James A. FitzPatrick
Nuclear Power Plant
P.O. Box 41
Lycoming, New York 13093
315 342-3840

NewYorkPower Authority

Harry P. Salmon, Jr.
Resident Manager

March 21, 1994
JAFP-94-0170

United States Nuclear Regulatory Commission
Document Control Desk
Mail Station P1-137
Washington, D.C. 20555

Dear Sir:

This report is provided to you in accordance with 10 CFR 26 Appendix A section 2.8 (e) (4), Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs, Quality Assurance and Quality Control.

On February 15, 1994, the laboratory contracted by the James A. FitzPatrick Nuclear Power Plant (JAFNPP) to perform fitness-for-duty sample analysis, reported an unsatisfactory carboxy acid THC test result on a blind test specimen (BTS) sent by the Authority. The Authority initiated an investigation that included notifying the testing laboratory of the unsatisfactory test result, contacting the BTS supplier and verifying the specimen concentration, and retaining another independent laboratory to analyze a duplicate specimen.

The following is the sequence of events surrounding this incident:

November, 1993	Subject batch was formulated by the Forensic Control Company
December 15, 1993	Subject batch was placed into service by Bensinger, DuPont & Associates
February 4, 1994	NYPA sent Kit # 3109 from subject batch to Roche Biomedical Laboratories, Inc. for BTS analysis.
February 15, 1994	NYPA received a report with an unsatisfactory BTS test result from Roche Biomedical Laboratories, Inc.
February 17, 1994	NYPA suspended services with Roche Biomedical Laboratories, Inc. until NYPA Corporate Quality Assurance completes an audit of their program.

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February 21, 1994 — NYPA received the investigation results from Roche Biomedical Laboratories, Inc. (See attached letter).

February 28, 1994 — NYPA requested Bensinger, DuPont & Associates to provide the history of the subject batch that the specimen was taken from. (See attached letter).

IMMEDIATE CORRECTIVE ACTION:

Upon receiving the unsatisfactory BTS test report, the Authority immediately discontinued using Roche Biomedical Laboratories, Inc. for specimen analysis.

LONG TERM CORRECTIVE ACTION:

NYPA Corporate Quality Assurance is to perform an audit of Roche Biomedical Laboratories, Inc. prior to resuming specimen analysis with them.

If you have questions concerning this matter, please contact Mr. Eric Mulcahey of my staff at (315) 349-6324.

HARRY P. SALMON, JR.

HPS:EAM:tlc

Enclosure

cc: USNRC, Region I
USNRC Resident Inspector
USNRC Project Directorate

Roche Biomedical Laboratories
ROCHE
a subsidiary of Hoffmann-La Roche Inc.

Roche Biomedical Laboratories, Inc.
[illegible] Avenue
P.O. Box [illegible]
Raritan, New Jersey [illegible]

[illegible]
[illegible]

February 21, 1994

Dr. Richard Jaeger
Industrial Medical Associates, P.C.
961 Canal Street
Syracuse, NY 13210-1287

Dear Dr. Jaeger,

Thank you for your time on Thursday, February 17. As per our discussion, I have completed an investigation into the causes of what appeared to be a discrepant result for a blind quality control specimen submitted by your client, the New York Power Authority (NYPA) on February 4.

The DOT sample at issue was received into this laboratory on Friday, February 5, 1994 and assigned a laboratory accession number of 035-718-0120 (SSN: 029 23-2930, external ID #: 62062049129). Following inspection, accessioning and initial screening, certified negative results were reported to the MRO of record on February 7.

Upon investigation, it was determined that the sample yielded an initial immunoassay screening result for carboxy-THC which was just below the screening cutoff of 100 ng/ml. Specifically, the immunoassay is calibrated with a validated carboxy-THC calibrator containing 100 ng/ml. The specimen produced an immunoassay response of 99 ng/ml equivalents, indicating presumptive presence of metabolite(s) at just under the assay's cutoff. Open and blind quality control materials for this screening batch were within acceptable limits. By our SOP, this sample was properly reported as negative.

Analysis of an aliquot of this specimen by GC/MS examination indicated a quantitative level of 9-carboxy-THC of exactly 100 ng/ml. A calibrator (or sample) containing this concentration would not be expected to consistently elicit a positive immunoassay response. Rather, it would deviate about the screening cutoff, within an acceptable standard deviation for the assay. Tolerance limits of ± 20% at or near the screening cutoff are generally recognized as acceptable, meaning that a sample containing upwards of 120 ng/ml of carboxy-THC may occasionally be expected to elicit a borderline negative response.

As per your request, an aliquot of this specimen is being forwarded to MetPath Laboratories (Teterboro, NJ) for carboxy-THC LOD analysis. I indicated to them on a copy of your letter, that they report to you the quantitative results for this retest.

I indicated to Ms. Carol Saucy and Tom Teifke of NYPA that positive blind quality control materials should contain concentrations of analyte sufficiently above the screening cutoff so that the laboratory's process can be effectively challenged. It has been my experience with certain vendors of carboxy-THC blind materials that analyte degradation, owing to adsorptive losses can be a concern. This may be the case in this instance. At the minimum, positive blind materials should be properly prepared and stabilized at minimum concentrations at least 30-50% above the screening cutoffs.

This concludes my investigation of this incident. Should you, Dr. Heitzman or other NYPA staff require additional information, please do not hesitate to contact me at (800) 437-4986. I look forward to a satisfactory resolution of this matter and the opportunity to discuss other testing needs with you in the future.

Sincerely,

Joseph P. Watson, M.S.
Laboratory Administrator,
Forensic Toxicology

CC: Dr. Heitzman

JPW:akt

Bensinger, DuPont & Associates

Management Consultants for a Drug-Free Workplace

BDA

CORPORATE OFFICES

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(301) 881-8210
FAX (301) 819-1061

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FAX (312) 726-1061

February 28, 1994

Carol Soucy, R.N.
Administrator
Medical Department
James A. Fitzpatrick Nuclear Power Plant
New York Power Authority
Lake Road
Oswego, New York 13126

RE: Proficiency Specimen SS# 029-23-293

Dear Ms. Soucy:

We have reviewed the history of the batch from which the above referenced specimen was taken and provide you the following information on and assessment of the quality of that specimen.

The batch was formulated in November, 1993 with a target level of 150 ng/ml. The batch was confirmed by gas chromatography/mass spectrometry by an initial DHHS-certified laboratory (#2) on November 25, 1993 at 159 ng/ml . It was confirmed by gas chromatography/mass spectrometry by a second DHHS-certified laboratory (#1) on December 13, 1993 at 150 ng/ml, and it was further confirmed by gas chromatography/mass spectrometry a third DHHS-certified laboratory (#3) on December 14, 1993 at 139 ng/ml. All of these confirmations were within the standards established by the formulator, Forensic Control Company (FCC), and are within the parameters of good practice in the field. The batch was put into service on December 15, 1993 (date first specimens were sent to BDA clients).

This batch was subsequently checked by a DHHS-laboratory as follows:

Date	Laboratory	Result
January 4, 1994	DHHS #1	120 ng/ml
January 7, 1994	DHHS #2	144 ng/ml
January 24, 1994	DHHS #2	135 ng/ml
January 3, 1994	DHHS #3	146 ng/ml
January 19, 1994	DHHS #3	141 ng/ml

In addition, specimens from this batch have been used by three other BDA clients, including the Authority's Indian Point 3 Plant, and all of these specimens have been correctly identified by those client DHHS-certified laboratories.

In the absence of any Federal standards, Bensinger DuPont and Associates (BDA) has worked hard to establish benchmark standards for its proficiency specimens. From the beginning in 1984, BDA has established spiked specimen targets of 150% of the standard screening cut-off rate. We established this criteria after discussions with officials at the National Institute on Drug Abuse (NIDA) and the Armed Forces Institute on Pathology (AFIP), and with laboratory directors of several DHHS-certified laboratories. At the 150% target BDA believe that it's spiked proficiency specimens provide a fair challenge to any laboratory.

In order to better ensure the sustaining quality of our proficiency specimens, in early 1993 our formulator (FCC) began to monitor its batches on a much more comprehensive basis. Since that time, all batches are initially confirmed by gas chromatography/mass spectrometry by at least two DHHS-certified laboratories. Subsequently, all batches are monitored on at least a monthly basis by at least one DHHS-certified laboratory. THC specimens are monitored by at least two and usually three DHHS-certified laboratories. We believe that this attention to the quality of the proficiency specimens is unprecedented and we are unable to identify any other provider of proficiency specimens who monitors its specimens with such rigor. As you know, DHHS has proposed for the first time that providers of proficiency specimens must be able to provide evidence of batch monitoring and this general requirement should become regulation later this year. BDA/FCC have been performing aggressive monitoring for over a year (it was done earlier on a less frequent basis).

For all of these reasons, it is our opinion that the specimen in question was properly formulated and delivered to you at a level which provided a fair challenge to your laboratory.

Sincerely yours,

RICHARD H. BUCHER, Ph.D.
Vice President