Entergy®

Indian Point Energy Center
450 Broadway, GSB
P.O. Box 249
Buchanan, N.Y. 10511-0249

Robert Walpole
Regulatory Assurance Manager
914-254-6710

January 29, 2014

NL-14-011

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
11555 Rockville Pike
Rockville, MD 20852

SUBJECT: Unsatisfactory 10 CFR 26 Fitness-For-Duty Blind Performance Testing Results
Indian Point Unit Number 2 & 3
Docket Nos. 50-247 and 50-286
License Nos. DPR-26 and DPR-64

Dear Sir or Madam:

Pursuant to 10 CFR 26.719 (c)(3), Entergy reported an unsatisfactory blind performance test result of a sample from the Indian Point Energy Center (IPEC) from the HHS-certified laboratory (EN#49573). In accordance with 10 CFR 26.719(c)(1), this letter provides a report of the incident and the corrective actions taken.

On November 21, 2013, during a Fitness-For-Duty (FFD) inspection, NRC Inspectors identified that laboratory testing of a blind FFD sample submitted on March 3, 2013, failed to provide anticipated testing results. Laboratory testing results for a sample should have reported the sample as "Dilute" but the report results came back as "Negative." The incident was recorded in the IPEC Corrective Action Program (CAP) as condition report CR-IP3-2013-04631. An event notification was provided within 24 hours of discovery on November 22, 2013, at 15:18 hours. The IPEC Medical Review Officer (MRO) was notified and the MRO initiated an investigation with the HHS-Certified Laboratory (Quest Diagnostic). In addition, an investigation was initiated with the vendor supplier of the blind sample (Professional Toxicology services).

An investigation of the event has been completed and is provided in the attachment to this letter. A description of the incident, investigation results and the corrective actions taken are included in the attachment.

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If you have any questions or require additional information, please contact me.

Sincerely,

RW/cbr

Attachment 1: Investigation Results: Unsatisfactory 10 CFR 26 Fitness-For-Duty Blind Performance Testing

cc: Mr. William M. Dean, Regional Administrator, NRC Region I
NRC Senior Resident Inspectors Office
Mrs. Bridget Frymire, New York State Dept. of Public Service

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

Event Description

On November 21, 2013, during an access authorization Fitness-for-Duty (FFD) baseline inspection, an NRC inspector identified results from a blind sample that were inconsistent with anticipated results.

On January 29, 2013, dilute blind samples were procured from Professional Toxicology Services. On March 3, 2013, the two dilute blind samples were sent to Quest Diagnostics (IPEC's HHS-Certified Laboratory) for analysis. Testing results for one of the blind samples (specimen #5196604) should have reported the sample as "Dilute" but the Lab (Quest diagnostics) identified the sample as "Negative."

When the results were presented to and reviewed by Entergy personnel in March 2013, Entergy personnel were unsuccessful in identifying the discrepancy between the test result and the expected test result. Therefore, the negative test result remained and the discrepancy was not investigated. Had the testing error or discrepancy been discovered during Entergy's blind sample testing results review, Entergy procedure EN-NS-110 (Error Testing) would require an investigation by the HHS-Certified laboratory while they still had the questionable sample in their possion to re-test.

Immediate Actions

The event was recorded in the Entergy corrective action program (CAP) and logged in the Security Safeguards Log as #2013-4-0327, and an event notification (EN#49573) placed to the NRC Emergency Operations Center for FFD program drug and alcohol testing errors in accordance with 10CFR26.719(c)(3). The Indian Point Energy Center (IPEC) initiated an investigation with the HHS-Certified Lab (Quest diagnostics) through the Entergy Medical Review Officer (MRO) (who is contracted through Health Quest) and the blind sample vendor (Professional Toxicology Services).

The Entergy investigation resulted in an evaluation report that had final review and approval by the Entergy Corrective Action Review Board on January 22, 2014.

Investigation Results

As part of our fitness for duty (FFD) program, Entergy purchased dilute samples from Professional Toxicology Services on January 29, 2013, for the purposes of performing initial blind sample testing. As part of the Entergy purchase were two dilute samples (specimen #5196605 and specimen #5196604) which were taken from the same Lot # (1212DIL). On March 3, 2013, both dilute blind samples were processed and sent to the HHS-Certified Laboratory (Quest Diagnostic).

On March 5, 2013, one of the two specimens (specimen #5196605) tested as expected showing a dilute sample with special testing [Limit of Detection (LOD) testing] indicating analytes not present above detectable levels on immunoassay test resulting in a negative test. Quest Diagnostic received, tested and reported on specimen #5196605 to the MRO on March 5, 2013. Also, on March 5, 2013, the second sample (specimen #5196604) was received by Quest Diagnostic but the laboratory did not report back to the Entergy MRO until March 12, 2013.

Quest Diagnostic stated the reason of the delay for sending the test results of specimen #5196604 was that their staff discovered that the result, although completed on March 5, 2013, did not transmit immediately after testing and the report was re-transmitted on March 12, 2013. The reporting was based on the test data from specimen #5196604 which was tested on March 5, 2013. The result for specimen #5196604 reported "Negative" not receiving LOD testing as required. This was not the anticipated result, as this sample (specimen #5196604) was expected to test as "Dilute" with special testing (LOD testing) conducted.

When this information was provided to Entergy, Entergy personnel reviewing the test data did not identify this discrepancy between expected test results and actual test results.

Entergy's investigation obtained information from the vendor/supplier of the blind sample used by IPEC at the time of the event. The blind sample provider Professional Toxicology Services indicated that a small amount of Lot #1212DIL was kept at their facility and was retested in December 2013 after being notified of the event on November 21, 2013. The re-testing of this lot indicated that the re-test sample from Lot #1212DIL reported as expected: a dilute sample. However, the re-test using a frozen sample had not been subjected to the same storage conditions as the shipped samples that were sent to the laboratory.

This re-test by the blind sample vendor using another sample from the sample Lot #1212DIL did not match the results reported by the HHS-Certified Laboratory (Quest Diagnostics) for specimen #5196604. The validity of the sample lot was assessed by a contractor to Professional Toxicology Services and it was determined each lot has a six month expiration period from the time the lot is manufactured. A Certificate of Analysis was provided for Lot #1212DIL with a manufactured date of December 10, 2012 and an expiration date of June 10, 2013.

Entergy's investigation obtained information from the HHS-Certified Laboratory (Quest Diagnostics) that the creatinine level's for the sample (specimen #5196604) were low (15.7 mg/dl) and the specific gravity values did not meet the dilute criteria. Both creatinine level and specific gravity values must be in the dilute range to report a sample as dilute. Quest Diagnostics noted they no longer have the sample to retest because all samples reporting as negative are discarded after seven days of initial testing. Therefore, it was not possible to verify proper testing by Quest Diagnostic of this specific sample.

Entergy's investigation has concluded that there is insufficient evidence to determine the cause of the event. However, a review of industry events (Operating Events) identified similar testing errors with blind samples provided by the blind sample vendor (Professional Toxicology Services). The most likely cause, based on the Lab details of the sample (low creatinine levels, specific gravity did not meet dilute criteria) and industry OEs with previous testing errors with

blind samples, is that the blind sample vendor used by IPEC likely provided an improper sample for specimen #5196604.

An investigation of Entergy personnel was performed to determine how the testing error was missed by Entergy staff during their review of the test results. The returned test results for specimen #5196604, that was tested by Quest Diagnostic was sent from Quest Diagnostic to IPEC's MRO for review as required by procedure for negative test results, and then released to IPEC. Entergy received testing documentation from the MRO on March 12, 2013, during a Refueling Outage when "Shared Services" personnel (other site personnel to augment workload escalation as a result of the outage) were assisting in performing an initial review of the HHS-Certified Laboratory (Quest Diagnostic) results. Recollection by review staff was that a blind sample packet containing the results of thirty samples including the results from specimen #5196604 had a note attached indicating "Blinds are complete." Based on the note further review was not performed. Entergy concluded based on this information that the apparent cause was poor use of Human Performance tools, multi-tasking and failure to use place keeping.

Corrective Actions

- Entergy at IPEC has changed the supplier of NRC Blind Samples to a new vendor. This new vendor is the vendor utilized by the Entergy fleet.
- The lead AA coordinator and AA/FFD staff were coached on management expectations on use of Human Performance tools and emphased the potential for errors when multi-tasking and to ensure distractions are minimized during review of HHS-Certified Laboratory results.
- AA shared the OE with the fleet access group to include all AA/FFD supervisors and AA/FFD shared resources stressing the potential for errors when multi-tasking.
- The blind sample review process was changed so that only AA/FFD staff will complete reviews of HHS-Certified Laboratory results.