

Nebraska Public Power District

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NLS9000497
November 5, 1990

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

Gentlemen:

Subject: Report of Unsatisfactory Blind Drug Performance Testing Results
Cooper Nuclear Station
NRC Docket No. 50-298, DPR-46

In accordance with the requirements of 10 CFR 26, attached are the investigation reports concerning two unsatisfactory blind performance test results experienced during administration of the Nebraska Public Power District's drug-testing laboratory quality control program.

Attachment 1 discusses a false positive and a false negative test result which resulted from the testing of a single batch. Attachment 2 discusses a separate false negative test result.

In certain cases, 10 CFR 26 Appendix A requires licensees to submit to the NRC a report of its investigation findings including the corrective actions taken by the laboratory. As discussed in the attachments, the District has determined that the false test results occurred due to factors outside of the laboratory's control; therefore, no corrective actions on the part of the testing laboratory were deemed necessary.

Please call me if you have any questions.

Sincerely,



G. A. Trevors
Senior Staff Advisor
Nuclear Power Group

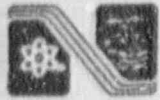
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Attachment

cc: Regional Administrator
USNRC - Region IV

NRC Senior Resident Inspector
Cooper Nuclear Station

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Nebraska Public Power District

COOPER NUCLEAR STATION
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Corporate Security Department
Security Services Office
Cooper Nuclear Station

REPORT OF INVESTIGATION

Prepared By: J. R. Bittner Date: July 10, 1990
Preparing Office: Cooper Nuclear Station

SUBJECT: Cooper Nuclear Station, June-July 1990, reported false positive test result for blind performance specimen #0139072.

STATUS: Closed. Referred to the Manager, Corporate Security, for action (10CFR26).

APPROVED BY:

A handwritten signature in cursive script, reading "James R. Bittner".
J. R. Bittner
Security Services Supervisor

Distribution:

Corporate Security Manager

CAUTION: This file contains sensitive personnel reliability information and should be handled on a confidential need-to-know basis.

1. This investigation was predicated upon information received through the District's Quality Assurance (QA) testing program that a blind performance test had been identified falsely as a positive test result. Based on this information, on July 5, 1990, a formal investigation was initiated to ascertain if the false positive test result was either a result of a technical and/or administrative error at the testing laboratory or the collection facility.
2. On July 6, 1990, a review of the Corporate Security Department's QA blind sample performance data was conducted by J. R. Bittner, Security Services Supervisor. The following is a recapitulation of this review.
 - (a) On March 8, 1990, Bensinger DuPont and Associates, the District's contract vendor for QA blind performance samples, provided the District with ten (10) blind urine samples.
 - (b) On March 20, 1990, Kit #360 was received and ten blind performance samples were inspected and processed by J. R. Bittner. After processing each sample individually, all ten were shipped via Airborne Courier Service to the Nichols Institute for Substance Abuse Testing (NISAT) in San Diego, California.
 - (c) On March 21, 1990, NISAT received and tested the ten blind performance specimens. Of the ten received and tested, eight were tested with two reported as being quantity insufficient to test. Specifically, this meant that the specimen prepared by the Contractor did not meet the minimum testing requirements of 60 ml.
 - (d) On March 24, 1990, the aforementioned test results were forwarded to the District's Medical Review Officer (MRO) for review and final evaluation. After reviewing the results, a formal request for quantitative test results was requested for the six specimens identified as positive for controlled substances.
 - (e) On May 10, 1990, Nina Green, Operations Manager, NISAT, responded to the MRO's request for quantitative test results. These results included the specimen that was incorrectly reported as a positive result.
 - (f) On June 6, 1990, Jeff Goldman, Operations Manager, Bensinger DuPont and Associates (BDA), provided a summary of findings concerning the false positive test result. In Goldman's analysis, he provided the following:

Summary of False Positive

- Specimen 9, Kit 360 (SS#649-85-9421)--False Positive--was spiked with methadone (which is not being tested for at Nichols Institute) but reported as propoxyphene.

- Specimen 8, Kit 360 (SS#449-74-5678)--False Negative--was spiked with propoxyphene and reported as blank. The propoxyphene was spiked in the following amounts, confirmed by GCMS:

Preparation Lab	Date	Confirmation Lab	Date	Date Released
872 ng/ml	3/1/90	762 ng/ml	3/8/90	3/20/90

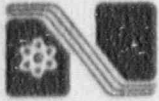
Conclusion:

BDA's investigation into the causes of the false positive in Kit #360 was inconclusive. The drugs were spiked at an amount which should have been accurately read by NISAT and specimens from the same spiked batches were read correctly by other laboratories. However, one explanation could be that specimens 8 and 9 were inadvertently switched with one another, either when poured into Nebraska Public Power District's containers, or at the laboratory accession area.

- (g) On June 29, 1990, based on the recommendation of BDA, specimen 9 was retested. The results were consistent with the initial results and identified a positive test result for propoxyphene.
3. As a result of findings by BDA and the follow-up test results by NISAT, a comprehensive review of the procedures used by the CSD to process QA blind performance specimens was accomplished. The results are as follows:
- (a) During the initial implementation of the blind performance testing program (January - March 1990), the CSD was operating under the constraints of a maintenance outage. Because of the increased work load of an outage, the development of a formal and standardized procedure to process blind performance specimens was delayed.
 - (b) No formal or standardized procedure was in place during the time period in which the questioned specimen was processed. Because no standard procedure existed and the time required to process blind samples during a critical manpower processing period, blind specimens were often times processed in production line fashion. This meant several kits may have been processed as a batch using two collectors; one to transfer the urine from the shipping containers to specimen containers and one to complete the required paperwork. This approach, while obviously weak from a systematic approach, was effective during critical manpower stages of the outage. It did, however, create the potential for administrative error by inadvertent switching of paperwork and/or specimens.
 - (c) At the conclusion of the outage in May of 1990, a formal procedure, Security Services Office Procedure 2.14; Handling Quality Assurance Blind Specimens, was developed. This procedure established a

step-by-step process for completing blind performance specimens and eliminated the potential for inadvertent specimen switching by removing the production line approach to processing the specimens.

STATUS: Closed



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Corporate Security Department
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REPORT OF INVESTIGATION

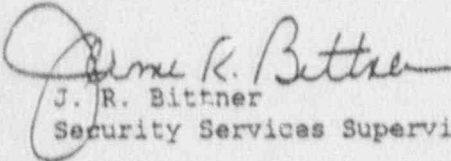
Prepared By: JaNay Oestmann
Preparing Office: Cooper Nuclear Station

Date: July 24, 1990

SUBJECT: Cooper Nuclear Station; June - July 1990, Reported false negative tests for blind performance specimens in kits 258 and 219.

STATUS: Closed. No further follow-up required.

APPROVED BY:


J. R. Bittner
Security Services Supervisor

Distribution:

Corporate Security Manager

CAUTION: This file contains sensitive personnel reliability information and should be handled on a confidential need-to-know basis.

DETAILS:

1. This investigation was predicated upon information received through the District's Quality Assurance (QA) Testing Program that two separate blind performance tests had been identified falsely as a negative test results. The test numbers in reference to this report were DOT 0166625 from kit 258 and DOT 0124986 from kit 219. Based on this, an inquiry was conducted to follow up on the incorrect laboratory results and to close the Corporate Security Department's Quality Assurance file concerning these tests.
2. On July 23, 1990, a review of the Corporate Security Department's QA blind sample performance data was conducted by J. M. Oestmann, Lead Fitness For Duty Analyst. Oestmann contacted Mr. Jeff Goldman, Operations Manager of Bonsinger, DuPont and Associates, in reference to the samples identified as false negative, who advised that the substance that should have been identified in kits 219 and 258 was Cocaine. Goldman also remarked that the substance was highly unstable and susceptible to rapid deterioration and that it was not uncommon for spiked specimens to be tested and reported as false negatives. Goldman assured Oestmann that the NPPD's contract laboratory's false negative rate for this substance was well below the over all industry standard of 20-30% and that no further investigative activity was warranted.

STATUS: Closed