



May 11, 2017

ULNRC-06371

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.
RENEWED FACILITY OPERATING LICENSE NPF-30
BLIND TEST SPECIMENS**

The enclosed report is submitted pursuant to 10CFR26.719(c)(1) in regard to an error or matter that adversely reflected on the integrity of the random selection or testing process associated with the Fitness for Duty program for Callaway Plant. The report describes the failure to include two specific drugs (or metabolites) in blind test specimens submitted to labs for testing, as well as the corrective actions taken. The late submittal of the report restores compliance with 10 CFR 26.719(c), as described in the attached report.

This letter does not contain new commitments.

If there are any questions, please contact Aaron Enloe at 573.676.4435.

Sincerely,

Mark A. McLachlan
Sr. Director Plant Support

Enclosure

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Blind Test Specimen Issue

In June 2016, the Nuclear Oversight department at Callaway conducted an audit of Callaway's Fitness for Duty (FFD) program. It was identified from the audit that, over a period of time, Callaway had not been submitting quarterly blind specimens for all of the drug metabolites required to be tested under Callaway's FFD program to the contracted HHS laboratories. This is contrary to the requirements of 10 CFR 26.168(b), "Blind performance testing." Specifically, no blind performance specimens containing 6- Acetylmorphine (6-AM) or Codeine had been submitted since the 3rd quarter of 2014. A corrective action document was generated to document and evaluate the deficiency.

Callaway's interpretation of the regulation allowed sending blind specimens by the drug class vice each individual drug. This interpretation carried through to procedures and forms used in the FFD program. It appears the blind sampling program, as described in its administrative procedure, was never directly compared to the regulation wording.

Corrective Actions:

The blind specimen provider, at that time, was contacted to discuss the availability of all opiate types required. That provider was unable to supply specimens for all of the required drug metabolites. A new blind specimen provider (Elsohly laboratories) was acquired who was able to meet the regulatory requirements.

The plant procedure for blind performance testing/sampling and associated forms were revised to ensure all drug metabolites included under the opiate and amphetamine classes are sent to the HHS laboratories as required. The revised procedure changes, applicable forms changes, and blind submittal process changes were reviewed with all FFD coordinators, medical staff, and FFD management.

Reportability:

At the time the issue was documented in a corrective action document, it was evaluated for reportability per 10 CFR 26.719(b), (c), and (d). It was concluded that the issue did not meet the reportability requirements under (b) significant FFD policy violations or programmatic failures or (c) drug and alcohol testing errors. It was considered a program weakness under (d) for which the licensee is required to document, trend, and correct the weakness in its corrective action program.

During a recent NRC inspection of the Fitness for Duty program, the inspector identified that the situation described above, with respect to not submitting blind test specimens for each of the drugs that are required to be tested, should have been reported to the NRC per 10 CFR 26.719(c)(1).

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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 ... 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. ..."

The inspector determined that the situation could adversely reflect on the integrity of the random selection or testing process. Consequently, a report required per 10 CFR 26.719(c) should have been submitted following the June 2016 audit of Callaway's FFD program. However, in light of the NRC inspector's recent determination, this report is being submitted now.

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