Nebraska Public Power District

COOPER NUCLEAR STATION
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NSD931200
December 27, 1993

U. S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D. C. 20555

Gentlemen:

Subject: Report of Fitness-For-Duty False Positive Test Result
Cooper Nuclear Station, NRC Docket 50-298, DPR-46

The Nebraska Public Power District (District) hereby provides a report concerning its investigation into a false positive drug test result. The false positive test was identified during the appeal process initiated by the affected District contractor as the result of the initial positive drug test finding. This report was requested by Mr. Loren Bush (NRC) during recent discussions with District personnel.

10 CFR 26 Appendix A requires the prompt reporting of false positive test results occurring during the administration of a licensee's Blind Performance Testing program. 10 CFR 26 Appendix A provides no guidance regarding the reporting of an actual false positive drug test result. Notwithstanding the absence of requirements to report this event, the NRC Staff requested the District to submit a report of the event to determine possible generic significance, and possibly, for referral to National Institute of Drug Abuse (NIDA) for further evaluation.

Accordingly, enclosed is a report of the District's evaluation of the false positive event. It should be noted that this "false positive" drug test result did not occur as a consequence of laboratory error; rather, as a result of a series of events leading to the District's contractor failure to specify and the Medical Review Officer's (MRO's) failure to identify over-the-counter medication apparently causing the positive test results. The enclosed evaluation was performed by the District's Quality Assurance Department. Please note that the recommendations provided therein are still under evaluation. Additionally, enclosed are copies of news updates provided by the District's testing laboratory to inform MRO's of various possibilities for positive drug test results based on the legal consumption of various over-the-counter and prescription drugs.

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Please contact me if you have any questions, or require any additional information.

Sincerely,

G. R. Horn
Vice President - Nuclear

Enclosures

cc: NRC Regional Administrator
Region IV
Arlington, TX

NRC Resident Inspector
Cooper Nuclear Station

E1-0387

NEBRASKA PUBLIC POWER DISTRICT

QAD930710

Date September 21, 1993

To V. L. Wolstennolm

FOR INTER-DISTRICT BUSINESS ONLY

From D. R. Robinson

Subject **Independent Evaluation of False Positive Fitness For Duty Report**

The purpose of the subject evaluation was to determine the circumstances which led to the false positive report and identify any recommended changes to the program or processes to prevent future occurrences. The evaluation was performed during the September 16-20 period of time and included review of the applicable files held by NPPD Corporate Security, Clinical Reference Laboratory and the Medical Review Officers (MROs). Interviews were also conducted with the MROs, CRL personnel and Corporate Security personnel.

My conclusion concerning this incident is that everyone involved acted in accordance with established District programs and procedures throughout and that everyone involved made all decisions in good faith using the information available to them at the time.

As a result of this evaluation the following recommendations are provided for consideration.

1. The District's Fitness For Duty Program process for testing hydrated (dilute) samples be reevaluated. Specifically, it is recommended that Corporate Security management, NPPD legal personnel, and the MROs evaluate the policy for retesting hydrated samples. It appears that the District's program requirements are very conservative when compared to other utilities and go well beyond current regulatory requirements. This review should also address reporting of test results as positive for samples identified as containing levels of drugs which are below the established cut-off levels.

2. The District's policy should be changed to require type testing of samples found to be positive for amphetamines/methamphetamine. This would assure all possible sources of the drug are know to the Medical Review Officers during their review and evaluation of test results.

EVALUATION DETAILS

Through interviews and record reviews the following sequence of events was established.

In late July of 1993 the individual involved provided a specimen as a result of being selected for random testing. The consent form for this specimen indicated that the subject was taking MAPOP (a generic form of Tylenol available over the counter), Tylenol, Advil, and PSEDDO 61 P51 caplets for Zephrez LA (prescription). This specimen screened negative for the District's panel of drugs, but was identified as being outside acceptable ranges for Specific Gravity and Creatinine. Both results were below acceptance criteria limits. These results indicate that the sample was dilute from the subject ingesting larger than normal amounts of fluids, thus diluting the sample through fluid intake. As a result, and in accordance with FFD Program requirements, the MRO directed Corporate Security to obtain a second specimen.

In late July of 1993 the second specimen was collected. The consent form for this specimen listed the same drugs as those identified on the previous specimen. This specimen also

screened negative but again tested low for Creatinine. The MRO again directed a retest based on the low Creatinine level identified.

In early August of 1993 the third specimen was collected. As required by the FFD program, this specimen was consider a for-cause test and, therefore, was a witnessed collection. In addition to the previously listed drugs, the subject also listed Ventolin Z-max, Pheneygan E Codeine, and PS ERCB 61 P51 caplets (all are prescription medications). MAPOP was no longer listed as being taken. This specimen also screened negative and again came up as low for both Specific Gravity and Creatinine. Based on the third consecutive sample indicating hydration, and in accordance with the FFD Program requirements, the MRO directed CRL to perform a Gas Chromatography/ Mass Spectrography test of all three samples to identify any presence of drugs in the District's panel of drugs.

The first specimen was subjected to the GC/MS. This test identified detectable levels of Levorphanol, which is a drug in the opiate family. This result was reported to the MRO.

The second specimen, when subjected to GC/MS testing, was found to contain detectable levels of amphetamines and methamphetamine (at approximately 67 and 7 times below established cut-off levels, respectively). These results were also reported to the MRO.

The third specimen tested negative for all drugs at any level when subjected to GC/MS testing. It should be noted that the GC/MS test for this specimen was completed and reported after the MRO had reported the first two results to Corporate Security as positive.

After the required interview with the subject by the MRO, the test results were reported to Corporate Security as being confirmed positive tests. Corporate Security notified Site Security and the remainder of the process apparently proceeded according to established program requirements. This evaluation did not include any of that portion of this incident. The MRO indicated that there was no medical or other information available at that time which would support a medically valid explanation for the Levorphanol in the subject's specimen.

Following appeal by the subject, a sequence of events took place which revealed additional information which eventually led to a reversal of the original decision and the test results were changed to negative. Some of these events included the following.

The testing laboratory, through discussions with the MRO and their own action determined that a metabolite of dextromethorphan has an almost identical "footprint" (it appears to be identical in a graphical representation) when subjected to GC/MS testing as does that of Levorphenol. Through additional testing of the specimens, they confirmed the presence of dextromethorphan in the subjects sample. Discussions with personnel at the lab, the MROs and District Corporate security personnel identified that dextromethorphan is a common ingredient in over the counter liquid cold medications. The MRO identified that in talking to the subject that the subject had been taking such a medication but had failed to list it on the consent form. Interviews with CRL personnel determined that the virtually matching footprint is apparently new information. Based on the commonality of dextromethorphan

in over the counter cold medications and the limited use of Levorphenol, they no longer plan to report its presence in GC/MS results. The lab director also indicated, in a letter to the MRO, that they plan to pursue this information further and perhaps publish a paper documenting their findings.

Regarding the amphetamine/methamphetamine presence identified in the second sample, two factors are considered significant. First, none of the drugs listed on the sample collection consent form would be consistent with the presence of amphetamine/methamphetamine. Discussion with lab personnel indicated that a follow -up test on this sample, which was not requested but ordered in error, identified that the drugs present in the sample were of the L-type. L-type amphetamines are readily available in non-prescription form through decongestant inhalers. Consideration should be given to changing our program to conduct this confirmatory test for any specimen which tests positive for these drugs. It must also be recognized that the levels detected in the specimen were well below the established cut-off level of 1000 nanograms per milliliter. The amphetamine presence was 65.78 times below that cut-off and the methamphetamine detected was 7.31 times below that level. In the interviews with the MROs it was learned that for hydrated samples, they have not established quantitative guidelines for making a positive determination. They did indicate that the detected levels would not present a linear relationship to specific gravity or Creatinine levels due to the different ways and times that different individuals metabolize ingested substances. They indicated that it has been their practice to make a positive determination for any detectable levels of drugs found in hydrated samples unless they can be explained medically. It appears that this policy is valid for the presence of illegal drugs such as marijuana and cocaine, but the policy should perhaps be reconsidered for drugs available through prescription drugs.

While complete statistical data is not available, interviews determined that several employees routinely provided hydrated samples because of their higher than normal daily fluid intake. In fact, the subject involved in this incident has a history of providing hydrated samples due to the fact that the subject apparently routinely drinks twenty or more cans of soda daily. Any revision of the policy should also address this matter to eliminate unnecessary testing and associated expenses.

Should you have any questions concerning the evaluation activities performed, the conclusions reached or the recommendations provided, please advise me.

D. R. Robinson
Quality Assurance Manager
Columbus General Office

DRR/lbw

CRL NEWS UPDATE

TO: Medical Review Officer
Human Resource Managers, etc.

FROM: Mark Magee
Vice President Laboratory Operation

DATE: July 26, 1993

Effective immediately Clinical Reference Laboratory will print the following message on all opiate positives.

> "Morphine positive samples may be the result of codeine, morphine use or abuse, or heroin abuse. However, it has been shown that ingestion of products containing poppy seeds may cause a urine sample to test positive for morphine."

In order to confirm heroin, a 6-monacetyl/morphine (6 MAM) test may be requested, at an additional charge. Poppy seeds contain trace amounts of morphine and codeine, so a donor who consumes poppy seed rolls may produce urine positive for morphine. The metabolite 6-monacetyl/morphine exists in the urine only as a result of heroin use. However, the absence of 6-MAM is not conclusive for the abstinence of heroin.

In addition Methamphetamine positive reports will include the following.

> "Methamphetamine positive samples may be the result of over the counter medications, prescription medication, and/or substance abuse."

Should the donor indicate use of an over the counter medication such as Vicks Inhaler, an additional test, dextro and levo isomers (D & L isomers) may be requested to determine if the medication may have caused a methamphetamine positive. This test will be at an additional charge, if requested.

We are providing these messages to assist you in making a determination of a positive result. CRL cannot control and takes no responsibility for the inappropriate use of any test results by an employer or information regarding an individual's prescription/medication history. CRL encourages its clients to use a Medical Review Officer (MRO) to evaluate and communicate test results. In view of laws like the Americans with Disabilities Act, employers should carefully consider whether prescription/medication information and testing results are being handled in an appropriate manner.

If you have any questions do not hesitate to contact me or your Account Executive.

CRL NEWS UPDATE

TO: Medical Review Officers
Human Resource Managers, etc.

FROM: Mark E. Magee
Vice President Laboratory Operations, CRL

DATE: August 24, 1993

Effective immediately, Clinical Reference Laboratory will print messages on positive reports relating to possible over-the-counter medications, prescription medication and/or substance abuse. These messages will appear on positive reports for barbiturates, benzodiazepines, methadone, and propoxyphene. Please see the following messages.

- *Barbiturate* positive reports will include the following message:

  "Barbiturate positive samples may be the result of over-the-counter medications, prescription medication, and/or substance abuse."

- *Benzodiazepine* positive reports will include the following message:

  "Benzodiazepine positive samples may be the result of prescription medication and/or substance abuse."

- *Methadone* positive reports will include the following message:

  "Methadone positive samples may be the result of prescription medication and/or substance abuse."

- *Propoxyphene* positive reports will include the following message:

  "Propoxyphene positive samples may be the result of prescription medication and/or substance abuse."

- In addition, the following messages will appear on positive *cannabinoid* reports:

  "Cannabinoid positive samples may be the result of synthetic drugs used in chemotherapy post-treatment for nausea and vomiting and/or substance abuse."

The National Cancer Institute has listed dronabinol and nabilone, synthetic drugs similar to marijuana, as acceptable agents in chemotherapy post-treatment for nausea and vomiting.

- *Cocaine* may be utilized by the medical profession as a local anesthetic during nasal surgery. For this reason, the following message will appear on positive cocaine reports:

  "Cocaine positive samples may result from usage as a local anesthetic for nasal surgery and/or substance abuse."

The above messages are intended to serve as reminders that one must always validate the individual's medication claims by viewing the prescription. Although marijuana and cocaine are seldom used as medication, such claims should be verified by their physician or prescription receipt.