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50-366 50-364 50-425

NL-06-1784

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:

Southern Nuclear Operating Company (SNC) operates the Joseph M. Farley Nuclear Plant, the Edwin I. Hatch Nuclear Plant, and the Vogtle Electric Generating Plant. The requirements of 10 CFR Part 26, Appendix A, Paragraph 2.8, include submittal of blind performance test specimens to a Department of Health and Human Services (HHS) certified laboratory for testing. On June 22, 2006, specimen C060400 was provided to Kroll Laboratory Specialists (Kroll), in Gretna, Louisiana as a blind performance test specimen spiked with amphetamine and methamphetamine.

Specimens C060400 and C060402 were received and tested by Kroll on June 22, 2006. On June 24, 2006, Kroll notified SNC that specimen C060402 tested positive for amphetamine and methamphetamine. SNC requested a confirmatory analysis of specimen C060402 which resulted in the discovery that specimens C060400 and C060402 had been mislabeled. That is, the Kroll lab identification numbers for specimens C060400 and C060402 had been interchanged. The specimens were retested and as a result, specimen C060400 tested positive for amphetamine and methamphetamine and specimen C060402 tested negative for prohibited substances.

Kroll performed an investigation of the events that led to the above described unsatisfactory performance testing result and determined the cause was failure of personnel to follow Kroll standard operating procedures. The findings of this investigation are provided in Enclosure 1.

SNC requested an independent review of the incident and the corresponding corrective action by Dr. Larry A. Broussard, Toxicology Consultant. Dr. Broussard's findings are provided as Enclosure 2. In summary, Dr. Broussard determined that the root cause analysis performed by Kroll identified the cause of the incident and the corrective action was appropriate and comprehensive. Accordingly, additional corrective action is not required.

This report is provided in accordance with the requirements of 10 CFR Part 26, Appendix A, Paragraph 2.8, as an unsatisfactory performance testing result.

This letter contains no NRC commitments. If you have any questions, please advise.

Sincerely,



Don E. Grissette

DEG/TWS/sdl

Enclosures: 1. Kroll Laboratory Specialists letter to SNC, dated June 29, 2006
2. Larry A. Broussard, Ph.D letter to SNC, dated July 19, 2006

cc: Southern Nuclear Operating Company
Mr. J. T. Gasser, Executive Vice President
Ms. K. S. King, Chief Financial Officer & VP Corporate Services
Mr. H. L. Sumner, Jr., Vice President – Plant Farley
Mr. L. M. Stinson., Vice President – Plant Hatch
Mr. J. R. Johnson, General Manager – Plant Farley
Mr. D. R. Madison, General Manager – Plant Hatch
Mr. T. E. Tynan, General Manager – Plant Vogtle
RType: CFA04.054; CHA02.004; CVC7000; LC# 14473

U. S. Nuclear Regulatory Commission
Dr. W. D. Travers, Regional Administrator
Mr. R. E. Martin, NRR Project Manager – Farley
Mr. C. Gratton, NRR Project Manager – Hatch
Mr. C. Gratton, NRR Project Manager – Vogtle
Mr. C. A. Patterson, Senior Resident Inspector – Farley
Mr. D. S. Simpkins, Senior Resident Inspector – Hatch
Mr. G. J. McCoy, Senior Resident Inspector – Vogtle

Southern Nuclear Operating Company
Report of Unsatisfactory Performance Testing

Enclosure 1

Kroll Laboratory Specialists letter to SNC, dated June 29, 2006



The Risk Consulting Company

Kroll Laboratory Specialists
1111 Newton Street
Gretna, Louisiana 70053
800-433-3823 / 504-361-8989
Fax: 504-361-1530
www.krollworldwide.com

June 29, 2006

Ms. April Brockson
Southern Nuclear Operating Company
Safety & Health Department
P.O. Box 1295
Birmingham, AL 35201

Dear Ms. Brockson,

May this letter serve to document our conversation of June 28, 2006 regarding a discrepancy noted in the processing of two specimens submitted by Southern Nuclear Operating Company for analysis of substances of abuse. The specimens were submitted to Kroll Laboratory Specialists (Kroll) in Gretna, Louisiana. Kroll received Specimen ID # 52389857 (with Donor ID C060402) and Specimen ID # 52389859 (with Donor ID C060400) on June 22, 2006. Further, the specimens were assigned Kroll Laboratory ID #'s 8720097 and 8720098, respectively. Unfortunately, the specimen bottles were mislabeled so that the actual specimen bottle containing Donor ID C060402 was mislabeled with Laboratory # 8720098 and Donor ID C060400 was mislabeled as Laboratory ID # 8720097; therefore, the results of the testing performed on Donor ID C060400 were reported as positive for amphetamine and methamphetamine under the Laboratory ID # assigned to Donor ID C060402.

Kroll became aware of discrepancies in the test results on the specimens noted above upon request from the Medical Review Officer that a D&L Isomer analysis be performed on Specimen ID # 52389857. Upon receiving the request, a Specimen Handler was assigned to retrieve the specimen from frozen storage and pour up an aliquot (portion of the sample) in order to perform the additional testing. At that time, the specimen handler noted that the Specimen ID # on the chain of custody form (CCF) did not match the Specimen ID # on the specimen bottle and immediately reported the finding to me as the Laboratory Director. In accordance with standard procedures, I began an investigation to determine the cause of the discrepancy and immediately contacted Ms. Brockson with the Southern Nuclear Operating Company to inform her of this matter.

Kroll has Standard Operating Procedures (SOP's) in place to safeguard against errors of this type and remains confident that the SOP's, when strictly followed, eliminate the possibility of such errors during the accessioning and specimen handling processes; however, my investigation found that two experienced individuals did not properly follow those procedures, resulting in the subsequent issue.

The accessioning process is the process in which samples are received, verified and prepared for analysis in the laboratory. The process is a multi step process as described below:

- Shipping packages containing the specimen transport bags which then contain both the specimen bottles and CCF are opened.
- An accessioner then opens each specimen transport bag and compares the Specimen ID # on each CCF form to the Specimen ID # on each specimen bottle seal to ensure (i) that they are a match, (ii) that the specimen bottle seals are intact and (iii) that the CCF has been completed correctly.
- The accessioner then signs and dates the "RECEIVED AT LAB" area on the external CCF that arrived with each specimen and then transfers the specimens to Temporary Storage.
- An accessioner then removes the specimens from Temporary Storage in order to begin the next steps in the specimen's processing which is the bar-coding and aliquoting processes.
- The barcoding and aliquoting processes call for the barcoder/aliquoter to affix unique bar coded labels containing the Laboratory ID #, which identifies the specimen throughout its analysis, to the external CCF, the original specimen bottle, and a test tube aliquot for each specimen in the batch.

- Prior to affixing the bar coded labels the barcoder/aliquoter must reconfirm that the Specimen ID # on the CCF matches the Specimen ID # on the specimen bottle seal.
- Once the labels have been verified and placed on the CCF, the specimen bottle and the aliquot tube, an aliquot is poured up and forwarded on for analysis.

During the barcoding process the barcoder (which also performed the initial accessioning steps) failed to reconfirm that the Specimen ID # on the CCF matched the Specimen ID # of the specimen bottle seal and inadvertently placed the Laboratory ID # on a CCF, a mismatched specimen bottle and aliquot vial from the same batch. With the CCF in front of the barcoder, the barcoder picked up the wrong specimen bottle and mislabeled it and then subsequently mislabeled the following specimen bottle with the opposing barcode. While the two CCFs were labeled with the correct laboratory numbers, the bottle containing Donor ID C060400 was mislabeled as Laboratory ID # 8720097 and the bottle containing Donor ID C060402 was mislabeled as Laboratory ID # 8720098.

My investigation further determined that the specimen handler who prepared the aliquot for confirmation failed to follow SOP's. Upon a sample screening positive for the presence of drugs, a separate aliquot must be poured up and forwarded for confirmatory testing. The specimen in question had screened positive for amphetamine and methamphetamine and a second aliquot was requested for confirmation. A trained specimen handler removed the original specimen from Temporary Storage, poured up another aliquot of the original specimen labeled Laboratory ID # 8720097, and submitted the aliquot for confirmation testing. In accordance with the SOP, the specimen handler must compare the Laboratory ID # and the Specimen ID # on the CCF to the Laboratory ID # and Specimen ID # on the specimen bottle seal prior to pouring up the aliquot. Although the Laboratory ID #'s matched, the Specimen ID #'s did not. The specimen handler did not note the mislabeled bottle, mislabeled the aliquot and forwarded the aliquot for analysis. Subsequently, the analysis of Donor ID C060400 (labeled Laboratory ID # 8720097) confirmed the presence of amphetamine and methamphetamine, and thus the results were reported out.

As a result of the investigation, the specimen test results have been corrected, employees have been counseled and disciplined, and additional corrective measures have been implemented to ensure that a situation like this does not reoccur.

- The results for Donor ID C060402 (Laboratory ID # 8720097) have been corrected to reflect the true negative result of the analysis of this specimen. Kroll is currently retesting Donor ID C060400 (Laboratory ID # 8720098), and anticipates that the results will concur with the original results as positive for amphetamine and methamphetamine.
- Kroll has reviewed its SOP's and believes the SOP's are adequate to prevent this type of error when followed. Two experienced individuals, however, did not follow these SOPs and are subject to disciplinary action and will have to submit to retraining and a competency examination in order to continue employment with Kroll.
- As a corrective measure, Kroll has instructed Accessioning personnel that the individual who accessions the specimen and the individual who barcodes and aliquots the specimen must be two different people.

We apologize for any inconvenience this has created for you and would like to again convey the seriousness with which we regard this matter. As follow-up to this letter, I am more than willing to meet with you and your staff in order to provide a reenactment of the events that occurred or answer any additional questions that you may have.

Sincerely,



David A. Green, Ph.D., DABCC, FACB
Laboratory Director

Southern Nuclear Operating Company
Report of Unsatisfactory Performance Testing

Enclosure 2

Larry A. Broussard, Ph.D letter to SNC, dated July 19, 2006

Larry A. Broussard, Ph.D.
Toxicology Consultant
8 Melrose Dr. Destrehan, LA 70047 985 764-2950

July 19, 2006

Ms. April Brockson
Medical Services Coordinator
Southern Nuclear Operating Company
Safety & Health Department
P.O. Box 1295
Birmingham, AL 35201

Re: Investigation of drug testing incident involving Specimen ID #52389857 (Donor ID C060402) at Kroll Laboratory Specialists

Dear Ms. Brockson:

Upon your request I have investigated the following incident concerning specimens submitted to Kroll Laboratory Specialists:

Mislabeling of specimens ID #52389857 (Donor ID C060402) and ID #52389859 (Donor ID C060400) submitted to the laboratory June 22, 2006 and reported incorrectly resulting in a false positive (amphetamine and methamphetamine) result for specimen ID #52389857 and a false negative result for ID #52389859. The false positive result was discovered when a D&L Isomer Resolution analysis was requested for specimen ID #52389857.

My investigation included the following actions:

1. Initial review of the June 29, 2006 letter of explanation from Dr. David Green describing their investigation into the incident, explanation of the cause of the mislabeling incident of June 22, subsequent corrective action and implementation of additional procedures to prevent reoccurrence of a similar incident.
2. Telephone discussion with Ms. Brockson during which it was decided that my investigation would include visiting the lab to view a reenactment of the incident and review corrective measures instituted.
3. Scheduling site visit of lab for July 19, 2006.
4. Site visit of Kroll Laboratory Specialists on July 19 (described on the following page) and completion of this report.

Discussion of site visit to laboratory on July 19, 2006:

I visited the lab and met with Dr. Green and Ms. Pat Pizzo, the laboratory directors, and Mr. John Peterson, the President of Kroll Laboratory Specialists. They walked me through an enactment/discussion of the incident and I toured the laboratory to view each activity occurring during a routine morning of laboratory operation. I reviewed the documentation of their investigation and subsequent corrective action. Briefly the mistake that occurred was that 2 samples were mislabeled (switched) at the step in which the bar-coded internal laboratory ID labels are affixed to a specimen and its corresponding chain of custody form (CCF). In this incident one person performed 2 steps typically performed in sequence by 2 different people and this person as well as a second person failed to follow the SOP requirement of verifying that all specimen ID numbers match. If a different person had performed the step of affixing the bar-coded label quite possibly the mistake would have been discovered but because the person who switched the labels proceeded directly to bar-coding the forms and samples that person apparently skipped the verification of ID labels.

Laboratory Action

The laboratory investigated the incident and instituted a policy that the 2 steps in the process (accessioning the specimen and bar-coding/aliquoting) be performed by different individuals. In addition disciplinary action was taken and the employees involved were retrained. Approximately two weeks later further action taken after review of their entire process was implementation of a policy requiring the Negative Certifying Scientist to physically examine the specimen bottle and CCF to verify accuracy of all identifying numbers and then transfer the sample into a designated temporary storage tray. This has added another person verifying identification information making a total of 4 people performing this action during the processing of the samples prior to reporting of results. All employees were informed of these policy changes and documentation of this notification retained in training files.

Summary and conclusions

In my opinion one of the fundamental causes of this incident was the special manner in which Nuclear Regulatory Commission (NRC) samples were handled. Because the testing requirements are different from those of DOT samples the NRC samples and corresponding CCFs were placed on a segregated area of the processing table instead of into a tray (bin) for subsequent batch processing. Having samples and their CCFs on an open area of the table could (and probably did) facilitate a mix-up of samples and forms as they are moved for the next step (applying bar-coded labels and pouring an aliquot into a tube for screening). Upon discussion during my visit it was decided that the laboratory would add another corrective action by changing their procedure for handling NRC samples to require placing samples and their CCFs in a tray designated/labeled for NRC samples. This would standardize the processing procedure to make the handling of NRC samples less unique/different from the handling of all other regulated (DOT) samples.

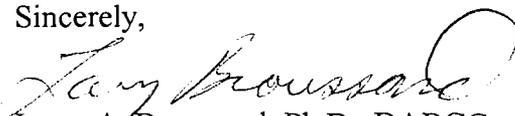
To summarize Kroll Laboratory Specialists' response to this incident included:

- investigation of the incident
- identification of employees who failed to follow written standard operating procedures (SOPs)
- disciplinary action (including suspension and reassignment) for employees failing to follow the SOPs
- retraining of these employees
- implementation of policy requiring different individuals perform accessioning and bar-coding/aliquoting steps
- implementation of policy requiring Negative Certifying Scientists to compare sample bottle and CCF for all non-negative regulated samples to verify that all identification information is correct
- training of all employees concerning new policies
- following visit of July 19, 2006 implementing procedure requiring that NRC samples and CCFs be placed in designated trays instead of on open table during the transition from the accessioning procedure to the bar-coding/aliquoting procedure

During my visit I reviewed all of the laboratory documentation of this incident including records of disciplinary action and retraining records. I have attached some of this documentation to this report. I requested that Kroll blacken out the names of the employees for any copies that I took and attached to this report but I verified that these were the employees who handled the samples involved in this incident. All representatives and employees of Kroll that I talked to were helpful, candid, open, very forthcoming with any information I requested, and seemed to be very concerned with the consequences to any donor resulting from an incident such as this one. None of the procedures and processes that I observed during this visit differed substantially from procedures and processes in other SAMHSA-certified laboratories that I have inspected. The root cause analysis that they performed identified the cause of the incident and the corrective action seemed to be appropriate and comprehensive.

Although we are dealing with regulated workplace drug testing in this incident, there is a parallel to the findings of studies investigating medical errors in general in which patient/ specimen (mis)identification has been shown to be the largest source of laboratory-associated medical errors. With this in mind our decision to incorporate factors such as specimen ID errors, incorrect CCFs, etc., into the blind samples submitted to testing laboratories will help Southern Nuclear Operating Company monitor the pre-analytical processing procedures of the labs to detect these errors just as the positive/adulterated samples monitor the lab's analytical processes. I hope that this report sheds further light on this incident and helps you when making decisions about the company's drug-testing program. I look forward to the continuation of our relationship even though we all wish incidents such as this one would never happen. Please feel free to call me if you have any questions about this report.

Sincerely,



Larry A. Broussard, Ph.D., DABCC