CENTERIOR ENERGY

Donald C. Shelton
Vice President - Nuclear
Davis-Besse

300 Madison Avenue
Toledo, OH 43652-0001
(419) 249-2300

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United States Nuclear Regulatory Commission
Document Control Desk
Washington, D. C. 20555

Subject: Fitness-For-Duty: Unsatisfactory Performance Test Result

Gentlemen:

On April 17, 1991, it was determined by the Medical Review Officer (MRO) that Southgate Medical Laboratory had inaccurately reported results on a confirmed positive Quality Assurance (QA) sample containing benzoylecgonine (cocaine) as negative. The QA sample was sent to the laboratory by Toledo Edison as a blind performance test sample as part of the Fitness-For-Duty (FFD) program. Subsequent retesting of the sample by the laboratory and back-up laboratory confirmed the blind to be positive.

The attached report is being submitted in accordance with 10CFR26, Appendix A, Subpart B, Section 2.8(e)(4).

A detailed investigation report is available onsite for review. Should you have any questions, please call Mr. R. W. Schrauder, Manager - Nuclear Licensing, at (419) 249-2366.

Very truly yours,

for DC Shelton

GAB/ach

Attachment

cc: P. M. Byron, NRC Region III, DB-1 Senior Resident Inspector
A. B. Davis, Regional Administrator, NRC Region III
J. B. Hopkins, NRC/NRR DB-1 Senior Project Manager
Utility Radiological Safety Review Board

Toledo Edison Report

on

Inaccurately Reported Results

of a

Confirmed Positive Sample

May, 1991

BACKGROUND:

On April 17, 1991, it was determined by the Medical Review Officer (MRO) that Southgate Medical Laboratory had inaccurately reported results on a confirmed positive Quality Assurance (QA) sample containing benzoylecgonine (cocaine) as negative. The QA sample was sent to the laboratory by Toledo Edison as a blind performance test sample as part of the Fitness-For-Duty (FFD) program. Subsequent retesting of the sample by the laboratory and back-up laboratory confirmed the blind to be positive.

DISCUSSION:

On April 10, 1991, Toledo Edison submitted two (2) QA blind performance test samples containing benzoylecgonine (cocaine) as part of the FFD program. The samples were extracted from the same certified pool and submitted for testing. On April 11, 1991, the Toledo Edison Health Center received non-certified results from the testing laboratory, which indicated that one of the blind samples was negative. The MRO reviewed the certified data on April 17, 1991 and confirmed that one of the blind samples was falsely reported as negative.

On April 17, 1991, the laboratory received notification from the MRO of reporting a false negative result. Subsequent to the notification, the laboratory repeated the test using the Emit Screen (Technicon Chem 1 and Technicon RA-XT Systems) which then indicated the blind sample to be positive. Additionally, confirmation using the Gas Chromatograph Mass Spectrometry indicated a positive level for benzoylecgonine of 1068 ng/ml for this sample.

Toledo Edison sent personnel to Southgate Medical Laboratory to further investigate the discrepancy and review the testing process. Additionally, Toledo Edison personnel obtained the remaining sample for back-up laboratory testing. On May 6, 1991, Toledo Edison's back-up laboratory, Southbend Medical Laboratory, reported the sample as positive.

The results of the initial Emit Screen for the cocaine metabolite assay were as follows: The cutoff calibrator had a mASB of 82.2, the negative Quality Control pool 68.5 mASB, while the QA sample in question had a reading of 71.1 mASB. The QA sample was above the laboratory negative control number, but was less than the value for the cut off calibrator and was administratively considered to be negative. The calibrations and subsequent quality control pools were within established limits, thus indicating that the instrument was operating within established specifications.

During Toledo Edison's investigation, two (2) potential causes for the false negative test result were identified:

° The initial screening test on the blind samples were performed at Southgate on a Technicon Chem 1 System which replaced the Technicon RA-XT System in October 1990. Chem 1 system works with a smaller sample and less consumption of reagent. During the sample extraction process, it is possible that the system could have drawn air instead of fluid. This could have resulted from an air bubble in the aliquot or not ensuring adequate sample insertion into the cassette sample. This inadequate sampling would result in a false negative test result during the assay, or

° Possibility that the SYVA reagent failed to identify the positive emit based on its 99% accuracy.

Upon further reviev of the above causes, Toledo Edison determined the cause to be inconclusive. However, Southgate Medical Laboratory's investigation concludes that the SYVA cocaine assay claims a 99% confidence level when samples contained either no or benzoylecgonine is at least 750 ng/ml. Therefore, the false negative result that was reported for the specimen reflects the limitations that are inherent in the SYVA Emit assays.

CONCLUSION:

Davis-Besse and Perry Nuclear Power Stations use the same laboratory and MRO for their Fitness-For-Duty programs. The results of the investigation were shared with the Perry Nuclear Power Station. The potential causes will be assessed. The upcoming annual audit (tentatively scheduled for May 20-22, 1991) of the Southgate Medical Laboratory which will be performed by Perry QA Dept. The results of the audit will be reviewed by Toledo Edison and appropriate actions will be taken if deemed necessary. In addition, a supplement to this report will be provided if corrective action(s) is taken on this incident.