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10CFR26

October 8, 1998
NRC-98-0137

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

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

Subject: Report of Unsatisfactory Laboratory Performance

In accordance with 10CFR26, Appendix A, Section 2.8(e)(4), enclosed are the investigative findings and corrective actions taken as a result of a false negative on a blind performance sample from our contracted laboratory.

If you have any questions regarding this report, please contact Mr. Joe Korte, Director Nuclear Security at (734)-586-1095.

Sincerely,

Enclosure

cc: Regional Administrator, USNRC Region III
B. L. Burgess
G. A. Harris
A. J. Kugler
M. V. Yudasz, Jr.
Region III
Wayne County Emergency Management Division

A022

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DEPARTMENT OF
FORENSIC TOXICOLOGY
PRENTISS JONES, JR., M.S., T.C.- NRCC
Technical Director
BETTE GAE DART
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PAUL F. MOORMAN
Technical Manager

September 15, 1998

Rich Fitzsimmons
Detroit Edison
Fermi 2
6400 North Dixie Hwy
Newport, Michigan 48166

Dear Mr. Fitzsimmons:

This document has been prepared in response to your notification to the South Bend Medical Foundation Department of Toxicology (SBMF) that a false negative result was reported for a blind performance sample you submitted to our laboratory. In responding to this issue, information contained herein has been chronologically organized to include the series of events that transpired prior to and subsequent to your notification.

Investigative Findings

August 5, 1998: Specimen Receipt/Specimen Accessioning

On August 5, 1998, the SBMF received a urine specimen for drugs of abuse testing identified as F0109684. Review of the accompanying Custody and Control Form (CCF) and inspection of the specimen and its tamper-evident seal suggested that the specimen was suitable for further forensic handling. This specimen was subsequently accessioned and assigned the laboratory accession number FT98-062712.

August 5, 1998: Specimen Aliquot created

To begin the testing process, a small portion of the original specimen (i.e., aliquot) was poured into a test tube labeled with the laboratory accession number FT98-062712. The aliquot was submitted for an initial screen via Enzyme Immunoassay (EIA) and assigned to EIA Run #4 of August 5, 1998. Also included in the run were fifty-five other donor aliquots, a SBMF Internal Blind aliquot, and the appropriate quality control samples as required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

August 6, 1998: Data Review

During the review of data generated for EIA Run #4, it was believed that an acceptable response had been achieved for the QC samples and the internal blind included in the run. The results from fifty-four donor samples and FT98-062712 were below the mandated Department of Health and Human Services (DHHS) cutoffs for the analytes tested and therefore considered "Negative".

August 6, 1998: Release of Negative Results

As per our standard operating protocol, no further testing was required for aliquots exhibiting EIA results less than the DHHS mandated cutoffs. The certifying scientist's decision was to electronically release all such results via the laboratory's computer system. A corresponding CCF was annotated "Negative" for each specimen with results below the expected cutoffs.

August 21, 1998: Query of results submitted for F0109684

On August 21, 1998 a call was placed to the SBMF from Rich Fitzsimmons. A request was made that we investigate the source of a possible false negative THC metabolite result for the FT98-062712.

August 21, 1998: Data review in response to query

Upon our re-review of EIA Run #4 it was determined that analysis of the run had been performed with masking* of the THC Metabolite 100 ng/mL channel.

*Masking:
This function is used to "turn off" a specific instrument channel or profile. Results are not generated from channels that are masked. Any channel that is masked remains inactivated until it is "unmasked".

Rationale for masking:
When performing an EIA screen, multiple panel types can be included in the run. An expeditious approach to EIA screening would be to perform the full complement of available tests on every specimen. However, it is a Federal violation to perform a test on a specimen not specified in the panel type (e.g., Analysis of THC metabolites at 50 ng/mL is not allowed for Detroit Edison specimens). To comply with such mandates we are required to mask channels on some EIA runs.

August 21, 1998: Error Notification

Telephone call placed to Rich Fitzsimmons from the SBMF. Mr. Fitzsimmons was informed of the error and advised of its source. He requested that a full investigation of the incident be started.

Corrective Action

August 21, 1998: Discussions with SBMF Toxicology staff

All involved parties were questioned and asked to give an account of all actions that may have precipitated the incident.

August 21, 1998: Interim Preventative Measures

To prevent a reoccurrence of the masking incident, each technologist assigned to work August 21, 22, or 23, 1998 was apprised of the error and cautioned to employ any means necessary to prevent the inadvertent masking of channels.

August 24, 1998: Interviews with SBMF Toxicology staff

The Technical Director (i.e., responsible person) interviewed each toxicology staff member individually. Items discussed during the interviews included, protocols to prevent similar errors, possible rationale for such errors, and the importance of thoroughness in the review process.

The consensus opinion held among those interviewed was a need for a non-manual way of detecting masked channels.

August 24 – September 4 1998: Investigation of Permanent Preventative Measures

To serve as a reminder, the issue of "masking" was discussed with the toxicology staff during a department meeting held August 27,1998.

The data generated from testing submitted from July 15, 1998 through August 31, 1998 was re-reviewed to determine if any EIA runs had been inadvertently masked. There were no incidents of masking in the data reviewed. To the best of our knowledge, the error in question was the first of its kind.

A protocol that would automatically alert the instrument operator of masking was tested.

September 10 1998: Introduction of New Protocol

A protocol for performing EIA screens that includes turning on an instrument alarm at the start of the run was introduced to the toxicology department staff at a department meeting held September 10, 1998. If any test is masked, an alarm will sound. This alarm will sound until the instrument operator verifies that all masking is correct. The instrument operator silences the alarm.

Summary

The troubleshooting strategies employed during the investigative review of testing performed for EIA run #4 of August 5, 1998 appear to be appropriate and resulted in a plausible explanation for the false negative result. Implementation of the suggested corrective actions should be sufficient to prevent a reoccurrence of this type of error.

We are cognizant of the magnitude of such errors and feel confident that the error was an inadvertent oversight rather than a purposeful attempt to release erroneous results or to put at risk the integrity of our drug-testing program.

If I can be of further assistance or if you have any questions regarding what is herein contained, please feel free to contact me.
Respectfully,

Prentiss Jones Jr. MS TC-NRCC
Technical Director Toxicology
South Bend Medical Foundation
Department of Toxicology