Entergy

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Manager, Licensing

GNRO-2010/00044

June 15, 2010

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

Subject: Unsatisfactory Laboratory Testing Report
Grand Gulf Nuclear Station – Unit 1
Docket Number: 50-416
License Number: NPF-29

Dear Sir or Madam:

On March 8, 2010, Grand Gulf Nuclear Station (GGNS) Fitness-for-Duty (FFD) Staff received inaccurate test results from blind Quality Assurance (QA) drug testing samples that were submitted to a Health and Human Services (HHS) Certified Laboratory for analysis.

Blind QA samples containing target levels of a controlled substance were analyzed by Quest Diagnostic Laboratory in Lenexa, Kansas. The results of these samples were reported to GGNS as invalid. The GGNS FFD Staff completed an investigation pertaining to the blind sample errors on May 20, 2010. Pursuant to the reporting requirements of 10 CFR 26.719(c)(1), the investigation results and corrective actions are documented in Attachment 1.

This letter contains no commitments. Should you have any questions concerning this issue, please contact Dennis Coulter at 601-437-6595.

Sincerely,

CLP/DMC/dmc

Attachments: 1. Grand Gulf Nuclear Station Blind QA Sample Error Investigation Report

cc: (See next page)

cc: U.S. Nuclear Regulatory Commission
ATTN: Mr. Elmo E. Collins, Jr. (w/a)
Region Administrator, Region IV
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011-4125

NRC Senior Resident Inspector
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Port Gibson, MS 39150

U. S. Nuclear Regulatory Commission
ATTN: Mr. Carl F. Lyon, NRR/ADRO/DORL (w/a)
Mail Stop OWFN/8 B1
Washington, DC 20555-0001

Attachment 1 to

GNRO-2010/00044

Grand Gulf Nuclear Station
Blind QA Sample Error Investigation Report

Grand Gulf Nuclear Station
Blind QA Sample Error Investigation Report

Identification of Error:

Blind Fitness for Duty (FFD) Quality Assurance (QA) samples were purchased from the vendor Professional Toxicology to meet the various Grand Gulf Nuclear Station (GGNS) sample results required for blind specimens. The vendor sent three specimens from lot number 1001PCP to GGNS for use as positive phencyclidine (PCP) challenges. Purchase documentation provided by Professional Toxicology indicated that the lot was originally certified as positive for PCP at a Health and Human Services (HHS) certified lab. These three blind specimens were shipped by GGNS to the Quest Diagnostics - Lenexa Kansas lab, an HHS certified lab, on 3/2/2010 and received in the lab on 3/4/2010. On 3/8/2010 the Quest Diagnostics - Lenexa Kansas confirmatory lab returned the expected positive result for one of the three blind PCP positive samples; however, two blind PCP Positive samples (sample number 7462252 and sample number 7462253) were reported as "Invalid – Gas Chromatograph / Mass Spectrometer (GM/MS) Interference." This event was documented in Condition Report CR-GGN-2010-01547.

Investigation:

Upon discovery of the error, Quest – Lenexa and Professional Toxicology were notified by GGNS and requested to initiate investigative actions to determine a cause for the discrepancy. The following information was provided from each vendor:

Professional Toxicology

- Lot number 1001PCP had initially been certified at the Quest Diagnostics Laboratory in Lenexa.
- Other samples from this lot number have been processed at other HHS labs without any errors being reported.
- Since the occurrence, other HHS certified labs were contacted by Professional Toxicology and asked to re-evaluate their GC/MS results to specifically look for contaminates or interfering substances. No such substances were identified.
- In recent months the process used by Quest – Lenexa to verify the presence of PCP using GC/MS was modified. Since this change, PCP samples manufactured by Professional Toxicology have, on occasion, produced interference with GC/MS verification.
- Subject matter experts from Quest searched for interfering substances. Among the substances under consideration were over-the-counter medications and plasticizers from the specimen containers.
- No changes in the preparation or processing of PCP samples have been made by Professional Toxicology.
- No explanation was known as to why the result from the same lot number was tested and reported valid at times and invalid at other times. Professional Toxicology did not believe the issue was caused by an interfering substance; initial belief was that Quest GC/MS protocol change was the likely reason for the inconsistent results.

Quest - Lenexa

- Quest – Lenexa has worked with Professional Toxicology since the incident was reported. Samples of Lot number 1001PCP were obtained directly from Professional Toxicology by Quest. An interfering substance appears to be present.
- Quest – Lenexa has processed PCP samples produced by other manufacturers without any difficulty.
- Quest assigned a subject matter expert to work with the toxicologist to investigate this situation. Their investigation focused on identifying the interfering substance and adapting their analytical procedures to work around it.

Cause:

The ultimate conclusion from the Quest investigation was that the interfering substance was over the counter medication containing doxylamine (a sleep aid).

Corrective Action:

On May 20, 2010, the laboratory director from Quest contacted GGNS with the result of their investigation as they pertained to the GGNS blind PCP specimens. The investigation revealed that they (Quest – Lenexa) were able to identify and separate the interfering substance in the blind samples which were received from the vendor. To eliminate the interference of the substance, the confirmatory laboratory developed and tested a new procedure which was incorporated into their standard operating procedure.

Additional corrective action testing was performed utilizing PCP Blind Specimens from Professional Toxicology. The corrective action testing using the new Quest GC/MS testing protocol resulted in the correct test results, thereby validating the investigative findings. Whereas Quest has validated their findings through the corrective action testing and formally incorporated the testing protocol change into their Standard Operating Procedure, GGNS closed the investigation May 20, 2010.