



Mark McNeely
General Manager, Nuclear Protective Services

Nuclear Protective Services
*526 South Church Street, EC05ZA-
HYB Charlotte, NC 28202*

980-373-6371
Mark.McNeely@duke-energy.com

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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:

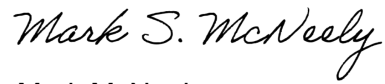
In accordance with 10 CFR 26.719(c)(1), Duke Energy Carolinas, LLC and Duke Energy Progress, LLC (collectively referred to as Duke Energy) is submitting a 30-day report detailing unsatisfactory performance of a Health and Human Services (HHS) Certified Laboratory.

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.

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
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
N. Jordan, NRR Project Manager
P. Harris, Senior Program Manager - Security Programs and Support Branch
B. Zaleski, FFD Specialist - Office of Nuclear Security and Incident Response

ENCLOSURE TO RA-22-0335

10 CFR 26.719(c)(1) Report

Unsatisfactory Performance of a Health and Human Services Certified Laboratory

Summary of Issue:

On August 25, 2022 Duke Energy Corporate Access Services determined that reported results for Blind PT Specimen 0106796832 were not within 30% of the target concentration for marijuana metabolite (THCA) by LabCorp of Research Triangle Park (RTP). The specimen was analyzed by GCMS on July 16, 2022; specimen results of 107 ng/mL exceeded the target of 75 ng/mL by 42.6%. Results for the batch quality control were acceptable, within 20% of target. On October 12, 2022 Duke received a response from the Lab stating the error was due to “isolated random variability in the assay, not reflective of any systemic issues”, with no corrective actions identified. Duke subsequently provided feedback to the Lab that this was not an acceptable response. On 11/4/22 Duke received the following revised report from the Lab.

Investigation:

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 up to date and no related instrument problems were noted prior to or after the blind PT analysis was performed.
- The quantitative results and chromatography for the quality control results were within the acceptable range.

Several blind PT samples from the same client that were analyzed for THCA in the weeks prior to this sample were identified and found to have quantitative results within 30% of target. All of those samples were analyzed with the same calibrator (Lot 040522) as the sample in question. Calibrator Lot 040522 was placed into service on 4/12/2022. Also, a second NRC blind PT sample was received and analyzed one day following the sample in question. That blind PT was extracted and analyzed using the same reagents, calibrator lot #, and instrumentation and was within 30% of target. Results from other external proficiency testing events in July 2022 were also reviewed and no bias was observed.

Sample 106796832 was re-extracted and reanalyzed with Calibrator Lot 040522 on 9/7/2022. Results from this repeat analysis were within the expected range. A summary of the results is below:

Batch	Specimen	Actual	Target	% Deviation
2500122	106796832	83.32	75	11.09

2500122	Below Threshold Control	6.95	5.3	3.73
2500122	Above Threshold Control	17.94	18.2	-1.43

Conclusion:

Based on our review of all relevant data as well as current quality control and external proficiency testing results, we believe the root cause of the discrepant result for SPID 0106796832 was isolated random variability in the assay. The assay is performed manually, and the human factor contributes to assay variability. Initial observation of the employee did not identify any specific errors. For corrective action, an updated competency assessment will be performed with the employee to verify all procedures are being performed in accordance with standard operating procedures.

Specimen 106796832 was reanalyzed and results were within 30% of target.