Omaha Public Power District
1623 Harney Omaha, Nebraska 68102-2247
402/536-4000

April 9, 1990
LIC-90-0308

U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Mail Station P1-137
Washington, DC 20555

Reference: Docket No. 50-285

Gentlemen:

SUBJECT: Report of Unsatisfactory Performance Testing

Pursuant to 10 CFR 26, Appendix A, Subpart B, Section 2.8(e)(4), this submittal provides a report of an unsatisfactory performance testing incident. The incident was reported to Omaha Public Power District (OPPD) on March 8, 1990, by M. A. Peat, Ph.D., Director, CompuChem Laboratories, Inc., with respect to testing which was conducted on March 2, 1990.

The attached correspondence from the supplier of the blind sample (Attachment A) and the testing laboratory (Attachment B), documents the investigation of the incident. The investigation concluded that inadequate sample mixing was the most likely explanation for the incident

In addition, OPPD has recently conducted an audit of CompuChem Laboratories' compliance with Quality Assurance (QA) requirements of 10 CFR 26, Appendix A. The QA program was found to be effectively implemented and adequately proceduralized.

If you have any questions, please contact me.

Sincerely,

W. G. Gates

W. G. Gates
Division Manager
Nuclear Operations

WGG/mc
Attachments
c: LeBoeuf, Lamb, Leiby & MacRae
A. Bournia, NRC Project Manager
R. D. Martin, NRC Regional Administrator, Region IV
P. H. Harrell, NRC Senior Resident Inspector

A001
1/1

ATTACHMENT A

ElSohly Laboratories, Incorporated
1215½ Jackson Avenue
Oxford, Mississippi 38655
(601) 236-2609

March 21, 1990

Dr. Ron Olnhausen
Physician's Clinic
10060 Regency Circle
Omaha, Nebraska 68114

Dear Dr. Olnhausen:

RE: ELI Quality Control Batch #111089B, THC

This is in reference to your inquiry about the possibilities of the above-mentioned quality control specimen testing negative in the initial screen. First, this particular batch is a true clinical urine pool which contains all THC metabolites at a concentration equivalent to about 100 ng/mL of the total metabolites calculated as the carboxy-THC. The concentration of the carboxy-THC metabolite (11-nor-delta-9-THC-9-COOH) by GC/MS in this batch was certified at 56 ng/mL. This certification was carried out not only in our lab but also in another NIDA-certified reference lab.

Second, regarding the smell of this urine sample, I can assure you that there is no "organic solvent" in this sample or in any of our quality control materials. The urine might smell differently than others in the same shipment, but so do normal employee urines depending on the food intake, medications, etc. But the point is, there is no organic solvent in the urines.

Third, it is my opinion and speculation that probably what happened at the lab is that the specimen might not have been mixed well prior to analysis and, therefore, the first aliquot used might not have been a true representation of the entire content of the bottle. This is not something peculiar to our QC samples, but it is a real phenomena with all specimens containing drugs.

And last, but not least, a false negative finding by a laboratory at this point is definitely not a serious problem since even under the NIDA guidelines a laboratory could miss 10% of the samples as false negatives without being considered to have a serious problem. These false negatives are sometimes true "outliers" that will happen sooner or later but not with high frequency. My personal recommendation would be just to bring it to the attention of the laboratory so that they might retest the specimen, help them fine tune their screening if need be, or do whatever is necessary to guard against frequent occurrence of false negatives.

I hope I answered all the questions you had, however, should you have any other questions or should you like us to provide you with any more information regarding this batch or require reanalysis of the specimen, we would be glad to comply with your needs.

We were involved in an inspection all day yesterday with the College of American Pathologists, and therefore I could not get the letter out to you. Please accept my apologies.

With best regards.

Sincerely,

Mahmoud A. ElSohly, Ph.D.
President
Laboratory Director

ATTACHMENT B

COMPUCHEM LABORATORIES, INC.

Western Division - 600W North Market Boulevard - Sacramento, CA 95834
Phone (916) 64[illegible]779 - (800) 562-6550 - Fax (916) 923-1938

March 23, 1990

Robert H. Guy
OPPD
444 South 16th Street Mall
Omaha, Nebraska 63102-2247

Dear Bob:

With reference to my letter of March 16, 1990 and your following correspondence with Dr. ElSohly regarding specimen with I.D. #LMP504916, I have talked to Dr. ElSohly and he has assured me that this specimen is one from a true clinical urine pool. I discussed with him the odor of "organic solvent" and he assured me that no such solvent had been added to the speciment. We discussed the issue of our negative finding and he has agreed to look at an aliquot of the specimen for me.

With regards to the possible reasons for the initial negative report, I concur with Dr. ElSohly that this is a statistical outlier and that the most likely explanation is an inadequte mixing of the sample before analysis. I have re-instructed the aliquoting technicians to swirl the contents before aliquoting for either screening or confirmatory analysis. We have invertigated the possibility of instrument problems and consider this an extremely unlikely source for the error.

Unlike the previous negative reports which could be traced directly to an administrative process, this one should be considered a statistical outlier which will occur when large numbers of specimens are analyzed.

If you require further information, please call.

Yours sincerely,

Michael A. Peat, Ph.D.
Director

cc: Dr. Olnhausen
J. Peat
L. Hyler
K. Metcalf