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Serial: RA-23-0135
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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.

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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)(1) Report, Unsatisfactory Performance of a Health and Human Services Certified Laboratory

cc:

L. Dudes, Regional Administrator USNRC Region II
P. Harris, Senior Program Manager – Security Programs and Support Branch
B. Zaleski, FFD Specialist – Office of Nuclear Security and Incident Response

USNRC Senior Resident Inspector – BNP
USNRC Senior Resident Inspector – CNS
USNRC Senior Resident Inspector – HNP
USNRC Senior Resident Inspector – MNS
USNRC Senior Resident Inspector – ONS
USNRC Senior Resident Inspector – RNP

ENCLOSURE TO RA-23-0135

10 CFR 26.719(c)(1) Report

Unsatisfactory Performance of a Health and Human Services Certified Laboratory

Summary of Issue:

Specimen identification (SPID) number 0528556663 was received at the Labcorp testing laboratory in Research Triangle Park on March 22, 2023 and was processed for drugs of abuse testing. The specimen had a presumptive positive test on the initial screen and was scheduled for confirmatory testing. The laboratory reported SPID 0528556663 with a positive result on March 29, 2023, which exceeded the expected turn-around time (TAT). On March 3, 2023, Duke received the Lab's report of their investigation. This report did not identify their corrective actions, so Duke subsequently requested an updated response. The Lab's updated response was received on May 30, 2023.

An investigation into the processing of this sample showed that the delay in TAT was due to unacceptable quality controls resulting in batch failures; the specimen was tested on multiple confirmation batches before final results were obtained. Rates for assay failure and technologist failure were evaluated as part of the investigation. There was an increase in the failure rate for the assay during the last two weeks of March. For corrective action, a fresh bottle of reagent was placed into service on March 29, 2023. No more failures were observed for the assay after the corrective action was implemented.

This exceeds the reporting requirements described in 10CFR 26.169. Labcorp actively monitors turn-around-time and make every effort to report results in a timely manner. While testing batches fail from time to time, multiple batch failures do not occur routinely. Labcorp has reviewed the data and reasons for failure to ensure that testing was performed in accordance with Standard Operating Procedure (SOP).