Ameren MISSOURI

Callaway Plant

November 16, 2018

ULNRC-06471

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

10 CFR 26.719(c)(1)

Ladies and Gentlemen:

DOCKET NUMBER 50-483
CALLAWAY PLANT UNIT 1
UNION ELECTRIC CO.
RENEWED FACILITY OPERATING LICENSE NPF-30
SPECIMEN HANDLING ERROR

The enclosed report is submitted pursuant to 10 CFR 26.719(c)(1) in regard to an error that resulted in two donors' specimens being switched prior to testing at the laboratory utilized for Callaway Plant's Fitness for Duty program. The report describes the error that occurred as well as the corrective action taken.

No new commitments are identified in this correspondence, and none of the material in this report is considered proprietary by Ameren Missouri – Callaway Plant.

If you have any questions or require additional information, please contact Mrs. Amy Findley, Supervisor of Access Authorization and Fitness for Duty at 573-676-4435.

Sincerely,

Mark A. McLachlan
Sr. Director Plant Support

Enclosure

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Specimen Handling Error

On September 24, 2018, a Fitness for Duty (FFD) Coordinator at the Callaway Plant logged into the Clinical Reference Laboratory's (CRL) Oasis website to view FFD specimen results for samples that had previously been submitted for two donors. For each donor, A and B specimen bottles had been provided. The coordinator observed that the results were listed as "rejected for testing" due to the donors specimen bottles being switched. Specimens for both donors were recollected and sent to a different laboratory, Laboratory Corporation of America Holdings (LabCorp), for testing. No issues were identified in the results for the two donors.

Investigations took place at the Callaway Plant and CRL to determine the events that led to the switching of specimen bottles. The investigations led to conflicting conclusions. The CRL investigation report indicated that upon arrival, the accessioner identified a switch in the B specimen bottles for the two donors and that the accessioner's supervisor verified the bottle switch. The investigation report stated that no actions were taken that could have caused or contributed to the inadvertent switching of specimens.

The Callaway Plant investigation, completed on October 18, 2018, concluded that it is likely the specimen switch occurred at CRL. The collection process at the Callaway Plant only allows one collection to be performed at a time. The donor certifies that the A and B bottles contain the specimen provided by the donor, and the donor observes the chain of custody, including observing that the A and B specimen bottles are sealed in the tamper evident bag. In addition, in this case, one of the two donor's specimen was being monitored by another member of management that observed the process from beginning to end including the sealing of the tamper evident bag. No actions leading to the switch in specimen bottles could be confirmed.

Corrective Action:
The Callaway Plant has administratively suspended CRL as the primary laboratory for employee specimen testing. The CRL contract will be maintained (as a backup lab) until another certified laboratory can be qualified.

Reportability:
10 CFR 26.719 states in part, (c) *Drug and alcohol testing errors*. (1) Within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of quality control or actual specimens, or through the processing of reviews under § 26.39 and MRO reviews under § 26.185, as well as any other errors or matters that could adversely reflect on the integrity of the random selection or testing process, the licensee or other entity shall submit to the NRC a report of the incident and corrective actions taken or planned. If the error involves an HHS-certified laboratory, the NRC shall ensure that HHS is notified of the finding.

This report is submitted pursuant to 10 CFR 26.719(c)(1) on the basis that the noted switching of samples could adversely reflect on the integrity of the testing process.