AmerenUE
Callaway Plant

PO Box 620
Fulton, MO 65251

June 4, 2010

ULNRC-05710

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 5-5-2010, blind positive specimens were submitted to three HHS certified laboratories who have contracts with Callaway Plant. On 5-6-2010, one laboratory returned unexpected results. On 5-7-2010, the other two laboratories returned the expected results. All three laboratories are Department of Health and Human Services (DHHS) laboratories. Two of the three specimens were manufactured from the same lot with the third specimen manufactured from a different lot, however similar results were expected for all three specimens. This information was provided to Duo Research, Callaway's blind specimen provider, who is currently conducting their own investigation.

In accordance with 10CFR26.719(c), enclosed is the documentation of investigative findings and the corrective actions taken by Clinical Reference Laboratory. Duo Research has also submitted an interim report of findings. 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,

Scott Sandbothe
Manager, Plant Support

CSP/nls

Enclosures

cc: Mr. Elmo E. Collins, Jr.
Regional Administrator
U.S. Nuclear Regulatory Commission
Region IV
612 E . Lamar Blvd., Suite 400
Arlington, TX 76011-4125

Senior Resident Inspector
Callaway Resident Office
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Mr. Mohan C. Thadani (2 copies)
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U. S. Nuclear Regulatory Commission
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AmerenUE
Callaway Plant

PO Box 620
Fulton, MO 65251

AAFFD10-0022

June 2, 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 reports submitted by Clinical Reference Laboratory and Duo Research. I am in agreement with the statements made and the corrective actions that are planned. As MRO, I am satisfied that the appropriate actions have been taken to resolve the issue. If any further questions arise please do not hesitate to give me a call at 573-676-4301.

Sincerely,

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

cc: A160.0001

Attachment 1 to ULNRC-05710
Review performed by Dr. William Cravens
Page 1 of 1

CLINICAL REFERENCE LABORATORY

Aaron Enloe, FFD coordinator
Union Electric Company D/B/A Ameren UE
Callaway Plant
JCT HWY CC and HWY O
Fulton, MO 65251

6/2/10

FAX: (573) 676-4615

Dear Mr. Enloe,

Clinical Reference Laboratory (CRL) issued a report of "negative" for urine specimen #6402184841 identified by laboratory accessioning number 47340347. CRL was subsequently notified that this specimen was an external blind that was expected to test positive for THC. This sample was received by the laboratory on 5/6/10. The sample screened negative for drugs. SVT analysis yielded a creatinine value of 71.1 mg/dL. The sample did not meet the FFD requirements for testing at LOQ because the creatinine was greater than 20.0 mg/dL. The sample was reported as negative in accordance with CRL SOP and FFD program guidelines.

On 5/07/10, the laboratory received notification that the sample was an external blind which had failed to meet the expected result of "positive for THC". The stated target range for the blind sample was 65.0 ng/mL to 77.5 ng/mL. At your request, the specimen was moved to long term storage on 5/7/10.

At your request on 5/10/10, the screening data was submitted and at the same time an investigation was initiated by CRL. The initial screening data was reviewed. The initial (semi-quantitative) THC screening value was 43 ng/mL. An aliquot of the sample was forwarded for confirmation testing. The result obtained by GCMS analysis was 36.1 ng/mL. This "confirmed" value is below the 50 ng/mL screening cutoff.

The laboratory requested further information from you on 5/10/10. Along with a narrative of the process, you submitted a copy of the instructions for submitting a blind to CRL and a DTI for submitting blind specimens. The first document specifically states the sample should be mixed before submission. The second does not mention mixing. To rule out a sample that was not sufficiently mixed, the laboratory sent to confirmation an aliquot of bottle B. The value obtained was 40.0 ng/mL. The similarities in obtained values indicates the sample was mixed on submission. However, both values from bottle A and bottle B are clearly below the stated target value and below a level that would trigger a positive of 50 ng/mL or greater on screening.

If we can be of further assistance in this matter, please let us know.

Sincerely,

John Irving
Responsible Person
Clinical Reference Laboratory
Lenexa, Kansas 66215
(913) 693-5405

David Kuntz
Responsible Person
Clinical Reference Laboratory
Lenexa, Kansas 66215
(913) 693-5406

Attachment 2 to ULNRC-05710
Investigative Report provided by CRL
Page 1 of 1

INTERIM 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)(2) and (3), i.e., positive samples and false negative challenge samples, containing THC-9-acid, to two laboratories. Only one of the laboratories reported the positive sample as positive and the other laboratory reported the sample as negative.

Findings (1):

1. The THC-9-acid positive samples were sent frozen to Ameren UE 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. Reference analysis was conducted on October 13, 2009, by MedTox Laboratories, which obtained a concentration of 95 ng/mL. The acceptable range for the THCA Positive sample type is 75 to 100 ng/mL. 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 three laboratories. The samples were submitted to the two laboratories May 5, 2010.

2. A negative result was reported by one of the laboratories and a positive result by the other laboratory. The results and review of the information provided by each laboratory are presented separately. A general comment about the screening reagents and how the results are presented: HHS certified laboratories are required to include a number of quality control samples in each screening batch. Amongst these are two that are at 25% above and 25% below the cutoff concentration. This is the acceptable range permitted for samples at the cutoff concentration to fall between. The laboratories may use different instrument settings to express the results compared to the instrument reading for the cutoff calibrator.

3. Clinical Reference Laboratory

This laboratory reported the sample as negative. The laboratory provided Ameren with printouts from the screening results, which had a reading of 42, which indicates it was negative. Ameren did not request the laboratory to conduct the quantitative test.

4. Quest Diagnostics, Lenexa, KS

This laboratory reported the sample as positive. The laboratory conducted the GC/MS analysis with a result of 49 ng/mL.

Observation:

Ameren submitted blind quality control samples meeting the requirements of §26.168(g)(2) and (3), i.e., positive samples and false negative challenge samples, containing THC-9-acid, to two laboratories. Only one of the laboratories reported the positive sample as positive and the other laboratory reported the sample as negative.

Findings (2):

1. The THC-9-acid false negative challenge samples were sent frozen to Ameren UE Callaway Plant by Duo Research Inc. on May 10, 2010. The samples were packaged in individual Nalgene bottles, which had remained frozen from the time of production. Reference analysis was conducted on October 13, 2009, by MedTox Laboratories, which obtained a concentration of 74 ng/mL. The acceptable range for the THCA Positive sample type is 65 to 77.5 ng/mL. 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 three laboratories. The samples were submitted to the two laboratories May 12, 2010.

2. A positive result was reported by both of the laboratories. The results and review of the information provided by each laboratory are presented separately.

3. Clinical Reference Laboratory

This laboratory reported the sample as positive with a quantitative value of 42 ng/mL. The laboratory was contacted to obtain additional data, i.e., the screening results to clarify what the values of the control samples were relative to the cutoff. Further information has not yet been received.

5. Quest Diagnostics, Lenexa, KS

This laboratory reported the sample as positive. The laboratory conducted the GC/MS analysis with a result of 48 ng/mL.

Discussion:

The intent of the NRC requirement in §26.168(g)(3) to submit blind quality control samples in the range of 130% to 155% above the cutoff is to challenge the testing laboratories ability to detect the presence of drugs above the +25% control limit required under HHS certification. For clarification, for the THC-9-acid metabolite, a sample at exactly 50 ng/mL should screen positive 50% of the time and negative 50% of the time on repeated testing. Over a range of increasing concentrations, a greater percentage of the samples should be positive. The NRC regulation has set 30% above the cutoff as the point that all samples should be positive. The assumption is that a sample of THC-9-acid at 66 ng/mL should be positive.

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 laboratories.

Because all of the time intervals are similar, with no obvious differences in the handling and processing of the samples, it is concluded that the laboratories obtained comparable and very similar results that must be considered correct. Until additional information is obtained it is not possible to determine what the cause of the discrepancy in values between the laboratories and the reference values.

A table with a summary of the results is attached.

Recommendation:

Duo Research is continuing to obtain additional information from the two laboratories and will submit a final report as soon as the investigation is considered complete.

Prepared for: **Ameren UE Callaway Plant**

by: Robert E. Willette Date: June 2, 2010

Duo Research Inc.

Addendum:

As noted in the March 4, 2010, Investigation report, a study was conducted to determine if the transfer of the THC-9-acid "False Negative Challenge" (FNC) sample to a laboratory specimen bottle and shipped overnight to the two laboratories contributed to their initial negative screening result. It was noted that an identical sample sent to the local laboratory screened positive the day the sample was prepared and was subsequently confirmed.

The other issue was whether a concentration close to the minimum 130% limit set by NRC for such samples poses a chance that quality control samples containing the THC-9-acid may have an increased risk of failing the initial screen. This is based on an extensive literature describing the stability and potential sources of loss of this analyte.

The study involved the production of a new batch of the THC-9-acid FNC samples. The target concentration was to be close to the upper 155% level for these samples, 77.5 ng/mL.

Two of the samples were sent frozen to the original reference laboratory, MedTox. One sample was thawed and transferred into two laboratory vials, the same type of sample bottle used by the Callaway Plant. One of the vials was stored at room temperature overnight. After a two hour delay the other sample was screened under standard laboratory condition along with other samples.

The screening result was positive with an instrument response of 95, compared to the +25% control (62.5 ng/mL) response of 98. The confirmation result, conducted the same day, was 75 ng/mL.

On the next day, the sample that was stored at laboratory temperature overnight was submitted to the screening assay. It gave a response of 79 compared to the +25% control response of 90, a larger separation than that of the sample tested the day it was thawed. The confirmation result for this sample was 62 ng/mL.

It is apparent that the sample does suffer some loss when transferred to the laboratory bottles and stored for about 24 hours before testing, simulating the time frame of the two samples that screened negative, although the actual storage conditions may differ to some extent.

In conclusion, for THC-9-acid, it is apparent that to avoid possible losses due to transferring the sample to laboratory bottles and conditions of shipping, the sample via commercial courier overnight, the concentration of this analyte must be at the upper limit of the 130% to 155% range specified by the NRC regulations.

Lab	Duo Number	COC #	Results	Quant Value	Ref. Values	Type of Blind	Date of Submittal
Quest	9657-125-88717	8126992	Negative	58 ng/mL[1]	74 ng/mL	False negative THC	02/23/2010
CRL	9657-125-84733	6402068862	Negative	48.9 ng/mL[1]	74 ng/mL	False Negative THC	02/23/2010
Toxicology	9657-125-43805	T110449	Positive	50 ng/mL	74 ng/mL	False Negative THC	02/23/2010
Quest	7418-190-17621	8126930	Positive	49 ng/mL	95 ng/mL[4]	Positive THC	05/05/2010
Toxicology	9657-125-29471	T113970	Positive	68 ng/mL	95 ng/mL	Positive THC	05/05/2010
CRL	7418-190-23981	6402184841	Negative	N/A[2]	95 ng/mL[4]	Positive THC	05/05/2010
Quest[3]	9657-125-00536	8126930	Positive	48 ng/mL	74 ng/mL	False Negative THC	05/12/2010
CRL[3]	9657-125-36483	6402184831	Positive	42 ng/mL	74 ng/mL	False Negative THC	05/12/2010

[1] Results were obtained during the investigation process after reanalyzing.

[2] Results from investigation have not yet been returned.

[3] Replacement samples that were submitted due to the failure of the 2-23-2010 samples.

[4] Samples from this lot were also submitted blind in two other workplace programs, prepared in the lab kits ready for testing, with results from one laboratory of 69 and 70 ng/mL, and from another at 105 ng/mL.

Note that the sample for lot 9657-125 were prepared exclusively for AmerenUE, whereas those from lot 7418-190 were prepared in a similar manner for DOT workplace programs.