Entergy

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

Otto W. Gustafson
Licensing Manager

PNP 2013-063

September 18, 2013

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, in Lenexa, Kansas, for the ENO Fitness For Duty Program at the Palisades Nuclear Plant (PNP).

An investigation was conducted pertaining to invalid blind performance testing results. The cause was determined to be chromatographic interference.

Attachment 1 contains the investigation report by PNP. Attachment 2 contains the investigation reports 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,

OWG/bed

Attachment: 1. Blind QA Sample Error Investigation Report
2. Quest Diagnostics Investigation Reports

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

ATTACHMENT 1
BLIND QA SAMPLE ERROR INVESTIGATION REPORT

Identification of Error

Blind samples were purchased from ElSohly Laboratories (Lot 0-4442) to meet requirements of sample testing for blind specimens. Blind performance samples were sent to Quest Diagnostics in Lenexa, Kansas in June 2013 for testing.

The laboratory, Quest Diagnostics, reported the results of one blind specimen, with accession number 144323E, as positive for codeine and morphine, however, 6-acetylmorphine (6-AM) results were reported as invalid rather than positive.

Investigation

Four samples from Lot 0-4442 were sent to Quest Diagnostics during the month of June. Blinds with accession numbers 144060E, 144187E and 166502E were reported as positive for codeine, morphine and 6-AM. The blind with accession number 144323E was reported as positive for codeine, morphine and invalid for gas chromatography–mass spectrometry (GC-MS) interference.

Quest Diagnostics reported that accession number 144323E exhibited chromatographic interference on three GC-MS confirmation loads for 6-AM and were unable to obtain acceptable ion-ratios for the specimen on those loads. The laboratory's acceptable ion-ratio criteria on drug confirmations are a 20% range of the ion-ratio established by the calibrator. The specimen was injected under their regular 6-AM GC-MS method and their alternative 6-AM method. Accession number 144323E failed to meet the laboratory's ion-ratio criteria on any of the confirmation loads.

The Palisades Nuclear Plant (PNP) Medical Review Officer requested that the laboratory, Quest Diagnostics, send the specimen to a Health and Human Services (HHS)-certified laboratory, MedTox laboratories, for re-testing. An aliquot of accession number 144323E was sent to MedTox Laboratories on July 5, 2013. MedTox was able to confirm the presence of codeine and morphine but unable to confirm the presence of 6-AM due to insufficient quantity of the remaining specimen.

Cause

Based on documentation from Quest Diagnostics, interference can be caused by a number of different factors such as specimen storage and transport conditions, specimen matrix, specimen container contaminations, preservatives used in the preservation of blind samples, etc., which may occur outside the laboratory's control.

ATTACHMENT 1
BLIND QA SAMPLE ERROR INVESTIGATION REPORT

The laboratory has been unable to identify the cause of the GC-MS interference. However, as the laboratory correctly identified the 6-AM in the other two specimens, the interference appears to be isolated to the one specific blind specimen and it does not appear that there are systematic problems with the laboratory's confirmation procedures for 6-AM. Therefore, it is not feasible for Quest Diagnostics to implement corrective actions to prevent the interference from recurring.

PNP Actions

1. Notified Entergy fleet plants of the discrepancy.
2. Notified the Manager, AA/FFD and the Medical Review Officer.
3. Notified ElSohly Laboratories and Quest Diagnostics – Lenexa of the discrepancy and requested an investigation/inquiry.
4. No additional actions are anticipated at this time.

ATTACHMENT 2

QUEST DIAGNOSTICS INVESTIGATION REPORTS

2 Pages Follow

Quest Diagnostics®

July 31, 2013

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

RE: Specimen ID 6468098, 6468101, 6468095, 6468107
Accession No: 144323E, 144060E, 144187E, 166502E

Dear Dr. Plapp,

Per your request, we have completed the investigation into the anaylsis of the above referenced specimens identified by you as blinds. The specimens were received into the laboratory during the month of June, 2013. Specimens with accession numbers 144060E, 144187E and 166502E were reported as positive for codeine, morphine and 6-acetylmorphine. The specimen with accession number 144323E was reported as positive for codeine, morphine and Invalid for GCMS Interference.

Accession number 144323E exhibited chromatographic interference on three GCMS confirmation loads for 6-acetylmorphine. The laboratory was unable to obtain acceptable ion-ratios for the specimen on those loads. The laboratory's acceptable ion-ratio criteria on drug confirmations is a 20% range of the ion-ratio established by the calibrator. The specimen was injected under our regular 6-acetylmorphine GCMS method and our alternative 6-acetylmorphine method. Specimen ID 6468098 failed to meet the laboratory's ion-ratio criteria on any of the confirmation loads.

An aliquot of accession number 144323E was sent to Medtox for testing on July 5, 2013 at your request.

Please let me know if you need any other information or have questions.

Sincerely,

Anne Roberts
Lab Manager

Quest Diagnostics

August 22, 2013

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

RE: Specimen ID 6468098, 6468101, 6468095, 6468107
Accession No: 144323E, 144060E, 144187E, 166502E

Dear Dr. Plapp,

Specimens with accession numbers 144060E, 144187E and 166502E were reported as positive for codeine, morphine and 6-acetylmorphine (6-AM). The specimen with accession number 144323E was reported as positive for codeine, morphine and Invalid for GC/MS Interference.

As mentioned in our previous correspondence, accession number 144323E exhibited chromatographic interference on three different GC/MS confirmation batches for 6-AM. The laboratory has two different GC/MS confirmation methods for 6-AM – a primary method and an alternative method, which is used when a chromatographic interference is exhibited. The specimen (144323E) was injected on both of these GC/MS testing methods and exhibited the chromatographic interference using both methods..

Interference can be caused by a number of different factors such as specimen storage and transport conditions, specimen matrix, specimen container contaminations, preservatives used in the preservation of blind samples, etc., which may occur outside the laboratory's control.

The laboratory has been unable to identify the cause of the GC/MS interference. However, as the laboratory correctly identified the 6-AM in the other two specimens, the interference appears to be isolated to the one specific blind specimen and it does not appear that there is systematic problem with the laboratory's confirmation procedures for 6-AM. Consequently, it is not feasible to implement corrective actions to prevent the interference from recurring with blind specimens submitted by your office.

Sincerely,

Anne Roberts
Lab Manager
Employer Solutions
Quest Diagnostics