Entergy

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Anthony J. Vitale
Site Vice President

NL-19-072

10 CFR 26.719(c)

August 15, 2019

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Subject: Unsatisfactory 10 CFR 26 Fitness-For-Duty
Blind Performance Testing Results

Indian Point Unit Nos. 2 and 3
Docket Nos. 50-247 and 50-286
Renewed Facility Operating License Nos. DPR-26 and DPR-64

In accordance with 10 CFR 26.719(c)(1), this letter provides a report of an unsatisfactory blind performance testing result associated with the Fitness For Duty program for the Indian Point Energy Center.

A description of the incident, investigation results and corrective actions taken are described in the attached reports.

Should you have any questions regarding this matter, please contact Mr. Robert Walpole, Manager, Regulatory Assurance, Indian Point Energy Center at (914) 254-6710.

Sincerely,

AJV/trj

ADZZ
NSIR

Attachment: 1. Blind Test Specimen Issue
Attachment: 2. Letter from Quest Diagnostics to Dr. Gupta, dated July 29, 2019

cc: NRC Region I Region Administrator
NRC Senior Resident Inspector - Indian Point Entergy Center
Mrs. Bridget Frymire, New York State Dept. of Public Service
NRC Senior Project Manager, Mr. Richard Guzman

Blind Test Specimen Issue

On January 23, 2019, Blind Performance Test Specimen #0926228, which was certified as negative-dilute, was sent to a HHS-certified laboratory with the Specimens for the day. Specimen #0926228 was received at the laboratory on January 25, 2019. The Specimen was tested and the results were reported to Entergy on January 25, 2019, as negative only. On January 25, 2019, the Entergy Medical Review Officer (MRO) was contacted and advised of the discrepancy. An investigation into the reason for the discrepancy was initiated with the laboratory to determine if there was an error during the testing of the Specimen or if the sample from the supplier was bad.

As part of the investigation into the unexpected results, the process of re-testing Specimen #0926228 began on January 28, 2019. On January 29, 2019, the laboratory reported the re-test of Specimen #0926228 as negative-dilute as originally expected. Upon further investigation the HHS-certified laboratory determined that on January 25, 2019, the results of two Specimens that were received had been reversed. Blind Specimen #0926228 which was reported as negative and should have reported as negative-dilute and Specimen #0926229 which belonged to a real donor reported as negative-dilute and should have reported as negative.

On February 13, 2019, through e-mail correspondence between the MRO's office and the HHS-certified laboratory it was believed that the investigation from the laboratory concluded that both Specimens originally reported as expected but the results of the two Specimens were reversed by the forensic processor. The HHS-certified laboratory indicated that, as a part of their corrective actions, the incident was reviewed with the appropriate staff and additionally the forensic processing technician was being retrained in their position which included an observation for competency evaluation. This information was viewed as the conclusion to the report and therefore no further information was requested. Since it was thought that this event did not adversely reflected on the integrity of the random selection process or on the ability of the laboratory to correctly test the samples, this event was not initially considered to be an unsatisfactory performance error and was not reported to the NRC at that time.

During an internal Entergy audit performed by Nuclear Independent Oversight, this issue was revisited and a condition report (CR-IP-2019-03115) was written. The Access Authorization / Fitness For Duty Supervisor re-opened the investigation and requested additional information from the laboratory. On July 29, 2019, the HHS-certified laboratory provided a report to the MRO which indicated that there was an error in the testing of the batch of Specimens that included Specimen #0926228. Based on that newly obtained information it was recognized that a report to the NRC under 10 CFR 26.719(c) was necessary.

Attached:
Quest Diagnostics letter dated July 29, 2019.

CORRECTIVE ACTIONS:
The corrective actions listed below have been taken;

1. CR-IP-2019-03115 was initiated to track this event.
2. This incident was review with the appropriated staff
3. The forensic processing technician who aliquoted the original screening batch underwent retraining and was subjected to a competency evaluation when retraining was completed.

Quest Diagnostics

July 29, 2019

Rajesh Gupta, MD
Entergy Indian Point
3379 Crompond Drive
Yorktown Heights, NY 10598

Re: Specimen ID: 0926228, Laboratory #: 923482V, Collection Date: 01/23/19

Dear Dr. Gupta:

I am writing to provide an explanation for the report that were issued on the blind quality control sample identified above. This sample was received at Quest Diagnostics in Norristown, Pennsylvania on January 25, 2019. A report was issued January 25, 2019 with a negative NRC panel result. A second, corrected report was issued January 30, 2019 that identified this as a negative and Dilute specimen.

Incident:

An issue was identified with a batch of 7 NRC specimens that were screened and reported on January 25, 2019. Specimen ID 0926228 was in this batch.

Investigation:

- The test data from the original screening (initial testing) batch, performed on January 25th, was reviewed along with calibrator and known quality control samples for acceptability and correct interpretation. The calibrator and known quality control samples satisfied acceptance criteria.
- Fresh aliquots were removed from the specimen bottles and the aliquots were tested again in a second screening batch.
- Additional specific gravity testing was performed, as indicated by the specimen validity test results in this second screening batch. Specimen ID 0926228 had creatinine and specific gravity values in the dilute range on this second test.
- The data from the original and second screening batches were compared for consistency. Based on this comparison, it appeared that the forensic processing technician did not properly transfer (aliquot) all of the original specimens to the correct sample cups causing this specimen to have the incorrect result.
- The forensic processing technician who aliquoted the batch was interviewed.

Corrective Action:

Corrective action steps have been taken.

1. This incident was reviewed with the appropriate staff.
2. The forensic processing technician who aliquoted the original screening batch underwent retraining and was subjected to competency evaluation when her retraining was completed.

We regret that we failed to accurately report this blind quality control sample but are confident that the corrective actions taken will be effective in preventing a recurrence of such an incident.

Should have any additional questions or concerns, please call me at (610) 631-4502.

Sincerely,

Susan Mills
Director, Laboratory Operations