168(g). An analysis of the "blind-specimen" was performed at the LGS onsite FFD testing facility and the results showed low creatinine level (i.e., "dilute"). The sample specimen was submitted to *Medtox Laboratories* for processing and analysis. The results from *Medtox Laboratories* indicated an invalid test because of a specific gravity of 1.0009, rather than "dilute."

10CFR26.167(f), *"Errors in testing,"* specifies that licensees shall ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing in the testing of actual specimens, or through the processing of reviews, as well as any other errors or matters that could adversely reflect on the testing process. Therefore, the Director of *PTS* (i.e., the supplier of the certified sample) was subsequently contacted and the following explanation was provided.

Attachment 1

Summary of Unsatisfactory Laboratory Performance Test
Sample No. 19818913

The relatively new requirements of 10CFR26.168(g)(5) specify that "dilute" blind performance test samples must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030. The Director explained that sometimes it is difficult to obtain a specific gravity within the required range between 1.0010 and 1.0030. This is a very narrow range taking into account the four decimal places. In this case, the specific gravity of the "blind-specimen" was measured by *Medtox Laboratories* to be 1.0009 (i.e., 0.0002 below the lower limit of 1.0010), even though the COA indicated the specific gravity of the "blind-specimen" sample was within the acceptable range. The Director further indicated that PTS would take efforts to develop samples with a specific gravity value closer to 1.0020 for the lower end of the range.

The Director of Forensic Toxicology for *Medtox Laboratories* was contacted and the response is noted in a letter dated May 26, 2009 (Enclosure 1), which was received by electronic mail. The letter provides the rationale for *Medtox Laboratories* reporting the result of "blind-specimen" Sample #19818913 as invalid rather than "dilute." Even though the specimen is actually "dilute," the result fell outside of the lower end of the range (i.e., less than 1.0010 for specific gravity). Therefore, it placed the test result in a different reporting requirement. Specifically, 10CFR26.161(f), *"Results indicating an invalid specimen,"* subpart (1) indicates that the laboratory shall report a specimen as invalid when:

> *"...Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests)...."*

Exelon's Medical Review Officer (MRO) was contacted on May 26, 2009, and was requested to review the data associated with results of the testing of "blind-specimen" sample. The MRO reported on May 27, 2009, and concurred with the information provided by the Director of Forensic Toxicology, *Medtox Laboratories,* in its letter dated May 26, 2009. The investigation was considered complete based on *Medtox Laboratories'* letter.

Therefore, as required by 10CFR26.719(c) this report is being submitted to the NRC within 30 days of completing the investigation of the unsatisfactory laboratory performance test of a "blind-specimen" sample by the HHS-certified laboratory.

In addition, while performing benchmarking for this particular incident with other licensees within Region I, Exelon determined that other licensees are experiencing similar problems in that the specific gravity of some "blind-specimen" samples have been reported slightly less than 1.0010. However, the samples were supplied from a different HHS-certified laboratory. Several licensees within Region I did report they

Summary of Unsatisfactory Laboratory Performance Test
Sample No. 19818913

used PTS as their "blind-specimen" provider; however, they found no issues with any of the "dilute" specimens.

Exelon has entered this identified discrepancy into the Corrective Action Program (CAP) under Issue Report (IR) 917486 in order to track any further issues with this incident.

ATTACHMENT 2

Limerick Generating Station, Units 1 and 2

Docket Nos. 50-352 and 50-353

10 CFR 26.719(c) Report
Summary of Unsatisfactory Laboratory Performance Test
Sample Specimen No. 19818863

Attachment 2

Summary of Unsatisfactory Laboratory Performance Test
Sample No. 19818863

Introduction

10CFR26.168, *"Blind performance testing,"* stipulates that each licensee shall submit blind performance test samples to the HHS-certified laboratory and shall use only blind performance test samples that have been certified by the supplier.

On May 27, 2009, Exelon Generation Company, LLC (Exelon) completed an investigation concerning a potential testing discrepancy with a "blind specimen" sample submitted by Limerick Generating Station (LGS), Units 1 and 2, to the Department of Health and Human Services (HHS) certified laboratory used by LGS. The HHS-certified laboratory is under contract with Exelon to perform drug testing as required by 10 CFR 26 in support of implementation of the Exelon Fitness-for-Duty (FFD) Program at the LGS facility.

As a result of the potential testing discrepancy identified with the "blind specimen," LGS FFD personnel initiated a follow-up investigation. The details of this investigation are summarized below.

Summary

A "blind-specimen" sample (i.e., #19818863) that was considered as "dilute," was submitted from the LGS facility to *Medtox Laboratories*, Exelon's HHS-certified laboratory for testing. 10CFR26.168(g) specifies several parameters for blind performance test samples. A "dilute" sample must be certified by the supplier and the test sample must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030.

The "blind-specimen" was purchased from *Professional Toxicology Services (PTS)*, an HHS-certified laboratory. The Certificate of Analysis (COA) from PTS verified the specimen to be "dilute" with a specific gravity target value of 1.0011 – 1.0029, which is within the range specified by 10CFR26.168(g). An analysis of the "blind-specimen" was performed at the LGS onsite FFD testing facility and the results showed low creatinine level (i.e., "dilute"). The sample specimen was submitted to *Medtox Laboratories* for processing and analysis. The results from *Medtox Laboratories* indicated an invalid test because of a specific gravity of 1.0009, rather than "dilute."

10CFR26.167(f), "*Errors in testing,*" specifies that licensees shall ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing in the testing of actual specimens, or through the processing of reviews, as well as any other errors or matters that could adversely reflect on the testing process. Therefore, the Director of *PTS* (i.e., the supplier of the certified sample) was subsequently contacted and the following explanation was provided.

Attachment 2

Summary of Unsatisfactory Laboratory Performance Test
Sample No. 19818863

The relatively new requirements of 10CFR26.168(g)(5) specify that "dilute" blind performance test samples must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030. The Director explained that sometimes it is difficult to obtain a specific gravity within the required range between 1.0010 and 1.0030. This is a very narrow range taking into account the four decimal places. In this case, the specific gravity of the "blind-specimen" was measured by *Medtox Laboratories* to be 1.0009 (i.e., 0.0002 below the lower limit of 1.0010), even though the COA indicated the specific gravity of the "blind-specimen" sample was within the acceptable range. The Director further indicated that PTS would take efforts to develop samples with a specific gravity value closer to 1.0020 for the lower end of the range.

The Director of Forensic Toxicology for *Medtox Laboratories* was contacted and the response is noted in a letter dated May 27, 2009 (Enclosure 2), which was received by electronic mail. The letter provides the rationale for *Medtox Laboratories* reporting the result of "blind-specimen" Sample #19818863 as invalid rather than "dilute." Even though the specimen is actually "dilute," the result fell outside of the lower end of the range (i.e., less than 1.0010 for specific gravity). Therefore, it placed the test result in a different reporting requirement. Specifically, 10CFR26.161(f), *"Results indicating an invalid specimen,"* subpart (1) indicates that the laboratory shall report a specimen as invalid when:

> *"...Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests)...."*

Exelon's Medical Review Officer (MRO) was contacted on May 14, 2009, and was requested to review the data associated with results of the testing of "blind-specimen" sample. The MRO reported on May 15, 2009, and concurred with the information provided by the Director of Forensic Toxicology, *Medtox Laboratories,* as subsequently documented in its letter dated May 27, 2009. The investigation was considered complete based on *Medtox Laboratories'* letter.

Therefore, as required by 10CFR26.719(c) this report is being submitted to the NRC within 30 days of completing the investigation of the unsatisfactory laboratory performance test of a "blind-specimen" sample by the HHS-certified laboratory.

In addition, while performing benchmarking for this particular incident with other licensees within Region I, Exelon determined that other licensees are experiencing similar problems in that the specific gravity of some "blind-specimen" samples have been reported slightly less than 1.0010. However, the samples were supplied from a different HHS-certified laboratory. Several licensees within Region I did report they

Summary of Unsatisfactory Laboratory Performance Test
Sample No. 19818863

used PTS as their "blind-specimen" provider; however, they found no issues with any of the "dilute" specimens.

Exelon has entered this identified discrepancy into the Corrective Action Program (CAP) under Issue Report (IR) 927241 in order to track any further issues with this incident.

ENCLOSURE 1

Limerick Generating Station, Units 1 and 2

Docket Nos. 50-352 and 50-353

Medtox Laboratories' Letter dated May 26, 2009
Sample Specimen No. 19818913

MEDTOX
LABORATORIES

May 26, 2009

Ms. Dolores Adams
Nuclear Security, FFD Lead Analyst
Exelon Corporation

By email: Dolores.adams@exeloncorp.com

Dear Ms. Adams:

This is in response to your inquiry regarding specimen number 19818913, Laboratory Accession Number H9468234. This specimen was received at MEDTOX Laboratories, Inc. on 04/28/2009 and was processed for routine testing. The results of the drug screen were negative, however, the initial creatinine result was < 20 mg/dl (13.0 mg/dl) which reflexed a specific gravity test performed by refractometry. The results of the first 4 decimal place refractometer test were 1.0009. This combination of creatinine and specific gravity results potentially placed the specimen in the invalid category which required confirmation of the SVT results on a fresh aliquot. Results of the additional testing were creatinine = 12.8 mg/dl and specific gravity = 1.0009. The confirmation testing verified the results of the initial test and the specimen was reported as "Invalid, Creatinine ≥ 2.0 mg/dl, Specific Gravity < 1.0010".

You contacted me regarding these results, and based on our conversation, I requested additional specific gravity testing on this sample, using two different refractometers. Results were 1.0010 which is also in the invalid range and 1.0012 which is in the dilute range. Acceptable tolerance for 4 decimal place refractometer values in the NLCP PT Program is +/- 0.0004 units; all of the specific gravity results performed on this specimen meet the criteria for reproducibility.

You indicated that this was a Blind Performance Testing specimen purchased from an outside vendor who did not provide a certified value, but rather indicated that the specific gravity was verified at 1.0011 – 1.0029. Clearly, if the actual specific gravity is on the low end of that range, the MEDTOX results are consistent with the targeted value and laboratory results could correctly be reported in either the invalid or dilute category. Similar issues could arise if the specific gravity of a blind sample was targeted closer to the high end of the range; a specimen with an actual specific gravity of 1.0027 may be reported as dilute or as normal if the 0.0004 tolerance is accepted. To avoid situations such as this, I would recommend that you require your provider to ensure that the certified values for creatinine and specific gravity are such that results clearly fall into one category or the other taking into account laboratory-to-laboratory variability and the accepted tolerance ranges for these analytes. For example, a specimen with certified specific gravity closer to 1.0020 (e.g. 1.0018 – 1.0022) would provide a reasonable expectation that the results would be reported as dilute 100% of the time.

Please let me know if you have additional questions in this regard.

Sincerely,

Jennifer A. Collins, Ph.D.
Director of Forensic Toxicology
MEDTOX Laboratories, Inc.

ENCLOSURE 2

Limerick Generating Station, Units 1 and 2

Docket Nos. 50-352 and 50-353

Medtox Laboratories' Letter dated May 27, 2009
Sample Specimen No. 19818863

MEDTOX
LABORATORIES

May 27, 2009

Ms. Dolores Adams
Nuclear Security, FFD Lead Analyst
Exelon Corporation

By email: Dolores.adams@exeloncorp.com

Dear Ms. Adams:

This is in response to your inquiry regarding specimen number 19818863, Laboratory Accession Number H9606402. This specimen was received at MEDTOX Laboratories, Inc. on 05/12/2009 and was processed for routine testing. Specific gravity testing was performed on two different aliquots of this specimen based on creatinine results < 20 mg/dl. Both specific gravity results were 1.0009; all associated quality control results were within the acceptable range, verifying the validity of the measurements. The combination of the creatinine and specific gravity results place the specimen into the "Invalid" reporting category rather than "Dilute". I have reviewed all relevant analytical data for this specimen and believe that the results reported were accurate.

As I indicated previously, blind specimens for validity testing should be targeted to ensure that the results unequivocally fall into specific categories. Specimens targeted too close to thresholds could accurately be reported in either category.

Please let me know if you have additional questions in this regard.

Sincerely,

Jennifer A. Collins, Ph.D.
Director of Forensic Toxicology
MEDTOX Laboratories, Inc.