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10 CFR 26.719(c)

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

Brunswick Steam Electric Plant, Unit Nos. 1 and 2
Docket Nos. 50-325, 50-324 / Renewed License Nos DPR-71 and DPR-62

Catawba Nuclear Station, Unit Nos. 1 and 2
Docket Nos. 50-413, 50-414 / Renewed License Nos. NPF-35 and NPF-52

H. B. Robinson Steam Electric Plant, Unit No. 2
Docket No. 50-261 / Renewed License No. DPR-23

McGuire Nuclear Station, Unit Nos. 1 and 2
Docket Nos. 50-369, 50-370 / Renewed License Nos. NPF-9 and NPF-17

Oconee Nuclear Station, Unit Nos. 1, 2 and 3
Docket Nos. 50-269, 50-270, and 50-287 / Renewed License Nos. DPR-38, DPR-47, and DPR-55

Shearon Harris Nuclear Power Plant, Unit 1
Docket No. 50-400 / Renewed License No. NPF-63

SUBJECT: 10 CFR 26.719(c)(1) Report - Unsatisfactory Performance of a Health and Human Services Certified Laboratory

Ladies and Gentlemen:

In accordance with 10 CFR 26.719(c)(1), Duke Energy Carolinas, LLC and Duke Energy Progress, LLC (collectively referred to as Duke Energy) is submitting a 30-day report detailing unsatisfactory performance of a Health and Human Services (HHS) Certified Laboratory.

10 CFR 26.719(c) stipulates in part that licensees shall notify the NRC within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered at either a licensee testing facility or an HHS-certified laboratory in the testing of quality control or actual specimens that could adversely reflect on the integrity of the random selection or testing process.

The enclosure to this letter provides a summary of the issue and planned corrective actions.

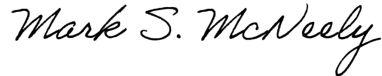
U.S. Nuclear Regulatory Commission

RA-22-0148

Page 2

This letter contains no new commitments. Should you have any questions, please contact Teddy Reed at (704) 471-5851.

Sincerely,



Mark McNeely

General Manager, Nuclear Protective Services

Enclosure: 10 CFR 26.719(c) Report Unsatisfactory Performance of a Health and Human Services Certified Laboratory

cc:

- L. Dudes, Regional Administrator USNRC Region II
- G. Smith, USNRC Senior Resident Inspector – BNP
- J. D. Austin, USNRC Senior Resident Inspector – CNS
- J. Zeiler, USNRC Senior Resident Inspector – HNP
- G. A. Hutto, USNRC Senior Resident Inspector – MNS
- J. Nadel, USNRC Senior Resident Inspector – ONS
- M. Fannon, USNRC Senior Resident Inspector – RNP
- P. Harris, Senior Program Manager – Security Programs and Support Branch
- B. Zaleski, FFD Specialist – Office of Nuclear Security and Incident Response

ENCLOSURE TO RA-22-0148

10 CFR 26.719(c) Report

Unsatisfactory Performance of a Health and Human Services Certified Laboratory

Summary of Issue:

On March 17, 2022 Duke Energy Corporate Access Services determined that reported results for blind performance test specimen 0107390965 were not reported within 30% of the target concentration for marijuana metabolite (THCA) by LabCorp of Research Triangle Park (RTP). The specimen was analyzed in batch 269564 on MSD #82 on February 17, 2022. Results for the specimen and batch quality control are shown in the table below:

Batch	Specimen	Actual	Target	% Deviation
269564	107390965	127	95	33.68
269564	Below Threshold QC	7.4	6.5	13.85
269564	Above Threshold QC	19.2	18.4	4.35

The laboratory performed a full investigation to determine the cause of the discrepant result as indicated:

- All relevant documentation was reviewed; no errors or omissions were identified. The analytical data supported the reported results. Chain of custody for the specimen and batch documentation were in accordance with the standard operating procedure.
- Instrument maintenance was performed on schedule for MSD # 82 and no related instrument problems were noted prior to or after the PT analysis was performed.
- The quantitative results and chromatography for the quality control results were within the acceptable range.
- Several blind PT samples that were analyzed for THCA in the weeks prior to this sample were identified and found to have quantitative results within 30% of target. Most of these samples were analyzed with calibrator lot 081321. On February 8, 2022, a new calibrator lot, 121621, was put into service and was used for the analysis of 0107390965.
- The calibrator material for lot 121621 was evaluated. New material (Lot 040522) was prepared and run against the old material (Lot 121621) and NIST-traceable standards. The table below outlines the results.

Specimen	Actual	Target	% Deviation
Lot 040522 Mean	15.19	15	1.27

Lot 121622 Mean	12.81	15	-14.60
NIST 1	23.47	24.1	-2.61
NIST2	23.596	24.1	-2.09

- Calibrator lot 121622 showed a low bias which would result in higher concentrations for patient samples.

Based on the review of all relevant data the lab determined that the cause of the quantitation bias for specimen 107390965 was deterioration of the calibrator material. Calibrator lot 121622 was removed from service and replaced with calibrator lot 040522.

Specimen 107390965 was reanalyzed with Lot 040522 and results within 30% of target were obtained.

Batch	Specimen	Actual	Target	% Deviation
QC8739	107390965	106.41	95	12.01
QC8739	Below Threshold Control	5.34	5.8	-7.93
QC8739	Above Threshold Control	15.71	16.9	-7.04

Corrective Actions:

1. The laboratory has implemented a weekly review of quality control charts to monitor the stability of the calibrator lot and re-verify with traceable standards as indicated.