Jon A. Franke
Site Vice President

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APR 0 9 2015

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

10CFR26.719(c)(1)

SUSQUEHANNA STEAM ELECTRIC STATION
NEGATIVE BLIND SPECIMEN REPORT
PLA-7311

Docket Nos. 50-387
and 50-388

In accordance with 10CFR26.719(c)(1), enclosed is the documentation of the investigative findings and the corrective actions taken for an incorrect result on a blind specimen.

This letter contains no new regulatory commitments.

If you should have any questions regarding this submittal, please contact Mr. Jeffery N Grisewood, (570) 542-1330.

J. A. Franke

Attachments:
1. Discussion of Test Error
2. MedTox Laboratories Report
3. PPL FFD Laboratory Director Report
4. Medical Review Officer Report
5. ELI Report

Copy: NRC Region I
Mr. J. E. Greives, NRC Sr. Resident Inspector
Mr. J. A. Whited, NRC Project Manager
Mr. L. J. Winker, PA DEP/BRP

A022
NRR

Attachment 1 to PLA-7311

Discussion of Test Error

DISCUSSION OF TEST ERROR

REQUIREMENT

10CFR26.719(c)(1) requires the following:

"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, or through the processing of reviews under § 26.39 and MRO reviews under § 26.185, as well as any other errors or matters that could adversely reflect on the integrity of the random selection or testing process, the licensee or other entity shall submit to the NRC a report of the incident and corrective actions taken or planned. If the error involves an HHS-certified laboratory, the NRC shall ensure that HHS is notified of the finding."

DESCRIPTION OF TESTING ERROR

The following provides a timeline associated with the testing error:

January 10, 2015	A laboratory report for a QC Blind Specimen test was received from MedTox, the HHS-certified laboratory used by PPL Susquehanna (PPL). The report listed the drug test for cocaine as negative. However, the QC Blind Specimen provider, ElSohly Laboratories, Incorporated (ELI), provided a POSITIVE cocaine QC Blind Specimen.
February 2, 2015	The QC Blind Specimen test results were being compiled for the month of January, 2015. During the compilation the HHS-certified laboratory discrepancy was discovered.
February 2, 2015	A PPL condition report was generated to document this discrepancy.
February 2, 2015	The QC Blind Specimen provider, ELI, was contacted about the discrepancy. A complaint ticket was opened at ELI to research the discrepant test result.
February 3, 2015	The HHS-certified lab, MedTox, was notified to investigate the discrepant test result.
February 3, 2015	The PPL FFD Lab Director and the Medical Review Officer (MRO) were notified of the discrepant test result.
February 9, 2015	Another QC Blind Specimen, spiked with cocaine, was provided to PPL by ELI.
February 10, 2015	PPL shipped the additional Blind Specimen to MedTox.

February 13, 2015	MedTox reported the specimen as POSITIVE for cocaine. The QC Blind Specimen was tested correctly and matched the QC Blind Specimen provider (ELI) sample.
February 18, 2015	A report was issued by MedTox on February 18, 2015 and was provided to PPL. The report concluded that: 1) the immunoassay was conducted in accordance with standard operating procedure and the analytical batch met acceptance criteria without error or bias, and 2) the results of the testing are consistent with those that would be expected when challenged with a urine specimen containing drug below the immunoassay administrative limit. A copy of the report is provided in Attachment 2.
February 24, 2015	The PPL FFD Lab Director provided a report to PPL, dated February 24, 2015. This report stated the following: "Benzoylecgonine is an amphoteric substance that is relatively unstable and subject to possible degradation. Upon storage, the benzoylecgonine can degrade lowering the concentration as a function of time." The report concluded that it appears that the benzoylecgonine sample had degraded to some extent resulting in a test value below the cut-off. A copy of this report is provided in Attachment 3.
March 4, 2015	The MRO provided a report to PPL, dated March 4, 2015. This report concluded that the explanations for the test discrepancy are reasonable. A copy of this report is provided in Attachment 4.
March 6, 2015	A report was issued by ELI on March 6, 2015 and was provided to PPL. A copy of this report is provided in Attachment 5.
March 11, 2015	The PPL FFD Lab Director and the MRO discussed the reports that were provided. One compensatory action resulted from their discussion. The action is that, after the 30 ml QC Blind Specimens have been shipped to MedTox, the remaining specimens will be kept at the PPL collection facility until the QC Blind Specimen tests are reported and verified. In addition, an action request was generated to revise the PPL procedure governing blind performance testing to include the guidance for retaining the remaining QC Blind Specimens.
March 12, 2015	The PPL Security Manager and the PPL Security Access and FFD Program Supervisor met to discuss the reports. All of the available information was reviewed and the PPL investigation was considered complete.

Attachment 2 to PLA-7311

MedTox Laboratories Report

MedTox LABORATORIES
LabCorp Specialty Testing Group

402 County Road D
St. Paul, MN 55112
800-832-3244

February 18, 2015

Ms. Judi Jagoda
Site Access Specialist
PPL Susquehanna LLC
769 Salem BLVD
Berwick, PA 18603

RE: NRC NEGATIVE BLIND SPECIMEN

Dear Ms Jagoda:

Following our conversation of February 3, 2015, an investigation into the negative test results for the blind specimen identified as Y31001307, laboratory accession number J9128140, was conducted. You indicated in our conversation that the expected result for the specimen was Positive for Cocaine Metabolite. The specimen was received at MedTox on January 9, 2015 and was processed for testing. The specimen was screened for drugs of abuse in accordance with requirements of 10CFR Part 26, including an initial immunoassay test for Cocaine Metabolite utilizing a cutoff of 300ng/mL. Review of the results indicated an initial screening result for cocaine metabolite below the cutoff but consistent with results obtained for the quality control sample spiked at 225 ng/ml benzoylecgonine. All quality control for the immunoassay testing was within the acceptable range. Consistent with the NRC 10 CFR Part 26 requirements; the results were reported as "Negative" on January 10, 2015. .

The specimen was disposed of on January 15, 2015 in accordance with standard operating procedures. Unfortunately, your inquiry regarding the discrepancy was received after that date so we are unable to perform any additional testing to verify the integrity of the sample.

In conclusion, the initial immunoassay was conducted in accordance with standard operating procedure and the analytical batch met acceptance criteria without error or bias. The results of the testing are consistent with those that would be expected when challenged with a urine specimen containing drug below the immunoassay administrative threshold.

If you should have any additional questions or concerns, please do not hesitate to contact me.

Sincerely,

Mitchell F. LeBard
Associate Director of Forensic Toxicology

Attachment 3 to PLA-7311

PPL FFD Laboratory Director Report

24 February, 2015

Judi Jagoda
PPL Susquehanna/ Access Processing
769B Salem Blvd.
Berwick, PA 18603

RE: Blind Proficiency Test sample (COC # Y310013007 ID # 116387)

Dear Judi,

I have reviewed the results of the blind proficiency tests for the samples sent to MEDTOX as per 10 CFR 26 blind testing requirements.

On January 9, 2015 a set of blind specimens were sent to MEDTOX Laboratories for analysis as per PPL FFD procedures. The results were returned and one sample (COC # Y310013007 ID # 116387) did not match the expected result from the quality control blind key. In particular, the result expected was 'Positive- cocaine metabolite (benzoylecgonine). The target value was spiked at 550 ng/ml as per El Sohly Laboratories records. The NRC screening cut-off is 300 ng/ml for Cocaine metabolite.

The results were reviewed and the discrepancy noted. The sample test request for re-evaluation was made to MEDTOX but the sample, being negative, had already been discarded as per their procedures. A letter dated February 18, 2015 received from MEDTOX, authored by Mitchell LeBard, explained the MEDTOX investigation. It summarized the immunoassay screening result of the sample (COC # Y310013007 ID # 116387). In particular, the screening value for the aforementioned sample was below the 300 cut-off but similar to the -25% (225 ng/ml) quality control. The sample essentially screened at a value below the cut-off but above the 'negative' screening value. These procedures, as described by MEDTOX are within the specified testing guidelines outlined in NRC 10 CFR Part 26.

As a follow-up, another sample with the same target concentration (550 ng/ml Benzoylecgonine) was forwarded to MEDTOX for analysis on 10 February, 2015. The result was returned and the result was positive confirmation for the presence of Benzoylecgonine. This result was expected for this blind submission.

A plausible explanation for these differing results can be made in looking at the specific characteristics of the Benzoylecgonine. Benzoylecgonine is an amphoteric substance that is relatively unstable and subject to possible degradation. Upon storage, the benzoylecgonine can degrade lowering the concentration as a function of time. The rate

at which this breakdown function occurs is dependent upon, but not limited to, temperature, pH of the solution, matrix of the sample and the presence of certain bacteria. In the case of the initial blind sample which tested negative, a value of approximately half of the target value was obtained according to immunoassay screening values from MEDTOX. This is evident in comparison of the estimated target value of 550 ng/ml Benzoylecgonine and the immunoassay estimated value of ~ 225 ng/ml. The second blind sample prepared by and supplied from El Sohly at the same target value of 550 ng/ml Benzoylecgonine, tested positive by both screening and confirmation during the February 2015 evaluation.

From the information provided to me, it appears that the Benzoylecgonine first sample sample (COC # Y310013007 ID # 116387) had degraded to some extent resulting in an assay value below the 300 ng/ml cut-off. This is not the only time I have experienced this phenomenon and there are documented cases in the scientific literature describing the instability of cocaine and cocaine metabolites. As mentioned, the Benzoylecgonine molecule is relatively unstable under certain conditions. The secondary sample resubmitted to MEDTOX and successfully analyzed, proved the testing procedures practiced at MEDTOX are within the guideline outlined by 10 CFR Part 26. It also lended evidence that the particular sample (COC # Y310013007 ID # 116387) submitted had undergone some level of degradation lowering the target concentration to the extent that it was below the 300 ng/ml screening cut-off value.

If there are any questions regarding this matter please feel free to contact me at anytime with questions.

Sincerely,

Michael J. Coyer, Ph.D., F-ABFT

Laboratory Director

Attachment 4 to PLA-7311

Medical Review Officer Report

March 4, 2015

MID-STATE
Occupational Health Services, Inc.

Dear Judy Jagoda,

I have reviewed the unexpected false negative blind specimen, and subsequent investigation. I recommend continuing with the blind quality assurance testing. The explanations are reasonable and previous cocaine blind samples have been detected.

Sincerely,

Mark A. Rainey, M.D.
Mid-State Occupational Health Services, Inc
1000 Meade Street
Medical Plaza
Dunmore, PA 18512
Phone: (570) 209-7160
Fax: (570) 209-7164
www.midstateohs.com

Attachment 5 to PLA-7311

ELI Report

Jagoda, Judith A

From: Mahmoud A. ElSohly, Ph.D. <elsohly@elsohly.com>
Sent: Friday, March 06, 2015 1:50 PM
To: Jagoda, Judith A
Cc: Denise Forsyth
Subject: RE: Cocaine Specimen
Attachments: C-4853 screening stability.pdf

Dear Judi,

This is in reference to the blind QC specimen which you had received a discrepant report on their content from your testing laboratory and the actions taken subsequent to that in order to determine the cause of the discrepancy. I will address the specifics of the discrepant specimen.

Specimen with **SSN 452-61-6806**– was supposed to be positive for benzoylecgonine at 550 ng/mL. This specimen was provided from blind QC batch # C-4853. This batch was prepared on October 31, 2014 and was certified by GC/MS at our laboratory at 551.3 ng/mL for benzoylecgonine. The reference lab value was 483 ng/mL for benzoylecgonine. At the time of shipment of that specimen to Pennsylvania Power & Light (PPL) we screened an aliquot to make sure there is no problem (a common practice at our lab for each shipment) and we did not have any problem (see attached screening results at the original time of shipment, highlighted in yellow). As you can see from the screening stability data, we haven't had an issue with that particular batch not screening positive.

Upon your conversation with our office, we sent you a retained sample we keep in our facility as a replacement, which I understand came out fine. It is unfortunate that the original specimen was destroyed, therefore not allowing us to reanalyze that specific specimen.

I hope this is what you need, but we will be happy to respond to any additional questions.

With regards,

Mahmoud A. ElSohly

Mahmoud A. ElSohly, Ph.D., BCFE, BCFM
President
ElSohly Laboratories, Incorporated (ELI)
5 Industrial Park Drive
Oxford, MS 38655
Tel (662) 236-2609
Fax (662) 234-0253
www.elsohly.com

From: Jagoda, Judith A [mailto:jajagoda@pplweb.com]
Sent: Wednesday, March 04, 2015 2:19 PM
To: Denise Forsyth
Subject: RE: Cocaine Specimen

Batch Details

Batch: C-4853

Stability Data on Blind QC Specimens

Drug: Benzoylecgonine

Ship Date	Analytical Batch	Immunoassay Response*		
		Blind Specimen	QC Response (30% above cut-off)	Date Tested
2014-11-03	STP Nuclear	285	60	11/04/14
2014-11-03	STP Nuclear	285	60	11/04/14
2014-11-03	Pennsylvania Power & Light	285	60	11/04/14
2014-11-04	Southern Nuclear-Farley	268	72	11/06/14
2014-11-10	Duke Energy	259	52	11/11/14
2014-11-10	Entergy Waterford 3	257	46	11/13/14
2014-11-11	Southern Nuclear-Corporate	263	46	11/13/14
2014-11-13	Southern Nuclear-Hatch	263	61	11/18/14
2014-11-17	Exelon Generation	260	61	11/18/14
2014-11-17	Southern California Edison	251	61	11/18/14
2014-11-17	Alegent Occupational Health	264	61	11/18/14
2014-12-01	Pennsylvania Power & Light	273	64	12/02/14
2014-12-01	Duke Energy	266	64	12/02/14
2014-12-03	Entergy Waterford 3	263	60	12/04/14
2014-12-08	Pacific Gas & Electric	264	56	12/09/14
2014-12-08	Florida Power & Light-St. Lucie	262	56	12/09/14
2014-12-08	Florida Power & Light-St. Lucie	261	56	12/09/14
2014-12-08	Exelon Nuclear-Limerick	270	56	12/09/14
2014-12-09	Southern Nuclear-Vogtle	260	35	12/11/14
2014-12-15	CB & I-Vogtle	254	55	12/16/14
2014-12-15	CB & I-Vogtle	254	55	12/16/14

2014-12-29	American Electric Power	265	69	12/23/14
2014-12-29	American Electric Power	265	69	12/23/14
2014-12-29	CBI-VC Summer	266	69	12/23/14
2014-12-29	NextEra Energy Point Beach, LLC	277	62	01/06/15
2014-12-29	Entergy Nuclear-Vermont Yankee Nuclear Power Plant	277	62	01/06/15
2014-12-29	Florida Power & Light-Turkey Point	270	62	01/06/15
2015-01-05	NextEra Energy Duane Arnold, LLC	272	54	01/06/15
2015-01-05	First Energy-Davis Besse	261	54	01/06/15
2015-01-06	Entergy Nuclear-Fitzpatrick	267	88	01/09/15
2015-01-06	First Energy-Perry Nuclear	267	54	01/06/15
2015-01-06	Southern Nuclear-Hatch	276	88	01/09/15
2015-01-07	Tennessee Valley Authority	264	88	01/09/15
2015-01-07	Entergy Nuclear-Indian Point Energy Center	268	58	01/09/15
2015-01-07	SCEG-VC Summer Nuclear Station	270	58	01/09/15
2015-01-07	Pennsylvania Power & Light	261	58	01/09/15
2015-01-07	Entergy Nuclear Pilgrim Station	266	58	01/09/15
2015-01-12	Energy-Northwest	248	36	01/13/15
2015-01-12	Detroit Edison	248	36	01/13/15
2015-01-12	Public Service Electric & Gas-Hancock's Bridge	262	58	01/09/15
2015-01-08	SCEG-VC Summer Nuclear Station	249	36	01/13/15
2015-01-12	Monticello Nuclear	240	36	01/13/15
2015-01-13	North Anna Power Station	259	55	01/15/15
2015-01-13	Beaver Valley Power Station	264	55	01/15/15
2015-01-13	Entergy Arkansas Nuclear One	258	55	01/15/15
2015-01-14	Duke Energy	257	55	01/15/15
2015-01-14	Southern Nuclear-Farley	256	55	01/15/15
2015-02-09	Pennsylvania Power & Light	258	55	02/11/15

Save/Update

* Specimen response at 0 or a positive value is considered positive in this test.