

**Jeffrey T. Gasser**  
Vice President

**Southern Nuclear  
Operating Company, Inc.**  
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November 11, 2003

Docket Nos.: 50-321 50-348 50-424  
50-366 50-364 50-425

NL-03-2313

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

**Southern Nuclear Operating Company**  
**Report of Unsatisfactory Performance Testing**

Ladies and Gentlemen:

In accordance with 10 CFR Part 26, Appendix A, Southern Nuclear Operating Company (SNC), the licensed operator for the Joseph M. Farley Nuclear Plant, the Edwin I. Hatch Nuclear Plant and the Vogtle Electric Generating Plant, requires that test specimens be submitted to a Department of Health and Human Services (HHS) certified laboratory for testing. On September 2, 2003, SNC began using LabCorp in Research Triangle Park, North Carolina for this purpose.

Because SNC was a new client, LabCorp personnel were to enter a new profile for SNC with the required cut-off levels for the panel of drugs at the NRC testing levels. The cutoff level which LabCorp personnel entered for opiates was 2000 ng/ml. The required NRC cutoff level is 300 ng/ml. This mistake was discovered by SNC personnel on September 19, 2003. At that time, LabCorp was instructed by SNC personnel to retest all of the aliquots that were still available and SNC recollected those individuals for which the aliquots had already been discarded. No individual was inappropriately granted unescorted access to any plant site; however, SNC noted this as a programmatic error on the part of the HHS laboratory and requested an immediate investigation.

The findings of LabCorp are provided as an enclosure (letters dated September 25, 2003, September 30, 2003, October 6, 2003 and October 13, 2003). SNC has determined that this error was not systemic and that corrective actions have been taken to prevent reoccurrence. This letter satisfies the reporting requirements of 10 CFR Part 26, Appendix A, paragraph 2.8.

Should you have any further questions, please advise.

Sincerely,

A handwritten signature in black ink that reads "Jeffrey T. Gasser". The signature is written in a cursive style with a long horizontal line extending to the right.

Jeffrey T. Gasser

Enclosure: LabCorp Reports (4 pages)

A022

U. S. Nuclear Regulatory Commission

NL-03-2313

Page 2

cc: Southern Nuclear Operating Company  
Mr. J. D. Woodard, Executive Vice President  
Mr. J. B. Beasley, Jr., Vice President, Plant Farley  
Mr. H. L. Sumner, Jr., Vice President, Plant Hatch  
Mr. J. W. Averett, Vice President – Administrative Services  
Mr. D. E. Grissette, General Manager – Plant Farley  
Mr. G. R. Frederick, General Manager – Plant Hatch  
Mr. W. F. Kitchens, General Manager – Plant Vogtle  
Document Services RTYPE: CFA04.054; CHA02.004; CVC7000; LC#13869

U. S. Nuclear Regulatory Commission  
Mr. L. A. Reyes, Regional Administrator  
Mr. F. Rinaldi, NRR Project Manager – Farley  
Mr. S. D. Bloom, NRR Project Manager – Hatch  
Mr. F. Rinaldi, NRR Project Manager – Vogtle  
Mr. T. P. Johnson, Senior Resident Inspector – Farley  
Mr. D. S. Simpkins, Senior Resident Inspector – Hatch  
Mr. J. Zeiler, Senior Resident Inspector – Vogtle



September 25, 2003

Ms. Billie Rooks  
Medical Services Supervisor  
Southern Nuclear

VIA FACSIMILE NUMBER: 205-992-<sup>5</sup>2568

RE: Specimen Processing Procedures

Dear Billie:

The drug testing accounts for Southern Nuclear's NRC testing program requirements were incorrectly set up in the laboratory's computer system. As a result, specimens were screened for opiates at 2000 ng/mL instead of the NRC requirement of 300 ng/mL and the automatic requirements of 6-MAM and d/l methamphetamine analysis were initially omitted. All accounts, regulated and non-regulated, have been reviewed by management and the necessary corrections completed. This system issue was promptly identified and only specimens tested from September 5<sup>th</sup> to September 11<sup>th</sup> were initially tested at the higher cutoff level. Eighty-one of the eighty-five specimens tested have been re-tested with the appropriate parameters for your accounts with either with the original Bottle A or Bottle B provided by you for the twenty-two specimens which had been discarded (as negatives are retained at our lab for 5 days).

Listed below is a summary of the actions taken by LabCorp to correct this mistake.

| <u>Account Number</u> | <u>Total number Effected</u> | <u>Total Cancelled</u> | <u>Total Corrected and Reported</u> |
|-----------------------|------------------------------|------------------------|-------------------------------------|
| 001076                | 14                           | 3                      | 11                                  |
| 001098                | 0                            | 0                      | 0                                   |
| 001116                | 9                            | 0                      | 9                                   |
| 001135                | 0                            | 0                      | 0                                   |
| 001144                | 62                           | 1                      | 61                                  |

Four specimens (identification numbers V031226-0024180101, C030399-0024050262, C030400-0024050270, and C030401-0024050288) were cancelled as "invalid" by Southern Nuclear as Bottle B could not be submitted.

To validate the changes, specimen identification numbers 0296775334 and 0296775360 are being monitored as of the writing to ensure the correct procedures are being followed. I apologize for any inconvenience this may have caused Southern Nuclear. If you require any further information, please do not hesitate to contact me direct at 800-833-3933, ext. 3645.

Sincerely,

Betsy Mitchell  
Associate Vice President



Laboratory Corporation of America® Holdings  
PO Box 12652  
1904 Alexander Drive  
Research Triangle Park, North Carolina 27709

September 30, 2003

Telephone: 800-833-3984  
919-572-6900

Ms. Billie Rooks  
Medical Services Supervisor  
Southern Nuclear

**VIA FACSIMILE NUMBER: 205-992-5568**

RE: Specimen Processing Procedures Follow-Up

Dear Billie:

As you know, this letter is in follow-up to our communication of September 25, 2003. On September 10, 2003, Southern Nuclear specimens were identified as being initially tested with an opiate cut-off level inconsistent with the NRC requirements. After the NRC opiate cut-off level was entered into the system, we proceeded to edit the specimens to apply the correct opiate cut-off level. The specimens were tested at the correct opiate cut-off level but the system applied the original (incorrect) opiate cut-off level (2000 ng/mL) and re-reported the incorrect results. A thorough investigation of this process determined that the system did not correctly edit the test. Therefore, where appropriate, system enhancements have been implemented. The specimens in question were edited to delete the incorrect opiate cut-off level (2000 ng/mL) and correctly accept the 300 ng/mL cut-off level and appropriately report the test results. LabCorp immediately contacted Southern Nuclear when we realized this process had occurred.

If you require any further information regarding this matter, please do not hesitate to contact me at the number indicated above or Mitzi Allison at the number above, ext.

3125- 3225

Sincerely,

A handwritten signature in cursive script that reads 'Betsy Mitchell'.

Betsy Mitchell  
Associate Vice President



Laboratory Corporation of America® Holdings  
PO Box 12652  
1904 Alexander Drive  
Research Triangle Park, North Carolina 27709

Telephone: 800-833-3984  
919-572-6900

October 6, 2003

Ms. Billie Rooks  
Medical Services Supervisor  
Southern Nuclear

**VIA FACSIMILE NUMBER: 205-992-5568**

RE: Specimen Processing Procedures Follow-Up

Dear Billie:

As you know, this letter is in follow-up to our communication of September 25, 2003. On September 10, 2003, Southern Nuclear specimens were identified as being initially tested with an opiate cut-off level inconsistent with the NRC requirements. After the NRC opiate cut-off level was entered into the system, we proceeded to edit the specimens to apply the correct opiate cut-off level. The specimens in the lab were tested at the correct opiate cut-off level but the system applied the original (incorrect) opiate cut-off level (2000 ng/mL) and re-reported the incorrect results (reports for each specimen indicated this was "an amended report"). A thorough investigation of this process determined that the system did not correctly edit the test. Therefore, where appropriate, system enhancements have been implemented. The specimens in question were edited to delete the incorrect opiate cut-off level (2000 ng/mL) and correctly accept the 300 ng/mL cut-off level and appropriately report the test results. LabCorp immediately contacted Southern Nuclear when we realized this process had occurred.

If you require any further information regarding this matter, please do not hesitate to contact me at the number indicated above or Mitzi Allison at the number above, ext. 3125.

Sincerely,

A handwritten signature in cursive that reads 'Betsy Mitchell' followed by a circled 'R'.

Betsy Mitchell  
Associate Vice President



Laboratory Corporation of America<sup>®</sup> Holdings  
PO Box 12652  
1904 Alexander Drive  
Research Triangle Park, North Carolina 27709

October 13, 2003

Telephone: 800-833-3984  
919-572-6900

Ms. Billie Rooks  
Medical Services Supervisor  
Southern Nuclear

**VIA FACSIMILE NUMBER: 205-992-5568**

RE: Specimen Processing Procedures Follow-Up

Dear Billie:

As previously explained, this letter is sent in follow-up to LabCorp's correspondences dated September 25, 2003, September 30, 2003 and October 6, 2003 and your request for additional information. On September 10, 2003, Southern Nuclear samples were identified by Southern Nuclear as having been tested for opiates at cut-off levels inconsistent with NRC requirements. Standard editing procedures were implemented on September 11, 2003 to apply the appropriate opiate cutoff levels within Southern Nuclear's NRC profile. The samples were then re-tested at the correct cutoff levels on the same day; however, the original results were re-reported as "an amended report."

A thorough investigation determined service weaknesses in two areas. First, Southern Nuclear's account record was set-up with the incorrect testing parameters. Second, reporting logic did not recognize Southern Nuclear's corrected testing profile when components within the profile had been adjusted to appropriate NRC levels.

This situation has been reviewed with appropriate staff and, where appropriate, action taken. In addition, additional training emphasizing the consequences of incorrect account set-up will be given to all members of the account set-up team.

Our IS team reviewed the programming logic within the editing and reporting routines. As a result, our procedure has been enhanced to create an entirely new and separate profile with the appropriate cutoff to prevent the reporting logic from "missing" the applied changes and triggering an amended report of the original results.

If you require any further information regarding this matter, please do not hesitate to contact me at the number indicated above or Mitzi Allison at the above number, ext. 3225.

Sincerely,

A handwritten signature in black ink that reads "Betsy Mitchell". The signature is written in a cursive style and includes a circled "R" at the end, likely indicating a registered trademark or a specific identifier.

Betsy Mitchell  
Associate Vice President