

**Detroit Edison**



10 CFR 26.719(c)(1)

June 15, 2009  
NRC-09-0042

U. S. Nuclear Regulatory Commission  
Attention: Document Control Desk  
Washington D C 20555-0001

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

Subject: **Report on Blind Sample Test Reporting Error**

In accordance with 10 CFR 26.719(c)(1), the following report is being submitted regarding an error that occurred at a Health and Human Services (HHS) certified laboratory during the processing of a blind performance test sample. Investigation of this error was completed on June 9, 2009.

**Description of Incident:**

On April 10, 2009, a positive blind performance test sample was submitted by Fermi 2 to a HHS certified laboratory, South Bend Medical Foundation (SBMF), for testing in accordance with 10 CFR 26.168. The laboratory conducted initial testing of the specimen which returned with a presumptive positive indication for amphetamines. A confirmatory analysis was conducted and determined to be negative for amphetamines and methamphetamines. These results were certified by the HHS laboratory and reported as negative on April 13, 2009 to the Fermi 2 Medical Review Officer (MRO). The MRO informed SBMF that the sample reported as negative was a blind performance specimen that should have been reported as positive amphetamines. An investigation into the potential error was initiated by the laboratory.

**Laboratory Investigation:**

The laboratory conducted a review of the reported result and determined that the accession numbers of two samples analyzed at the same time may have been misread by laboratory personnel. On April 14, 2009, SBMF re-tested the samples and determined

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that this was the likely cause of the incident as the Fermi 2 blind sample tested positive for methamphetamines, and the second sample tested negative, as expected during the retest. A review of the label on the collection bottle indicated that the sample was properly labeled at the time it was received and during the accessioning process. On April 22, 2009, SBMF issued a report of its investigation which determined that the probable cause was the misidentification of the accession numbers by laboratory personnel.

**Corrective Actions:**

On April 13, 2009, SBMF alerted its staff of the possible error and advised them to exercise care and caution at all sample handling levels. In their April 22, 2009 report, SBMF reported that it would evaluate a computer assisted program that requires the specimen numbers be read using a bar code reader rather than relying solely on a human readable number. Validation of the proposed plan was to be completed on or before May 1, 2009.

On follow-up by the Fermi 2 Security staff, it was determined that the proposed corrective actions detailed in the SBMF report dated April 22, 2009 had not been achieved due to unforeseen delays. The implementation of a bar coding system was delayed to June 1, 2009. On June 9, 2009, SBMF confirmed to Fermi 2 that the bar coding system was in place. Upon confirmation that SBMF has implemented the corrective action, Fermi 2 considers this investigation completed.

Should you have any questions or require additional information, please contact me at (734) 586-5076.

Sincerely,



*for*

Rodney W. Johnson  
Manager, Nuclear Licensing

cc: NRC Project Manager  
NRC Resident Office  
Reactor Projects Chief, Branch 4, Region III  
Regional Administrator, Region III  
Supervisor, Electric Operators,  
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