



Entergy Nuclear Operations, Inc.
Palisades Nuclear Plant
27780 Blue Star Memorial Highway
Covert, MI 49043
Tel 269 764 2000

Paula K. Anderson
Licensing Manager

November 9, 2010

10 CFR 26.719(c)

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

SUBJECT: Unsatisfactory Laboratory Testing Report

Palisades Nuclear Plant
Docket 50-255
License No. DPR-20

Dear Sir or Madam:

In accordance with 10 CFR Part 26.719(c), Entergy Nuclear Operations (ENO) is reporting unsatisfactory blind performance confirmatory testing results from Quest Diagnostics Incorporated, in Lenexa, Kansas, for the ENO Fitness For Duty Program at the Palisades Nuclear Plant.

An investigation was conducted pertaining to invalid blind performance testing results received for three samples of 6-acetylmorphine. The cause was determined to be the testing method used at the time of the confirmation testing.

Quest Diagnostics Incorporated has taken action to correct the deficiency. Attachment 1 contains the investigation report. Attachment 2 contains the investigation report from Quest Diagnostics.

If you have any questions, please contact Brian Rabideau at (269) 764-2575.

This letter contains no new commitments and no revisions to existing commitments.

Sincerely,

A handwritten signature in black ink, appearing to read "Paula Anderson", written over the word "Sincerely,".
pka/bed

Attachment: 1. Blind Sample Investigation Report
2. Quest Diagnostics Incorporated Investigation Report

cc: Administrator, Region III, USNRC
Project Manager, Palisades, USNRC
Resident Inspectors, Palisades, USNRC

ATTACHMENT 1 BLIND SAMPLE INVESTIGATION REPORT

Identification of Error

Blind samples were purchased from EISOhly Laboratories (Lot O-3632) to meet requirements for various sample testing for blind specimens. Blind performance samples were sent to Quest Diagnostics Incorporated, in Lenexa, Kansas in August 2010, for confirmatory testing.

The confirmatory laboratory, Quest Diagnostics, reported the results of two blind specimens, with accession numbers 719805R and 630427R, as positive for codeine and morphine, however, 6-acetylmorphine (6-AM (heroin)) results were reported as invalid with gas chromatography-mass spectrometry (GC/MS) interference. The specimen with accession number 719853R was reported as positive for codeine and morphine, and 6-AM results were reported as quantity not sufficient (QNS) to complete the testing.

Investigation

The blind sample vendor, EISOhly Laboratories, was contacted and advised of the invalid results described above. EISOhly Laboratories informed Quest Diagnostics that they had previously tested other blind specimens from the same lot, but had not encountered validity issues.

Quest Diagnostics spoke with EISOhly's laboratory regarding the blind specimen preparation, and noted that there was an interference with a component of their blind specimen matrix and Quest Diagnostic's current GC/MS confirmation method.

The Palisades Nuclear Plant Medical Review Officer requested that the confirmatory laboratory, Quest Diagnostics, send the specimens to a Health and Human Services (HHS)-certified laboratory, MedTox Laboratories, for re-testing. MedTox test results were appropriately positive for codeine, morphine and 6-AM.

Cause

The tests were positive for 6-AM, but a quantitative result could not be obtained. The laboratory's current confirmation method was ineffective for these blind samples. Per Quest Diagnostics, all three of the specimens exhibited incomplete chromatographic peak resolution for the quantification ion, 473 m/z, on multiple confirmation batches using multiple dilution factors. The laboratory's chromatographic resolution criteria for reporting is >90% resolution with the peak of interest. The inability to resolve the resolution issue prevented the laboratory from reporting the concentration on these blind specimens.

**ATTACHMENT 1
BLIND SAMPLE INVESTIGATION REPORT**

Corrective Action

Quest Diagnostic Laboratories has validated an alternate confirmation method for 6-AM using a different temperature program. The alternate method uses the same extraction process as is currently used, but requires an adjustment to the temperature heating ramp of the GC oven.

This change allows the laboratory to use the alternate method to resolve interference seen on the primary method. Quest Diagnostic Laboratories' standard operating procedure was updated on September 21, 2010, to include the use of the new alternate method. Three blind specimens from Lot O-3632 were sent to Quest Diagnostic Laboratories on October 7, 2010, for confirmation testing. Test results were appropriately positive for codeine, morphine and 6-AM.

No additional corrective actions are anticipated at this time.

ATTACHMENT 2

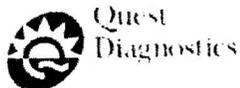
**QUEST DIAGNOSTICS INCORPORATED
INVESTIGATION REPORT**

3 Pages Follow

Quest Diagnostics

10101 Renner Blvd
Lenexa, KS 66219
800 873 8815
www.questdiagnostics.com

LOT # 0-3632



September 14, 2010

Dale Plapp, M.D.
728 E 8th Street Suite 2
Holland MI, 49423

RE: Specimen ID: 3343592, 3343604, 3343583
Accession No: 719805R, 630427R, 719853R

Dear Dr. Plapp:

Per your request, the laboratory has completed our investigation into the analysis of the above referenced specimens identified by you as blinds. The specimens were received in the laboratory during the month of August, 2010. Specimens with accession numbers 719805R and 630427R were reported as positive for codeine and morphine and the 6-acetylmorphine (6-AM) results were reported as invalid with a GC/MS interference. The specimen with accession number 719853R was reported as positive for codeine and morphine and the 6-acetylmorphine was reported as quantity not sufficient (QNS) to complete the testing.

All three of the above specimens exhibited incomplete chromatographic peak resolution for the quantification ion, 473 m/z, on multiple confirmation batches using multiple dilution factors. The laboratory's chromatographic resolution criteria for reporting is >90% resolution with the peak of interest. The inability to resolve the resolution issue prevented the laboratory from reporting the concentration on these blind specimens. The laboratory spoke with Dr. ElSohly's laboratory about the blind specimen preparation and we believe there is an interference with a component of their blind specimen matrix and our current GC/MS confirmation method. Based on our conversations, it is also our understanding that we have previously tested other blind specimens from the same lot of blind material and we did not encounter this resolution issue.

As a part of the investigation, and with your permission, the specimens 719853R and 719805R were tested for 6-AM using the split specimen bottles. The concentrations of 6-AM were 22.0 ng/mL and 19.6 ng/mL, respectively. Specimen 630427R was sent to MedTox laboratories at your request, and therefore we could not test the split specimen.

The laboratory is currently validating an alternate confirmation method for 6-AM using a different temperature program and the same extraction process as is currently used. Pending favorable validation, this method would be utilized in the event we encounter specimens in the future that do not meet the resolution criteria for reporting. This alternate 6-AM confirmation method validation and its corresponding standard operating procedure if favorably validated should be completed within the next two weeks.

If you have any additional questions or concerns, please call me at 913-577-1828.

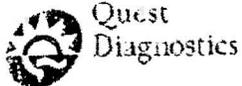
Sincerely,



Barbara Rowland
Director, Laboratory Operations
Employer Solutions
Quest Diagnostics Incorporated

Quest Diagnostics

10101 Renner Road
Lenexa, KS 66219
300.873.8845
www.questdiagnostics.com



October 29, 2010

Dale Plapp, M.D.
728 E 8th Street Suite 2
Holland MI, 49423

RE: Additional Information

Dear Dr. Plapp:

This letter is to further clarify information requested by the NRC concerning our recent 6-acetylmorphine (6-AM) blinds reported as invalid due to GC/MS interference. The laboratory successfully validated an alternate confirmation procedure. The alternate procedure consists of an adjustment to the temperature heating ramp of the GC oven. This change allows the laboratory to utilize the alternate method to resolve interference seen on the primary method.

The standard operating procedure was updated on September 21, 2010 to include the use of the new alternate method. All associated validations were completed and approved prior to this implementation date.

If you have any additional questions or concerns, please call me at 913-577-1828.

Sincerely,

A handwritten signature in black ink, appearing to read "Barbara Rowland".

Barbara Rowland
Director, Laboratory Operations
Employer Solutions
Quest Diagnostics Incorporated