

July 26, 2010

ULNRC-05720

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

10CFR26.719(c)

Ladies and Gentlemen:



**DOCKET NUMBER 50-483
CALLAWAY PLANT UNIT 1
UNION ELECTRIC CO.
FACILITY OPERATING LICENSE NPF-30
BLIND SPECIMEN TEST RESULTS**

On June 25, 2010, Ameren received unexpected blind specimen results from Clinical Reference Laboratory. This specimen originated from lot 7418-190-37.2 which was manufactured to be positive for Marijuana metabolite. A specimen from the aforementioned lot was also sent to Quest Diagnostics in Lenexa, KS. The expected results were returned from Quest on 6-27-2010; however, the quantitative value reported was 31 ng/ml lower than the Certificate of Analysis reference lab value. Neither of these laboratories has received actual employee specimens between January 1 and July 15, 2010.

Later on June 25, 2010, Ameren was notified that lot 7418-190-37.2 had been quarantined by the supplier, Duo Research; the quarantine was based on study #2 as described in the attached report. In response to the enacted quarantine, Ameren replaced all second quarter blind specimens that originated from lot 7418-190-37.2 with new blind specimens to meet the second quarter blind requirements of 10CFR26. All replacement blind specimens were returned with the expected results as compared to the certificate of analysis values.

Based on this third occurrence within a year of unexpected THC results, Ameren has initiated further investigation into the cause of these issues. A new lot of specimens have been ordered from the existing supplier as well as a new supplier and those specimens will be received, stored and shipped under varying environmental conditions to determine whether factors other than the obvious quality of lot 7418-190-37.2 contributed to these events. Results of this testing should be completed by the end of August, 2010.

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Ameren's previous report, ULNRC-05710 dated June 4, 2010, documents an unexpected blind specimen result from Clinical Reference Laboratory for Marijuana. This specimen also originated from the now quarantined lot 7418-190-37.2.

In accordance with 10CFR26.719(c), enclosed is the documentation of investigative finding and the corrective actions taken by Duo Research. Please contact Anna Lee at 573/676-4435 if any additional action is needed as a result of this information.

This letter does not contain new commitments.

Sincerely,

A handwritten signature in black ink, appearing to read "Luke H. Graessle", with a long horizontal flourish extending to the right.

Luke H. Graessle
Director, Operations Support

CSP/nls

Enclosures

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cc: Mr. Elmo E. Collins, Jr.
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Missouri Public Service Commission

AAFFD10-0024

July 20, 2010

Mrs. Anna Lee
Supervisor Access Authorization/Fitness for Duty
Ameren UE
Callaway Plant
P.O. Box 620
Fulton, MO 65251



RE: Investigation of Blind performance testing error

I have received and reviewed the investigative report submitted by Duo Research. I am in agreement with the statements made and the corrective actions that are planned. I have also received and reviewed AmerenUE's report of findings and planned corrective actions. As MRO, I am satisfied that the appropriate actions are being taken to resolve the issue. If any further questions arise please do not hesitate to give me a call at 573-676-4301.

Sincerely,

A handwritten signature in black ink, appearing to read "William P. Cravens M.D.", written over a horizontal line.

William P. Cravens M.D.
Callaway Plant Medical Review Officer

cc: A160.0001

Attachment 1 to ULNRC-05720
Review performed by Dr. William Cravens
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INVESTIGATION REPORT

on

Blind Performance Test Samples

Objective:

The licensee shall investigate any unsatisfactory performance testing result. A record shall be made of the investigative findings and the corrective action taken by the laboratory. The licensee shall send the document to the NRC as a report of the unsatisfactory performance testing incident within 30 days.

References:

10 CFR 26 Subpart G, §26.168(g) (3)

Observation:

Ameren submitted blind quality control samples meeting the requirements of §26.168(g) (3), i.e., positive challenge samples, containing THC-9-acid, to three laboratories. Two of the laboratories reported the sample as positive, the third laboratory reported the sample as negative. The three laboratories, Quest, CRL and Toxicology Laboratory, provided the screening and subsequent GC/MS confirmation results.

Findings:

1. The samples were sent frozen to AmerenUE Callaway Plant by Duo Research Inc. on April 6, 2010. The samples were packaged in individual Nalgene bottles, which had remained frozen from the time of production. Quest and Clinical Reference Laboratories (CRL) received samples from the same lot and Toxicology Laboratory from another lot for which an acceptable result was received. For the lot in question, a reference analysis was conducted by MedTox Laboratories on October 13, 2009, which obtained a concentration of 95 ng/mL. The six month reanalysis by MedTox was conducted on April 8 with a concentration of 82 ng/mL. The acceptable range for the THCA Positive Challenge sample type is 75 to 100 ng/mL, i.e., in the 150% to 200% range of the 50 ng/mL screening cutoff, as per the NRC regulations. It is the usual procedure for Ameren staff to thaw the sample bottles, transfer the samples into the specimen vials provided by the laboratories, and submit the samples appearing as real specimens to the two laboratories. They were submitted to the laboratories June 24, 2010.
2. A negative results was reported by CRL and a positive result was reported by Quest. The results and review of the information provided by each laboratory are presented below.

3. Clinical Reference Laboratories (CRL), Lenexa, KS

This laboratory reported the sample as negative. The sample was received on June 25, 2010. The laboratory reported the result as negative that day. CRL provided the following information: The screening result was negative with a result of 22 compared to that of 50 for the cutoff calibrator using DRI screening reagents. CRL, in a follow up investigation, conducted a GC/MS analysis with a result of 34 ng/mL.

4. Quest Diagnostics, Lenexa, KS

This laboratory received the sample on June 25 and reported it as positive on June 27. The sample screened positive and was confirmed using GC/MS, with a result of 51 ng/mL.

Discussion:

The intent of the NRC requirement in §26.168(g)(3) to submit blind quality control samples in the positive range of 150% to 200% above the cutoff.

The quality control samples submitted to the reference laboratory, MedTox, and by Ameren to the two laboratories were subjected to somewhat different handling and shipping. The reference sample was sent frozen to MedTox, which had to thaw the sample and conduct the analysis. This occurred within a day of its receipt. The samples were also sent frozen to Ameren and stored frozen until they were thawed and prepared for shipment as blinds to the three laboratories.

Although it is known that the THC-9-acid metabolite is not totally stable, a one day difference in testing does not support a stability problem as the quantitative results are all within the range of variability allowed for quantitation. In order to investigate what factors could account for the differences, a study was conducted to determine the cause of these differences.

Study 1:

Four samples, from the same lot of THC-9-acid that was discussed above, were sent frozen to Ameren. Ameren prepared the four samples for submission to the four laboratories in the same manner. Three went to the Ameren contract laboratories: Toxicology Laboratories, Quest and CRL. The fourth was sent to MedTox, the reference laboratory used by Duo Research, using a custody form and air bill that is routinely used to submit quality control samples blind to MedTox. MedTox reported the sample as negative. In a follow-up investigation, the sample gave a screening result of -58 compared to the value of -89 for the 37.5 ng/mL control. The cutoff control of 50 ng/mL is set a zero.

The other three samples were reported as positive, with the following results: Toxicology Laboratory 49 ng/mL, Quest 58 ng/mL, and CRL 51 ng/mL.

It appears that the difference between the reference value of 82 ng/mL by MedTox in April and the results from these samples from the same lot may be related to the differences in handling and shipment to the laboratories. The samples in this lot are deteriorating somewhere in the process.

This is an unusual occurrence. Records were reviewed for the results on other samples for this lot that were submitted to MedTox by a Duo Research client. The client is located in Minnesota and has its workplace specimens picked up by a MedTox courier, delivered to the laboratory that day and often tested within hours of receipt. The client receives the samples frozen, like Ameren, and thaws them the morning of preparation. One was prepared December 3, 2009, and received by the laboratory that day and eventually reported negative. Duo Research investigated the result. MedTox reported that it screened negative and followed up by conducting a confirmation. The result was 47.

Another sample from this lot was processed and received at MedTox on April 16, 2010. It was reported positive with a quantitative value of 77 ng/mL. The previous result appeared to be an anomaly as no other sample from this lot had been reported as negative.

Study 2:

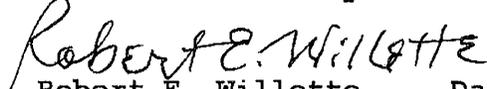
To further investigate the erratic phenomenon of this sample lot, a study was conducted to gauge the effect of shipping the samples frozen or thawed to a reference laboratory. Two frozen sample of the THC-9-acid from this lot were removed from the storage freezer. One was kept frozen and sent to ElSohly Laboratories frozen and the other sent thawed. Both samples were shipped overnight. The results were 69.8 ng/mL for the sample that was received frozen and 68 ng/mL for the liquid sample.

Conclusion:

It is clear from this last study that shipping the samples from this lot frozen or thawed did not make a significant difference in the results. From the earlier study with the samples submitted by Ameren, there did appear to be some additional loss of the analyte although not that much. The +/- 20% range of the average of the three results obtained by Ameren is 52.7 +/- 10.5, or a range of 42.2 to 63.2 ng/mL. The higher range is not that different from the results received from ElSohly Laboratories. However, these results do clearly indicate that this lot of THC-9-acid has become unstable and will be destroyed.

A new lot of THC-9-acid positive challenge samples was prepared and 20 samples sent to Ameren to investigate if any possible contribution to sample handling and processing is a factor.

Prepared for: Ameren UE Callaway Plant

by: 
Robert E. Willette Date: July 15, 2010
Duo Research Inc.