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SUBJECT: Provides results of investigation of unsatisfactory performance testing result in fitness for duty program.

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May 11, 1990

PG&E Letter No. DCL-90-125

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

Re: Docket No. 50-275, OL-DPR-80
Docket No. 50-323, OL-DPR-82
Diablo Canyon Units 1 and 2
10 CFR 26, Appendix A Notification

Gentlemen:

Pursuant to 10 CFR 26, Appendix A, Section 2.8(e)(4), PG&E is submitting the following results of an investigation of an unsatisfactory performance testing result in the Fitness for Duty (FFD) Program.

On April 1, 1990, during a review of laboratory blind specimen test results, it was discovered that five "spiked" blinds were reported by PG&E's contract DHHS-certified laboratory as negative (false negatives). The following summary provides the sequence of events.

April 2, 1990

At 0800 hours, a representative of the vendor providing certified blind specimens was contacted by the DCPP FFD Supervisor to ascertain what the test results for the five referenced spiked blinds should have indicated. He stated that the specimens should have shown a "positive" for cocaine (benzoylecgonine). He was then asked to provide the following information:

- When were the blinds in question prepared?
- What level of benzoylecgonine was the specimen certified to contain?
- How long were the specimens stored at the laboratory (American Bio-Test) before they were shipped to PG&E?
- How were the specimens stored (frozen/room temperature)?
- Were all five specimens obtained from the same batch?
- What were the test results from the second NIDA certified laboratory?

The medical representative indicated that he would respond to the above questions as quickly as possible.

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NOTE: PG&E's FFD Program utilizes NRC-recommended cutoff levels for all five substances. A blind specimen is a specimen certified to contain a drug metabolite. Blind specimens are introduced to the DHHS laboratory to monitor test result proficiency. To date, 580 blind specimens have been submitted by PG&E, of which 120 were certified to contain a drug metabolite. Spiked blind specimens are produced at 40% over the NRC minimum threshold cutoffs.

At 0805 hours, the PG&E FFD Supervisor contacted the director of CompuChem Laboratories - Western Division (PG&E's DHHS-certified laboratory) and informed him of the situation.

At 0830 hours, the director of CompuChem contacted PG&E's FFD Supervisor and stated that specimens 513-13-9916 and 271-14-3932 had already been dumped. (CompuChem's SOP is to discard specimens which report out as "negative" within 2 weeks.) The director did state that all five specimens reported out as "negatives." The director stated that specimens 349-14-8021, 575-14-8216, and 318-13-7550 would be re-tested to ascertain if the specimens contain "any" cocaine (benzoylecgonine).

April 4, 1990

At 1030 hours, the director of CompuChem contacted PG&E's FFD Supervisor and informed him of the test results of the specimens (enclosed).

April 16, 1990

At 0800 hours, the medical representative of the blind provider provided the following information.

1. Specimens 513-13-9916 and 271-14-3932 were produced from Batch 1990-3 and were prepared on February 1, 1990. They were stored frozen until shipment on February 22, 1990. They were certified at 485 ng/ml and confirmed by "the second" NIDA reference lab on February 28, 1990 at 482 ng/ml.

2. Specimens 349-14-8021, 575-15-8216, and 318-13-7550 were produced from Batch 1990-5 and were prepared on February 28, 1990. They were stored frozen until shipment on March 15, 1990. They were certified at 924 ng/ml and confirmed by "the second" NIDA reference lab on April 10, 1990 at 401 ng/ml.

The enclosed report reflects the opinion of the director of CompuChem regarding the cause of the false negatives. The director attributed the incorrect test results to a degradation of benzoylecgonine due to specimen exposure to undesirable time (duration)/storage temperatures and a resulting pH change in the specimens. Combined cyclic effects of time/temperature-induced specimen degradation and associated pH changes continue to promote and sustain the degradation process. The medical representative of the blind (specimen) provider concurred with this finding. The investigation was concluded on April 16, 1990. The laboratory reports were submitted to PG&E as confidential information and PG&E requests that they be treated confidentially in accordance with 10 CFR 2.790.

Although blind specimens are not refrigerated during transit via approved courier, blind specimens are now refrigerated at DCPP upon receipt and shipped to PG&E's DHHS-certified laboratory within 24 hours to reduce the likelihood of storage time/temperature-induced degradation.

Kindly acknowledge receipt of this material on the enclosed copy of this letter and return it in the enclosed addressed envelope.

Sincerely,

B. L. Depew for

J. D. Shiffer

cc: R. F. Locke
J. B. Martin
R. J. McDevitt
CCC (w/o enc.)
GONPRAC (w/o enc.)
RMS

Enclosure

3133S/0083K/KAH/2200