CATEGORY 1

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50-251 Turkey Point Plant, Unit 4, Florida Power and Light C 05000251
AUTH.NAME AUTHOR AFFILIATION
HOVEY,R.J. Florida Power & Light Co.
RECIP.NAME RECIPIENT AFFILIATION
Records Management Branch (Document Control Desk)

SUBJECT: Informs that on 990722,util determined blind specimen submitted to SmithKline Beecham Clinical Labs on 990721,was reported back with unsatisfactory results.Attachment 1 is summary of investigation of unsatisfactory performance.

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FPL

AUG 20 1999
L-99-173
10 CFR 26

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

Re: Turkey Point Units 3 and 4
Docket Nos. 50-250 and 50-251
Investigation of Unsatisfactory Performance

On July 22, 1999, Florida Power and Light Company (FPL) determined that a blind specimen submitted to SmithKline Beecham Clinical Laboratories on July 21, 1999, was reported back with unsatisfactory results.

Attachment 1 is a summary of the investigation of the unsatisfactory performance. Attachments 2 and 3 are the reports of the investigation by SmithKline Beecham Clinical Laboratories, as required by 10 CFR 26, Appendix A, Section 2.8(e)(4).

Should there be any questions or comments regarding this information, please contact us.

Very truly yours,

R. J. Hovey
Vice President
Turkey Point Plant

CLM

Attachment

cc: Regional Administrator, Region II, USNRC
Senior Resident Inspector, USNRC, Turkey Point Plant

1/1

A022

Subject: Investigation of Unsatisfactory Performance

Incident: On July 22, 1999, FPL determined that a blind specimen that had been submitted to SmithKline Beecham Clinical Laboratories on July 21, 1999, was reported back with unsatisfactory results (false negative). The blind specimen had been spiked with Amphetamine at the level of 1839 ng/ml and Methamphetamine at the level of 1860 ng/ml. The lab reported the specimen back as negative. The lab is located at Leesburg, Florida. This event was reported to the NRCOC as a 24 hour reportable event.

Requirements: In accordance with 10CFR Part 26, Appendix A 2.8(e)(4), "The licensee shall investigate, or refer to DHHS for investigation, any unsatisfactory performance testing result, and based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigation findings and the corrective actions taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management of the HHS-certified laboratory. Then the licensee shall send the document to the NRC as a report of unsatisfactory performance testing incident within 30 days. The NRC shall ensure notification of the finding to DHHS."

Investigation: The laboratory was contacted immediately after FPL determined that the results of the blind sample were unsatisfactory. The laboratory was requested to conduct an investigation into what had happened. On July 29, 1999, the laboratory reported back the resulted of their investigation. That report is included as Attachment 2.

On August 5, 1999, FPL Nuclear Assurance and Florida Power Corporation Quality Assurance inspectors conducted an audit at SmithKline Beecham Clinical Laboratories, Leesburg Florida, regarding the reporting of the negative result on the positive blind sample. The audit revealed that the changes had not yet been proceduralized; four corrective actions were agreed upon to close this investigation.

On August 11, 1999, documentation was received from SmithKline Beecham Clinical Laboratories to indicate that the corrective actions had been accomplished. Their letter of August 10, 1999 is included as Attachment 3.

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Attachment 2
Page 1 of 2

SmithKline Beecham
Clinical Laboratories
801 East Dixie Avenue
Leesburg, FL 34748
1(800) 342-9520, FAX (352) 728-0293

July 29, 1999

Gloria Garcia, MD
James E. Denton
Florida Power & Light Company
PO Box 14000
Juno Beach, FL 33408-0420

Re: Accn # 176095I, Req # 2406158, SS# 294-82-3998

Dear Dr. Garcia and Mr. Denton:

After reviewing the events, which led to the reporting of the above referenced specimen originally as all negative, the following determinations have been made:

A barcode read failure occurred during the initial screening of this sample.

This prevented the transfer of immunoassay data across the instrument/host computer interface.

The technologist manually indicated all negative results (in error). The raw UV absorbance data clearly indicates a positive response for Amphetamines.

The certifying scientist released the results based on the technologist's comments.

To insure that this error does not re-occur, the certifying scientist will double check the raw UV absorbance data any time a manual entry process is used to recover non-transferred data due to interface failures.

The re-analysis of this specimen gave the expected results.

I hope this clarifies matters for you. If you have any additional questions, please call me.

Sincerely Yours,

Michael S. Feldman, PhD
Director of ForensicToxicology

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Attachment 3
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SmithKline Beecham
Clinical Laboratories
801 East Dixie Avenue
Leesburg, FL 34748
1(800)342-9520, FAX (352)728-0293

August 10, 1999

Mr. James E. Denton, Security Department
Florida Power & Light Company, Turkey Point Nuclear Plant
9760 SW 344th Street
Florida City, FL 33035

RE: Response to blind QC audit, 8/5/99

Dear Mr. Denton:

On August 5th, Mr. Richard Abrams and Mr. Lane Hay, Jr. (Florida Power Corporation) conducted an investigation into the reporting of negative result on the positive blind specimen, as described in my July 29th letter to you. As a result of their visit, we agreed to take the following corrective actions to prevent the reoccurrence of this event:

1. Amend the Standard Operating Procedures (SOP), Volume I, Section 1 to require a certifying scientist to review any manual edits and/or data entry.

2. Amend the SOP, Volume I, Section 13 to require that a memo for the record which is created to correct an error that is discovered by our client must be reviewed by the Director.

3. Amend the SOP, Volume II, Section 1, to include a description of the manual edit process for recovering data lost to barcode errors.

4. Distribute a memo clarifying that the forensic correction procedure applies to all manual edits.

These corrective actions have been completed and I have enclosed copies of these actions for your review.

I hope these actions are acceptable. If you have any questions or concerns, please contact me.

Sincerely Yours,

Michael S. Feldman, PhD
Director of ForensicToxicology

Cc: R. Abrams
L. Hay, Jr.

II. Results Review

A. Obtain the printout, summary report Exception report, Screening worklist, and the EIA checklist from the Operator.

B. Print the Certifying Scientist Worklist. Review the Summary Report, the Certifying Scientist Worklist and data for open and blind QCs and the result.

QUALITY CONTROL FOR TXNIDA2 BATCH/INITIAL SCREEN

A set of quality control samples consists of a combined number of controls to equal 10% of the total number of specimens in each batch being analyzed. A batch is defined as a group of specimens not to exceed 39 samples. for a TXNIDA2 batch it would include 3 open controls and one blind quality control sample, for a total of 4 out of 39 samples or 10% control samples.

A. Criteria for Acceptance/Rejection of an EIA Batch

1. Failure of the accessioning staff to place a blind quality control specimen in the batch. Realiquot and repeat the batch.

2. Failure to achieve 10% quality control specimens in a batch. Realiquot and repeat the batch.

3. Failure of the positive blind quality control sample in the run to test positive. Reject run. Realiquot and repeat the batch.

4. Failure of the negative blind quality control sample to test negative.Reject run In this case all samples will be realiquotted.

5. Failure of the +25% control. If the +25% fails to screen positive for a specific analyte, repeat analysis for all specimens for the required analyte. If the control still reads negative, the certifying scientist may release all immuno non-reactive specimens as negative and reschedule all immuno-reactive specimens.

Approved by: _____ *Date:* 8/10/99

6. Failure of the -25% control. If the -25% control fails to screen negative for a specific analyte, repeat analysis for all specimens for the required analyte. If the control still reads positive, the certifying scientist may release all negatives and reschedule all presumptive positives.

B. Review the screening results, the Summary Report, and the Certifying Scientist Worklist for agreement. Double check all manual entries and document review. A specimen is deemed presumptive positive if the absorbance of the specimen is greater than or equal to the absorbance of the cutoff calibrator.

C. Review the sample integrity check results on the Screening Summary report and the Certifying Scientist Worklist. Verify that the message codes appear on the Certifying Scientist Worklist.

1. Specimens with a creatinine of less than 200 mg/l (20 mg/dl) and sp-gr less than 1.003 must have the message code #LSGCR.

2. Specimens with a pH of less than 5 or greater than 9 must have the message codes pHL and pHH attached to their results respectively. (Not to be used for Regulated testing)

3. Specimens with a specific gravity less than 1.003 or greater than 1.025 must have the message code #LSGCRor SPGRH attached to their results, respectively.

D. Sign and date the worklist and initial all verifications, totelist, loadlist, data, Summary Report, Exception Report, Blind QC records, Open QC records and calibration records.

E. Result DNR for each positive analyte for the positive blinds to ensure that only positive results from actual

samples are reported. Negative blinds require no edits.

III. Result Release

For all the screened negative specimens, no further testing is necessary. Release the screened negative results after verifying the chain of custody, quality control of the load, and the integrity check results.

A. To release the results, log onto the NIDA-NTN system and from the main menu select the option RESULTS PROCESSING.

Approved by: _____ Date: 8/10/98

B:SOP
VOLI-SECI

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QUALITY CONTROL-MFR

The Memorandum for Record (MFR) is prepared when there is a quality control error which needs to be corrected, reviewed and released after consideration by a Certifying Scientist, Director of Toxicology or a responsible person.

The MFR should be prepared after review of some QC error, and should describe the problem and the solution to the QC error. It should be reviewed by the next line of supervisor(s), Certifying Scientist(s) or responsible person. This MFR shall remain as a permanent record in the batch folder.

Types of errors where the MFR are created include errors in accessioning; errors which occur during the testing procedures such as during EIA screening or GC/MS confirmation; control failure; standards omitted; the wrong number of controls; not including a blind QC; clerical error; missing a specimen in a run; some problem with the Chain of Custody; some inconsistency with the results of the blind QC; and others not enumerated above. These forms are to be generated and reviewed prior to specimen release or rescheduling. These decisions should be made by the Certifying Scientist(s). All errors discovered by clients must be brought to the attention of the Director.

The decisions regarding the above types of specimens should be made with quality control practices and good judgement concerning acceptable Quality Control practices within a laboratory setting. These types of decisions can be reviewed and overruled by the responsible person.

MFR FORM

Any clerical error which has been overlooked by the Analyst in charge of the patient's samples and corrected by another officer, must be documented on a MFR form.

_____ Part I - QC officer will fill out MFR form or C.S. by describing problem and including batch name, Accession number and worksheet cup in describing problem.

_____ Part II - Explains the corrective action taken to resolve problem.

_____ Part III - Sign and date, prepared by.

_____ Place MFR form on Review Bench for review by QC officer and Certifying Scientist.

_____ Place copy of MFR in batch folder.

Approved By: _____ Date: 8/10/98

B:ADMSECVI

2. Review the Olympus printout and TOPLAB or NTN summary reports to verify calibration data and positive results data. Highlight allthe positive results on the printouts.

NOTE: If barcode read errors have occurred, the data may be recovered and manually entered during load autoedit. Using the Olympus instrument report, determine the data sets that failed to transfer. Compare raw absorbance of the specimen to the calibrators and manually calculate all positive ratios. Initial and date manual calculations. Enter the ratio or negative results during autoedit.

3. Highlight space corresponding to positive assay and accession number for which the screen is positive on the Olympus summary report.

4. Manually recheck all the absorbance values for positives against the threshold standard. If any discrepancies are observed, report this to the NIDA Laboratory Director or designee.

5. Review results for adulterant checks (pH and creatinine). Perform specific gravity if necessary. See Result Entry, Report Comments, for directions on how to enter adulterant check messages.

6. Complete all chain of custody documentation on the load list.

7. Sign and date the Olympus raw data, summary report, and load list.

All the ethanol at or above 40 mg/dL must be quantitated by Gas Chromatography.
All the initial screen positive samples MUST be confirmed by GC/MS before they can be reported as positive.

RESULT ENTRY
To enter the results into the NTN system:

1. Select the result processing (Menu 3), then Instrument (menu 20). Select Auto-Edit (Menu 2).

2. At the prompts:

   a. At the Release Y : Enter "N".

   b. Worklist: Enter the worklist TXNIDA2, TXNRC, TXNSAP or TX10S.

   c. Test codes Auto : Enter

Approved By: _____ Date: 9/10/99

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Attachment 3
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(4)

SmithKline Beecham

Clinical Laboratories

MEMORANDUM
Forensic Toxicology

DATE: 8/10/99

TO: Staff

FROM: Michael Feldman, PhD MF

RE: Forensic Corrections

This memo serves as a reminder that the standard procedure regarding forensic corrections applies to all manual edits to any document. Any manual edit requires appropriate documentation to be able to determine who performed the edit and when the edit occurred. This includes corrections and/or annotations. If you need to add information, or if you are correcting information, an initial and date must be included with the manual entry.

If you have any questions, please see me.