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July 9, 2004

Walter F. Vogl, Ph.D.
Drug Testing Section
Division of Workplace Programs, CSAP
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

Re: Docket # 04-7984
Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673 (April 13, 2004)

Dear Dr. Vogl:

I was a practicing forensic toxicologist in the medical examiner arena for more than 32 years until I retired from my position as Chief Toxicologist with the Alabama Department of Forensic Sciences in May of last year. I am also presently, and have been since 1994, an NLCP inspector. I am not connected with any agency or entity (aside from Research Triangle Institute) that has any financial interest in the Federal Workplace Drug Testing Program or its Guidelines.

I appreciate the opportunity to comment on the proposed changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. In general, I am in agreement with the proposed revisions except for the following reservations:

1. Subpart H, Specimen Collection Procedure
   Section 8.3 (a) (6)
   I am concerned that the donor is required to expectorate in to the specimen tube. To the best of my knowledge, such a collection procedure has not been employed in any of the validation studies of currently available oral fluid testing technology. Given the unpredictable nature of opportunities for contamination (microbial and otherwise), problems associated with trying to manipulate a viscous specimen such as saliva, the whole question of how to properly and efficiently preserve the specimens for shipment to the laboratory, not to mention the fundamental offensive grossness of the procedure, the mind boggles. The people who have developed this technology have already solved all of these problems, and it seems like false economy indeed to discard the various collection devices (some of them already FDA approved, I believe) they have devised. A much better approach would be to require that oral fluid be collected with an approved collection device specified by whatever brand of technology was selected.

2. Subpart I, HHS Certification of Laboratories and IITFs
   Section 9.23 (b)
   Even in a small laboratory more than one inspector is required to do a proper job. Given the fact that now *all* non-negative cases are reviewed, and considering the added complexity of specimen validity testing and reporting, along with the usual documentation of validation studies, PT performance, routine QA/QC, annual linearity, interference, LOD and LOQ studies, etc., at least two inspectors (a dedicated records auditor and a "checklist" inspector) are really necessary for a truly adequate maintenance inspection of even the smallest certified urine drug testing laboratory. Admittedly, the proposed change would reduce costs somewhat, but the overall quality of the program would suffer disproportionately in my opinion.

I applaud your proposal [Subpart K, Laboratory; Section 11.26 (h)] that an HHS-certified laboratory report the concentration of the drug for *any* positive result. This would eliminate a significant amount of paperwork (and the associated administrative errors), not to mention it would eliminate problems many laboratories seem to have in getting their electronic reports to agree with their CCF reports, which frequently do not include (subsequently requested) quantitative results.

Very truly yours,

M. T. Barnhill, Jr.

Matthew T. Barnhill, Jr., Ph.D., DABFT