Douglas P. Ginsen
Assistant Vice President
and Manager - Nuclear Production

Detroit Edison

Fermi 2
6400 North Dixie Highway
Newport, Michigan 48166
(313) 586-5325

January 10, 1991
NRC-91-0001

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

Reference: Fermi 2
NRC Docket No. 50-341
NRC License No. NPF-43

Subject: Unsatisfactory Performance of Drug Testing

On September 18, 1990, Detroit Edison discovered that false negative results had been received in response to a blind performance specimen. Details of this event, the follow-up investigation and corrective actions are contained in the enclosed report of the investigation.

This report is being submitted in accordance with 10 CFR 26, Appendix A, 2.8(e)(4).

If there are any question regarding this report, please contact Robert R. Kelm Sr., Fermi 2 Fitness for Duty Program Manager, at (313) 586-4949, or John Louwers, Acting Supervisor of Security Compliance at (313) 586-4570.

Sincerely,

DPGinsen

Enclosure

cc: A. B. Davis
R. W. DeFayette
W. G. Rogers
G. Pirtle
J. F. Stang

A021
1/1

Detroit Edison Company
Nuclear Security Department
Report of Investigation

Date:	January 10, 1991
File Number:	90-0408
Period Covered:	October 21 through January 10, 1991
Subject:	MetPath Laboratory, 1355 Mittel Boulevard, Wooddale, Illinois 60191
Matter Under Investigation:	Unsatisfactory Performance of Drug Testing Laboratory 10CFR26, Appendix A, Section 2.8 (e)(4)

On October 21, 1990, the Nuclear Security Department, Enrico Fermi 2, Newport, Michigan, initiated an investigation of MetPath Laboratories, Wooddale, Ill. The investigation was in response to an audit performed on October 18, 1990, for Detroit Edison by Duo Research, Inc., 164 Conduit Street, Annapolis, Maryland, 21401, to review a possible false negative test of a blind specimen by Detroit Edison's Fitness For Duty contract laboratory, MetPath. The Duo Research audit reported that one Blind Performance Specimen was incorrectly reported as negative by MetPath laboratories in February, 1990 when in fact the specimen was positive for amphetamines. Detroit Edison routinely forwards blind specimens to MetPath to verify laboratory effectiveness and also meet the performance requirements of 10CFR26 Appendix A.

Detroit Edison contracts Duo Research, Inc., to provide blind performance specimens, to evaluate results of MetPath's ability to detect the drug panel at 10CFR26 Appendix A cut-off levels and to investigate any performance problems identified in the administration of the blind performance program. Dr. Robert E. Willette, President, Duo Research, Inc., detected a possible false negative result on a blind specimen. During a July, 1990 audit Dr. Willette was unable to immediately obtain the drug screening records pertaining to the possible false negative blind specimen. It was determined that the MetPath facility, under contract to Detroit Edison facility to analyze specimens, stores all records over two (2) months old at a records facility separate and distant from the laboratory. Dr. Willette requested that the documentation be recalled for his review. On October 18, 1990, Dr. Willette conducted a follow-up audit at MetPath laboratories to review the possible false negative result and supporting documentation. Dr. Willette concluded that the false negative result occurred when MetPath laboratory made an administrative error in the processing of the blind specimen. The blind specimen when analyzed was determined to be positive for amphetamines. However, it was treated as a negative specimen and disposed of instead of undergoing confirmatory testing as required. Dr. Willette classified the administrative error as unsatisfactory performance. Dr. Willette notified Detroit Edison on November 1, 1990, and an investigation was initiated.

On November 15, 1990, investigation by Detroit Edison determined that the MetPath Laboratory had been conducting two (2) immunoassay screens on specimens submitted for drug testing. Only one such test is required and Detroit Edison required that the Enzyme Multiplied Immunoassay Technique (EMIT) be used. The MetPath testing protocol utilized the two initial screens and was in effect during the period of January 1, 1990 - February 16, 1990 when the incident occurred. The dual initial immunoassay screens were conducted for amphetamines and tetrahydrocannabinol (THC) only. Amphetamines were tested at 300 and 1000 ng/ml and THC was tested at 50 and 100 ng/ml. All other drugs on the NIDA panel of drugs were tested at the NIDA specified cut-off level contained in 10CFR26 Appendix A. MetPath Laboratories had been performing both cut-off immunoassays prior to and during the Department of Health and Human Services (DHHS) certification. Prior to the implementation of 10CFR26, the testing protocol was approved during the certification process by DHHS and continued to be used for analysis of specimens when the Detroit Edison Company contracted MetPath to analyze specimens.

Additional investigation disclosed that during the period, January 1, 1990 - February 16, 1990, when the two immunoassays were being routinely conducted on specimens, MetPath laboratory technicians had to physically stop the automatic reporting function feature of the mainframe computer used to process specimens at DHHS cut-off levels to conduct a second immunoassay screen on a TDX analyzer machine. It was determined that the technician would then manually compare the results of both immunoassay screens against cut-off levels and only allow positive drug tests to go on for confirmatory testing. The drug testing data base would then be released to the automated function and a confirmatory Gas Chromatography/Mass Spectrometry (GC/MS) work load list would be generated. Specimens with results of "negative" would not go for GC/MS testing and are reported as negative. The blind specimen reported as false negative was screened by MetPath technicians on January 18, 1990. It was determined that the technician performing the drug screening failed to input the correct information in the drug testing mainframe which caused the blind specimen to be released as negative, when it was actually positive for amphetamines and should have undergone GC/MS confirmatory testing.

On February 16, 1990, MetPath Laboratories revised their drug testing procedures and eliminated the immunoassay screen with the lower cut-off level. It was determined that this corrective action was taken because of industry concerns regarding the conduct of two (2) immunoassay screens, not because of the possible false negative result which MetPath did not become aware of until July 11, 1990. The corrective actions taken by MetPath effectively eliminated the manual interface with the drug testing data base. The change in the drug testing protocol should prevent recurrence of a similar incident.

To insure that the administrative error that caused the false negative result on the blind performance specimen did not adversely affect any actual Detroit Edison specimens, screening results reported during the period of January 1, 1990 through February 16, 1990, were reviewed. One (1) actual Detroit Edison urine specimen was reported by MetPath as positive for cocaine. Drug screening documentation for this specimen was reviewed. It was verified that MetPath tested the specimen at National Institute of Drug Abuse (NIDA) cut-off level (300 ng/ml) for the immunoassay screen and NIDA cut-off level (150 ng/ml) for the GC/MS screen. Work load lists and batch load lists verified that the specimen was tested appropriately and confirmed as higher than the cut-off level and properly confirmed as positive.

Dr. Willette, when interviewed reported that it took approximately six (6) months to confirm the administrative error on the blind specimen because Duo Research utilizes NIDA guidance for determining satisfactory performance since there is no specific Nuclear Regulatory Commission (NRC) guidance. NIDA guidelines, which are utilized by Laboratories for DHHS certification identify acceptable performance testing which allows a 10% error rate in blind performance testing programs. NRC guidance is silent on this issue. This resulted in a delay in the review of the false negative results, since Duo Research considered the MetPath false negative result as within the 10% acceptable range in accordance with NIDA Standards. Dr. Willette noted that the practice he described is based on industry experience that false negatives usually occur due to the spiked blind specimen being at or immediately above the cut-off level.

On November 20, 1990, the Detroit Edison Medical Department decided to review documentation related to any false negative results reported by Duo Research, Inc., on a monthly basis. In order to identify future problems in a more timely fashion the Detroit Edison Medical Review Officer (MRO) or designate will request from MetPath, all drug testing documentation on false negative results and determine if the result is due to an administrative or technical error. If an administrative or technical error is suspected, the MRO or designate will initiate an investigation in accordance with the requirements of 10CFR26. This action will ensure that investigations of suspected problems are conducted in a timely manner consistent with expectations of Fermi 2, Fitness for Duty Program Manager.

Detroit Edison considers this matter resolved. This report of the investigation will be submitted to the Nuclear Regulatory Commission (NRC) in accordance with 10CFR26, Appendix A.

1/10/91

John R. Louwers
Acting Supervisor, Security Compliance

M. Rahmanian /s/ 1/10/91

Dr. M. Rahmanian
Director, Toxicology
MetPath Laboratory