**KorManagement Services**

44324 157th Street
Florence, SD 57235
Phone: 605-758-2325
Fax: 605-758-2333
Email: kornmann@itctel.com

FR Doc #04-7984
Public Comment 8400099

July 8, 2004

Docket # 04-7984

Walter F. Vogl, Drug Testing Section, Division of Workplace Programs, CSAP

Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673 (April 13, 2004)

Dr. Vogl:

KorManagement Services does training on collections to many collectors in five states, one such training is utilizing Intercept® oral fluid testing for company's drug-free workplace program. Since the beginning of drug testing in 1986 when President Regan put it into place the drug free workplace program we have been working with companies in different positions. Marketing for NISAT (Quest) Laboratories in San Diego – one of the first laboratories to be approved to do testing. Then I working in occupational medicine and assisting companies in setting up workplace drug programs. Currently our company trains collectors in the collection of urine, Intercept oral fluid specimens and POCT (point of collection) collections. We have found that Intercept oral fluid testing program to be a cost-effective, convenient and reliable way to meet the goals of companies.

We appreciate the opportunity to comment on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and we applaud the efforts by HHS to expand the program. We understand that HHS is making these proposed revisions to fulfill a mandate to utilize the "best available technology" for drug-free programs. We wish to comment on three recommendations in the proposed regulations addressing oral fluid testing.

1. Proposal for the collection of oral fluid as a "neat" specimen

In section 2.5(b), the collection of oral fluid is specified as **"2mL collected as a 'neat specimen' (divided as follows: at least 1.5mL for the primary specimen and at least 0.5mL for the split specimen)."** We believe that collection of oral fluid using an FDA-cleared collection device is also an acceptable if not preferred collection method. We have experience with this method in the collection of over 100's of specimens at companies that I have trained in the collections.

Spitting into a tube to obtain a "neat" specimen does not necessarily represent the "best available technology," nor do we believe this collection method would be practical. Our associates appreciate the dignity of an oral fluid collection, which we do not believe exists for donors required to spit into a container. The additional cost and time required for collecting "neat" specimens could be significant. The collection environment would require control and possibly sanitizing, and the allowance of 15 minutes to provide a specimen is five times longer than the collection process with the FDA-cleared oral specimen collection device. Specimen collection of oral fluid by an absorbent pad has been shown to be relatively consistent, and the donor is not able to control any variances by attempting to dilute or adulterate the sample.

2. Proposal for collecting a urine specimen with each oral fluid specimen.

In section 2.3(a) and section 8.3(a)(16) addressing the specific collection procedures for an oral fluid specimen, it is specified to also collect a urine specimen, for the purpose of addressing the possibility of a positive oral fluid test result from passive exposure to cannabis smoke. We believe this additional specimen collection is unnecessary and adds unjustified burden and cost for employers. Scientific data demonstrates that positive oral fluid test results from any realistic exposure situation would be extremely unlikely.

We would like to alert HHS that since these proposed guidelines were drafted, authoritative scientific data on the effect of environmental exposure to cannabis smoke on oral fluid tests has been developed and accepted by the Journal of Analytical Toxicology for publication (Dr. Edward Cone et al.). Specifically, this research demonstrates that environmental contamination is limited to only extreme exposure conditions (several joints smoked in a small, sealed room), and then for only short periods after exposure (up to 30 minutes). The likelihood of environmentally caused positive test results is extremely low if not negligible.

3. Applicability of oral fluids testing to return-to-duty, follow-up testing.

In section 2.2, oral fluid is specified for "**pre-employment, random, reasonable suspicion/cause and post-accident testing.**" Although the basis for this change was stated as due to the claimed short detection time for drugs in oral fluids, a review of published data demonstrates that oral fluid has sensitivities comparable to urine for detection of drug use in the workplace.

We believe oral fluid testing is appropriate for all testing scenarios. It is clearly suited for Return-to-Duty and Follow-Up testing, because it detects recent drug use. A worker successfully completing a substance abuse recovery program and staying clean from drugs will appropriately test clean soonest with oral fluid testing.

Oral fluid testing is also uniquely able to detect illicit drug use. A worker trying to cheat on an SAP's program is very likely to attempt to tamper with urine specimens by diluting or adulterating them, or by substituting clean urine. Oral fluid testing provides a directly observed collection that virtually eliminates the opportunity to tamper with specimens.

Other concerns we have as a collector and trainer are:

The implementation of these rules and enforcement to provide accuracy of testing plus assurance that all collectors have mandatory training to maintain integrity of workplace testing of drugs and alcohol. In review there are some testing procedures which need to be studied further. To do testing such as oral fluid testing that you will also have to collect urine samples doesn't make sense as the cost and time for these procedures will be more.

Definition as to who decides what tests can or will be done when there is a choice of " alternative testing". To leave this as a judgement of the collector would not make good sense. This needs to have clear expectations outline in the rules.

The differences in the determination of time of drug use has always been a problem in figuring out if the person on the job has "impairment " I don't see that this is addresses and wondering what the guidelines for abuse will be.

Hair testing: as collectors we had the "invasion of privacy" topics when blood alcohol's vs.. breathe alcohol were discussed and put into the regulations. There have been donors who see this procedure as "invasive". The comments of using "head " hair would be used also causes concern. The procedures must be clearer as to the steps to take if there is not enough hair on the head. And, there are people who have "no" hair anywhere on the body. Will this be addressed in the rules to state the person would need to have another type of test and who would make that decision?

Oral Fluid: Easier to collect as the donor does the actual collection and collector is the observer. There is less chance of adulteration, currently, but in the future there could be ways to influence the testing. This is not addressed as to how to identify this possibility. Training of the collectors would need to include the understanding of the chemical reactions and what to look for in the oral fluids.

Training of collectors: Need to address the actual certification times for each type of collections – also- who is qualified to do the training, how the training is required to be done, and what constitutes an organization to do the training.

- Sweat: this should only be used for follow-ups and return to duty, It appears that donors will have a real privacy issue with use of this collection.
- IITF- this appears to be just another step added into the cost of doing drug testing. Therefore if POCT's are allowed I see no need for this type of laboratory testing, as doing POCT and needing confirmation who still need to further go the confirmation steps through a certified laboratory.
  POCT's - who will be allowed to do this testing? Layman feel they can do this procedure. This issue needs to be defined in the rules who will and who will NOT be allowed to act as collector's. The point that collections could be done anywhere at anytime sounds good but, will the accuracy and integrity be the same as a sample that is sent into a certified laboratory?
  Who is going to "police" the alternative testing procedures of collectors? This is another added expense for the drug workplace programs. But, this is actually very necessary to have procedures in place before the testing is approved.

The CCF's (Chain of custody forms) - To eliminate errors and the possibility of using incorrect CCF's as a collector we would like to see one (1) form to standardize the procedure. One form could have an area of each type of collection and keep the chain consistent.

The issue on not allowing collector to write on the CCF: I agree that the only place that collectors should be allowed to write would be in the "remarks" area. This is to assist the Certifying Scientist and MRO in determination if collection is done according to procedure.

In regards to who would be a trained tester or collector in remote areas: definition of what constitutes a "remote" area. There are places that the closest collection site is over 50 miles. Will this be defined by miles or how will this be determined? And, how will collectors be trained in these "remote" areas?
Will collectors need to be medical professionals or will they allow layman to do the collection or POCT?

One other question is what is an "established " organization who would be allowed to train – trainers to do these collections and train collectors?

We again thank the Department for this opportunity to provide information to assist it in drafting and finalizing drug testing guidelines and for their careful consideration of these points. We are eager to offer whatever further information and comments that will allow HHS to fulfill its statutory obligations to "establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive order Numbered 12564, including standards which require the use of the best available technology for ensuring the full reliability and accuracy of the drug tests".

Sincerely,

Jan Kornmann, BS, R-CPCT DATIA certified
KorManagement Services
44324 157th Street
Florence, SD 57235
ph: 605-758-2325