



September 20, 2012

ULNRC-05913

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**

In accordance with 10CFR26.719(c)(1), enclosed is the documentation of investigative findings and the corrective actions taken for unexpected results for a substituted blind specimen. A report from Quest Diagnostics is included in the enclosed documentation of investigative 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 A. Maglio
Regulatory Affairs Manager

CSP/nls

Enclosure

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cc: Mr. Elmo E. Collins
Regional Administrator
U. S. Nuclear Regulatory Commission
Region IV
1600 East Lamar Boulevard
Arlington, TX 76011-4511

Senior Resident Inspector
Callaway Resident Office
U.S. Nuclear Regulatory Commission
8201 NRC Road
Steedman, MO 65077

Mr. Fred Lyon
Senior Project Manager, Callaway Plant
Office of Nuclear Reactor Regulation
U. S. Nuclear Regulatory Commission
Mail Stop O-8G14
Washington, DC 20555-2738

Index and send hardcopy to QA File A160.0761

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Missouri Public Service Commission



Callaway Plant

AAFFD12-0003

September 18, 2012

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

RE: Investigation of Blind performance testing error

Attached is the investigative report and corrective actions regarding the unexpected blind results received from Quest Laboratories. 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,

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

William P. Cravens, M.D.
Callaway Energy Center Medical Review Officer

cc: A160.0001

Investigation of Blind Performance Testing Error 8/22/2012
Callaway Energy Center

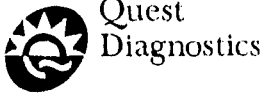
On 08-22-12, Callaway Energy Center received unexpected results on a blind specimen from Quest HHS lab in Lenexa, KS. Quest did report the specimen as a substituted specimen with creatinine < 0.5 mg/dL, sp. Gr. 1.0003. Quest also reported an invalid result, which was not expected, of a pH of 9. Two other HHS labs that were sent blind specimens from the same lot reported expected results of a substituted specimen.

Upon receipt of the results, the MRO contacted Quest Laboratory to initiate an investigation into the unexpected results. On 8/23/2012, Director, Laboratory Operation at Quest reviewed the initial results of the blind specimen and reported that their initial screening results were accurate. CRL and University of Missouri, Toxicology labs were also contacted to inquire about the pH readings that they found within the blind specimens they received. Toxicology screened the specimen on the analyzer with a pH of 6.5, and then put the specimen on a pH meter providing a pH of 8.6. CRL's analyzer presented a result of 6.9 pH. On 8/23/2012, Callaway contacted the blind specimen provider, Protox Services, regarding the high pH reading resulting in an invalid result in the Quest specimen. Protox reported no issues with that lot # of blind specimen, however the blind specimen provider was concerned that the pH was reading that high in a specimen with a creatinine level <0.5 mg/dL and a specific gravity of 1.0003. Upon receipt of this information, on 8/23/2012, Callaway's MRO requested that Quest test the Bottle B specimen to see if consistent results were achieved through a second screening. The investigation report from Quest was received by Callaway on 9/05/12 with the following information. On the original blind specimen, the pH meter initial reading of the specimen was 9.49; when a confirmation was done on the pH Meter on 08/16/12 the result was reported with a pH of 9.68. The testing of the bottle B specimen yielded a creatinine level of 0.1 mg/dL, sp. Gr. 1.0004 and a pH meter reading of 8.35. The pH reading for Bottle B did not meet the criteria of ≥ 9 . The Quest Investigation report is attached.

The Director, Laboratory Operation at Quest was contacted by Callaway FFD Staff by phone on 09-06-12 to discuss the results of the investigation report. The Lab Director at Quest was concerned that the pH in this specimen was unstable and suggested that the blind specimen provider be contacted. Quest was concerned that a blind specimen with such a low ionic strength presented an unstable pH level and that this issue could be repeated. Quest suggested that the blind provider consider adding a buffer to these specimens to stabilize the pH. Callaway FFD Personnel contacted the blind specimen provider to provide the results of the Quest investigation and to inquire about the pH. The blind specimen provider reviewed the last four pH readings provided by the HHS lab that certifies the blind specimens. The results were as follows: 6.8, 6.9, 7.3, and 8.5. Protox then checked a sample of the blind lot on a pH meter with a resulting pH reading of 9.

Callaway was contacted by the Protox Director at approximately 15:15 on 09-06-12. He reported that the blind specimen lot in question was made using tap water to create the substituted specimen. CRL was the testing laboratory for the certification of the blind samples and used a colorimetric screening method for pH and obtained a pH of 7. Protox requested that CRL provide a reading on a specimen that tested 7 by colorimetric screening and then use a meter to read pH. A meter reading of 9 was obtained. The provider requested that another lab check the pH from tap water in the area and both tested with a pH of 9 using a meter. By adding a small amount of buffer salt to the lot of substituted specimen, the pH level by meter was brought down to 7. Protox will continue to work with CRL to determine why the colorimetric and meter pH measurements are producing different results.

In summary, it appears that the low ionic content of the specimen provided by Protox is subject to labile pH readings that vary depending on reading by Analyzer or pH meter. Quest, in retesting, has found their analyzer to be consistent and accurate in their readings. There does seem to be some variance in each lab in reporting pH readings whether by analyzer or by pH meter. To be consistent and accurate when comparing results from each lab one needs to determine whether the method of measuring pH readings is the same. The above mentioned use of a buffer salt to the specimen should provide a stability to maintain a consistency in pH readings.



September 5, 2012

Dr. William P. Cravens
MRO Callaway Plant
P.O. Box 620
Fulton, MO 65251

RE: Specimen ID: 2887032
Accession #: 519507A

Dear Dr. Cravens:

This letter is in response to your request concerning the above referenced specimen. The specimen was received and tested at our Lenexa, KS, laboratory on 08/15/2012. The initial testing of this specimen was done in batch TXNRC 0815002. The creatinine result was < 2.0 mg/dL (0.1 mg/dL). The screening pH on the Olympus was 5.9. The standard operating procedure requires all specimens with creatinines < 5.0 mg/dL to have a pH meter and four decimal point refractometer test performed. The initial pH meter result was 9.49. A confirmation aliquot was tested on August 16, 2012 and the pH result was 9.68.

The initial test for a four decimal point refractometer was performed on August 18, 2012. The result was 1.0003. This aliquot was used for the confirmation creatinine which was 0.0 mg/dL. A confirmation specific gravity aliquot was tested on August 22, 2012 and the result was 1.0003


The specimen was reported on August 22, 2012 as substituted and invalid. The results were creatinine < 0.5 mg/dL, specific gravity 1.0003, and pH 9.6.

A letter was received from your office requesting an investigation. As part of that investigation, the laboratory tested bottle B. This specimen was given laboratory accession number 632577A and screened on August 24, 2012. The creatinine result was 0.0 mg/dL and the screening pH on the Olympus was 5.8. The pH meter result was 8.35, therefore it did not meet the invalid criteria of ≥ 9.0 . The initial four decimal point refractometer was 1.0003. The confirmation creatinine and specific gravity were performed on August 25, 2012. The results were creatinine 0.1 mg/dL and specific gravity 1.0004.

A review of the data indicates that the quality control specimens are within acceptable limits, the calibration data is within the appropriate time limit and standard operating procedures were followed.

Please do not hesitate to call if you have any questions or need additional information at 913-577-1828.

Sincerely,

A handwritten signature in black ink, appearing to read 'Barbara Rowland', written in a cursive style.

Barbara Rowland
Director, Laboratory Operations
Employer Solutions
Quest Diagnostics Incorporated
Lenexa, KS