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**Date:** 7/12/04 8:43PM
**Subject:** Comments on the Proposed Revisions to Mandatory Guidelines forFederal Workplace Drug Testing

Dr. Vogl,
Attached please find my comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing, specifically addressing oral fluid testing.

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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,

First, I wish to take this opportunity to commend HHS and its staff for their exemplary efforts in drafting proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs availing itself of advances in drug testing technologies to allow more effective drug testing programs.

I am also thankful to have this opportunity to provide my comments to HHS to assist HHS in fulfilling its statutory responsibility 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 ..." Pub. L. 100–71, Title V, § 503 (a)(1)(A)(ii)(I).

My comments herein specifically apply to oral fluid testing. Below I address those sections of the Proposed Rules addressing oral fluid testing on which I wish to comment.

# Subpart B—Specimens

*Section 2.2 Under what circumstances can the different types of specimens be collected?*

Oral Fluid ...Pre-employment, random, reasonable suspicion/cause, post-accident

Comments:
In addressing the use of oral fluid as an alternative specimen in its discussion under Subpart B—Specimens—Major Change (69 FR 19679) the Department indicated "Because of the short detection window, oral fluid is not suited for return to duty, and follow-up testing." It is also noted that in its discussion of Advantages of POCTs (69 FR 19678) the Department indicated that "Oral fluid is not suited for return to duty, follow-up testing and pre-employment."
However, in Draft 4 of the guidelines, oral fluid was recognized as suitable specimen for all authorized testing scenarios. Although the basis for this change was stated as due to the claimed short detection time for drugs in oral fluids, a review of epidemiologic data demonstrates that oral fluid has sensitivities comparable to urine for detection of drug use. Furthermore, there appear to be no significant differences between the purposes and detection windows between return-for-duty and pre-employment tests and follow-up and random tests. Thus I can see no reason to preclude the use of oral fluid as a specimen for these situations.

Also, in supporting the use of oral fluid testing the Department indicated "the Department proposes to incorporate this new technology as an optional selection for Federal agencies because oral fluid testing may be useful in certain missions and tasks that only individual Federal agencies can identify." 69 FR 19676 I believe that the choice to use oral fluid testing in these various testing scenarios should accordingly be left to the judgment of each federal agency.

In addition I can see no sound reason why POCT testing using oral fluid would not be suitable for these applications as well.

*Section 2.3 Can more than one type of specimen be collected at the same time from the same donor?*

(a) When an oral fluid specimen is collected, a urine specimen must also be collected;

Comments:
This issue of a concomitant collection of a urine specimen whenever an oral fluid specimen is collected was addressed in several places in the Proposed Rules. I believe that recent scientific data eliminates the need for a urine specimen to be collected concomitant with an oral fluid specimen.

In its discussion of Oral Fluid under the heading Alternative Specimens (69 FR 19676) the Department wrote "Unfortunately, further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination, i.e. the individual was present in a room when others smoked marijuana, for example. In order to protect Federal workers from incorrect test results for marijuana, the Department proposes that a second biological specimen, a urine specimen, will need to be collected under the current Guidelines at the same time the oral fluid specimen is obtained, primarily for the purpose of testing for marijuana when the oral fluid specimen is positive for marijuana. The

Department will revise the Guidelines when the science is available to differentiate between actual use and environmental contamination."

Also in its discussion of Oral Fluid under Subpart B –Specimens–Major Change (69 FR 19679) the Department again indicated "In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is collected."

This issue was also addressed in the discussion of oral fluid under Advantages of POCTs. "In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained." 69 FR 19678

Finally, this issue was again addressed as an Issue of Special Interest where the Department wrote "To ensure that a THC result on an oral fluid specimen is from active exposure, the Department is proposing to always collect a urine specimen with an oral fluid specimen that would be available if the oral fluid specimen was positive for THC. The Department is requesting comments on this proposed policy." 69 FR 19687.

I first wish to point out that it would be the test interpretation rather than the test results which could be incorrect as a result of the possibility of environmental contamination of the oral fluid.

I recognize that at the time of the drafting of these Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs scientific data on the effect of environmental contamination by cannabis smoke on oral fluid tests had not been published in the peer reviewed literature. I have since been presented pre-publication data from authoritative scientific studies which allow for the differentiation of actual use and environmental exposure. These studies were performed at Johns Hopkins Medical School by Dr. Ed Cone et al. and were designed to specifically address this issue. The results of these studies have also been submitted to the Journal of Analytical Toxicology for peer review and publication.

In this controlled study, 4 subjects were passively exposed to marijuana smoke generated by 5 marijuana smokers each smoking a single marijuana cigarette (1.75% THC) over 20 minutes in an unventilated sealed room of 36 $m^3$. Oral fluid specimens were collected from all 9 subjects, both the 5 active smokers and as well as the 4 passively exposed subjects, over the next 4 hours. Only 8 of 12 specimens collected from the passively exposed subjects between 0–30 minutes after the end of the 20 minute smoke exposure period were confirmed positive for THC (avg. 9.5 ng/mL, 3.6–26.4). Of these 8 positive oral fluid specimens, only two were above 10 ng/mL (12.3 and 26.4 ng/mL), both collected immediately at the end of the 20 minute smoking exposure period. At 30 minutes after the 20 minute exposure period only 1 subject tested positive (at 3.6 ng/mL). All urine specimens except one from the passively exposed subjects tested negative for THC-COOH at an LOD of 1 ng/mL (with only one specimen demonstrating 3.4 ng/mL THC-COOH).

This research demonstrates that although THC may be detected in the oral fluid of subjects environmentally exposed to cannabis smoke, it is only under relatively extreme exposure conditions (several joints in a small room ) and at relatively low levels for only short periods of time (30 minutes) after environmental exposure.

Although it is possible to test positive under current oral fluid test criteria as a result of environmental exposure in extreme exposure conditions, the likelihood of such positive test results is extremely low if not negligible. Thus I do not believe that passive inhalation is a reasonable defense or that significant exposure can occur through passive inhalation to cause an oral fluid specimen to be reported positive. In fact this is precisely the language HHS published in the Federal Register in 1994 stating its position on the possibility of passive cannabis exposure and urine testing. "The Department does not believe that passive inhalation is a reasonable defense or that significant exposure can occur through passive inhalation to cause a urine specimen to be reported positive." HHS, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29908, 6/9/94

The remote possibility of testing positive in oral fluid from environmental exposure to cannabis smoke is analogous to the situation for urine drug testing where it is acknowledged that it is scientifically possible to test positive by environmental exposure to cannabis smoke (as demonstrated in the published peer-reviewed scientific literature) but importantly only under the most extreme exposure conditions. This remote possibility of positive urine test results from environmental exposure has not precluded the use of urine drug testing to assess cannabis use in federal workplace drug testing programs.

It should also be noted that given the possibility, albeit remote, of positive urine drug test results from environmental exposure, what then utility does collecting a urine specimen have in addressing positive oral fluid test results. Either or both specimens could demonstrate the presence of cannabinoids as a result of environmental exposure, but again only under extreme exposure conditions.

Although one might propose simply raising the oral fluid cut-off for a confirmed positive result to 20 or 30 ng/mL to avoid any possibility of a positive test from environmental exposure, such a policy would lead to significantly reduced detection of cannabis use. Recent epidemiologic data (Cone et al., Oral Fluid Testing for Drugs of Abuse: Positive Prevalence Rates by Intercept Immunoassay Screening and GC-MS-MS Confirmation and Suggested CutOff Concentrations, J. Anal. Toxicol., 26, 541 (2002) and personal communications from these authors) demonstrates that if a cut-off of 20 ng/mL were used, about 75% of users may avoid detection. The effectiveness of a drug testing and deterrence program is clearly dependent on the likelihood of detection. Raising the detection cut-off for a confirmed positive result in oral fluid to such a level to avoid any possibility of a positive test result from environmental exposure would eviscerate the effectiveness of oral fluid testing. If oral fluid testing were to be rendered so insensitive and ineffective, then it would be hard to establish a sufficient nexus between the testing and program goals to fulfill Constitutional 4th Amendment requirements. Such an ineffective testing program could easily be considered an unreasonable search and seizure.

Thus the mere possibility of contamination of oral fluid from environmental exposure is so remote that there is no firm scientific basis on which to justify mandating a concomitant urine specimen.

*Section 2.5 What is the minimum quantity of specimen to be collected for each type of specimen?*

(b) Oral Fluid: 2 mL collected as a "neat specimen" (divided as follows: at least 1.5 mL for the

primary specimen and at least 0.5 mL for the split specimen)

Comments:
Oral fluid specimen collection through directly spitting into a collection tube is mentioned in numerous places throughout the Proposed Rules. In addressing oral fluid in its discussion of Subpart B-Specimens–Major Change, the Department indicated that "For oral fluid, the Department is proposing that 2 mL be collected in a collection tube rather than allowing oral fluid to be collected directly into a collection device that does not provide an accurate measurement of the volume of oral fluid collected. This approach allows establishing specific cutoffs for oral fluid testing." 69 FR 19680

In addressing the collection of oral fluid under its discussion of Subpart E—Collection Sites, the Department indicated that "For oral fluid, the Department proposes that he donor provide a specimen directly into an appropriate container. This approach will ensure that a minimum amount of oral fluid is collected and can then be split for on-site testing or sent to a laboratory for both initial and confirmatory testing." 69 FR 19682

I recommend that consideration also be given to oral fluid specimen collection using an FDA-cleared collection device. It is clear that such absorbent devices have demonstrated their reliability and acceptance in the huge number of oral fluid specimens collected with such devices.

Although the Department has noted a study demonstrating a higher drug concentrations in specimens obtained by spitting relative to specimens collected through stimulation 69 FR 19676, I do not believe that this issue alone should be dispositive.

Studies clearly demonstrate sufficient drug concentrations in oral fluid specimens collected using absorbent collection devices to allow for effective detection and deterrence of drug use. In addition, for spitting, there are issues of donor acceptability, ease of specimen handling, and biosafety to be considered. Donor reluctance to spitting has even been recognized by the Department. "To avoid saliva stimulation some recommend spitting into a cup, but some donors may be opposed to spitting, especially when observed, and may experience dry mouth" 69 FR 19676

Furthermore, existing DOT specimen collection procedures for saliva alcohol testing specifically incorporate language involving the use of a collection device placed in the donor's mouth.
Department of Transportation
Procedures for Transportation Workplace Drug and Alcohol Testing Programs
Final Rule
12/19/00
65 FR 79461

Subpart L--Alcohol Screening Tests

Sec. 40.245 What is the procedure for an alcohol screening test using a saliva ASD?

As the STT, you must take the following steps:
(c) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device's manufacturer.

(d) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (g) of this section), you must insert the device into the employee's mouth and gather saliva in the manner described by the device's manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.
(e) When the device is removed from the employee's mouth, you must follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

Thus I believe that oral fluid specimen collection procedures should allow for use of FDA-cleared absorbent collectors in addition to a directly expectorated specimen.

The Department here also mentioned "dry mouth" and also asked for information about dry mouth as an Issue of Special Interest. "Again with regard to oral fluids, the preamble mentions a possibility of an individual having a "dry mouth." The Department would appreciate any comments on whether the Department should adopt a specific procedure for "dry mouth" as it has for "shy bladder" under urine." 69 FR 19687 My comments regarding specimen collection procedures in cases where dry mouth is claimed as a basis for an insufficient specimen are found in Subpart H—Specimen Collection Procedure.

# Subpart E—Collection Sites

*Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?*

The donor provides the sample directly into an appropriate container under the direct observation of the collector. Only the collector may be present while the donor provides the oral fluid specimen.

Comments:
As addressed above, I again recommend that the collection of oral fluid specimens allow for collection using an FDA-cleared absorbent device. The wording "appropriate container" may be construed to preclude use of such a device.

# Subpart G—Collection Device

*Section 7.1 What is a collection device?*
(c) For oral fluid, it is the single-use plastic specimen container.

Comments:
As addressed above, I again recommend that the collection of oral fluid specimens allow for collection using an FDA-cleared absorbent device.

*Section 7.2 Which collection devices may be used?*
(b) These Guidelines do not determine if a collection device must be cleared by the FDA.

Comments:
I believe that only collection devices which have been cleared by the FDA are suitable for use in federal workplace drug testing programs "for ensuring the full reliability and accuracy of the drug tests ..." Pub. L. 100–71, Title V, § 503 (a)(1)(A)(ii)(I).

# Subpart H—Specimen Collection Procedure

*Section 8.3 What procedure is used to collect an oral fluid specimen?*
(a) The collector must use the following procedure to collect an oral fluid specimen:
(5) The collector will give the donor a clean specimen tube.

Comments:
I believe that the collection procedures should allow for the use of an FDA-cleared absorbent collection device as discussed above.

(6) Under direct observation, the collector will instruct the donor to expectorate (to spit) 2 mL of oral fluid into the specimen tube. This can be accomplished over a 15 minute time period or until the appropriate volume of specimen is collected.

Comments:
I believe that the collection procedures should allow for the use of an FDA-cleared absorbent collection device as discussed above.

(7) Both the donor and the collector must keep the specimen tube in view at all times prior to its being sealed and labeled.

Comments:
I believe that the collection procedures should allow for the use of an FDA-cleared absorbent collection device as discussed above.

(8) The collector, in the presence of the donor, mixes the specimen and transfers the oral fluid into two specimen tubes that are labeled Tube A and Tube B. A minimum of 2 mL of oral fluid is required, i.e., 1.5 mL for Tube A and 0.5 mL for Tube B.

Comments:
I believe that the collection procedures should allow for the use of an FDA-cleared absorbent collection device as discussed above.

(9) The Tube A specimen, containing a minimum of 1.5 mL of oral fluid, is to be used for the drug test. If there is no additional oral fluid available for the second specimen tube (Tube B), the first specimen tube (Tube A) shall nevertheless be processed for testing.

Comments:
I believe that the collection procedures should allow for the use of an FDA-cleared absorbent collection device as discussed above.

(10) A minimum of 0.5 mL of oral fluid shall be transferred into the second specimen tube (Tube B).

Comments:
I believe that the collection procedures should allow for the use of an FDA-cleared absorbent collection device as discussed above.

(16) After completing the oral fluid specimen collection procedure, the collector must also collect a urine specimen following the procedures described in section 8.5.

Comments:
The basis for the collection of a urine specimen was stated by HHS as due to concerns about distinguishing use from environmental contamination. I have above reviewed the results of just such scientific studies which provide persuasive evidence that concerns of environmental contamination are negligible. Accordingly the proposed requirement for the concomitant collection of a urine specimen along with the oral fluid specimen is unnecessary.

(17) The collector must send the oral fluid and urine split specimens at the same time to an HHS-certified laboratory or IITF or transfer the specimens to the POCT tester (if a POCT is being conducted).

Comments:
Again, as addressed above, I believe it unnecessary to collect a urine specimen concomitant with an oral fluid specimen.

The Department earlier mentioned "dry mouth" and also asked for information about dry mouth as an Issue of Special Interest. "Again with regard to oral fluids, the preamble mentions a possibility of an individual having a "dry mouth." The Department would appreciate any comments on whether the Department should adopt a specific procedure for "dry mouth" as it has for "shy bladder" under urine." 69 FR 19687

I recommend that procedures already in place for DOT saliva alcohol testing be considered.

Department of Transportation
Procedures for Transportation Workplace Drug and Alcohol Testing Programs
Final Rule
12/19/00
65 FR 79461

Subpart N--Problems in Alcohol Testing

Sec. 40.263 What happens when an employee is unable to provide a sufficient amount of saliva for an alcohol screening test?

(a) As the STT, you must take the following steps if an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (e.g., the employee does not provide sufficient saliva to activate the device).

(1) You must conduct a new screening test using a new screening device.

(2) If the employee refuses to make the attempt to complete the new test, you must discontinue testing, note the fact on the "Remarks" line of the ATF, and immediately notify the DER. This is a refusal to test.

(3) If the employee has not provided a sufficient amount of saliva to complete the new test, you must note the fact on the "Remarks" line of the ATF and immediately notify the DER.

(b) As the DER, when the STT informs you that the employee has not provided a sufficient amount of saliva (see paragraph (a)(3) of this section), you must immediately arrange to administer an alcohol test to the employee using an EBT or other breath testing device.

# Subpart K—Laboratory

*Section 11.27 What are the requirements for an HHS-certified laboratory to report an oral fluid test result?*

(c) A primary (Tube A) oral fluid specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive. For only those oral fluid tests that result in a confirmed positive for marijuana, the laboratory must not report the result for the oral fluid specimen to the MRO but, instead must test the primary (Bottle A) urine specimen for marijuana and report that result in accordance with section 11.29.

Comments:
Since I have demonstrated above the lack of necessity for collection of a urine specimen when collecting an oral fluid specimen the reference to testing a concomitantly collected urine specimen should be deleted from the Mandatory Guidelines.

# Subpart L—Point of Collection Test (POCT)

*Section 12.18 What are the requirements for conducting a POCT?*
(e) If the aliquot tests presumptive drug positive, adulterated, substituted, or invalid on the POCTs, the primary specimen must be resealed using a new tamper-evident label/seal and sent with the split specimen to an HHS-certified laboratory for testing. The POCT tester must initial and date the new label/seal that was used to reseal the primary specimen. The POCT tester must report the POCT result on the OMB-approved custody and control form. The aliquot used to conduct the POCTs is discarded. When a POCT is conducted on an oral fluid specimen aliquot and it is presumptive positive for marijuana, the POCT tester must send the urine split specimen bottles to an HHS-certified laboratory for testing rather than the oral fluid specimen tubes. For all other presumptive positive drug test results on an oral fluid POCT, the POCT tester may only send the oral fluid split specimen tubes to the HHS-certified laboratory for testing.

Comments:
Again, since there should be no need to collect a urine specimen when collecting an oral fluid specimen, any reference to a concomitantly collected urine specimen should be deleted from the Mandatory Guidelines.

I 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. I am eager to offer whatever further information and comments to the Section that will allow it 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,

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