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From: "Moran, Michael" <Michael.Moran@ost.dot.gov>
To: <wvogl@samhsa.gov>
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The following is submitted in response to Federal Register Notice of April 13, 2004, Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs

The U. S. Department of Transportation (DOT) drug testing program for federal employees has been operating since 1987. Currently, DOT administers a federal employee drug and alcohol testing program for all 11 DOT operating administrations, the United States Coast Guard, the Transportation Security Administration, and the Federal Air Marshal Program under the approved DOT Drug and Alcohol-Free Workplace Plan. This Plan covers over 125,000 federal employees with approximately 85,000 in safety and national security testing designated positions (about 20% of all TDPs in the government). Split specimen testing has been exclusively in place since 1995. All of our agencies conduct a vigorous random testing program with a minimum of 25% annual drug testing rate. Therefore in FY 03, we accomplished over 21,000 random, 1250 follow-up, and 120 post-accident and reasonable suspicion drug tests nationwide. Urine collection and alcohol testing is carried out through a contractor performing collections at agency work sites and not in collection clinics/offices. We estimate that 1300 to 1400 federal work sites are involved utilizing even more than that number of public and private rest rooms secured for the time testing is underway. Monitored collection procedures are typically used. We forecast that the FY 04 testing volume will exceed FY 03 and we expect FY 05 to be even higher. Mostly due to TSA hiring, over 78,000 pre-employment tests were done in FY 03 and these are almost exclusively done in collection clinics/offices.

Based on the most recent statistics available from the Substance Abuse and Mental Health Services Administration (SAMHSA), we estimate that approximately 32% of all random, 45% of all follow-up, and almost 70% of all post-accident testing performed each year for federal employees is performed under the DOT federal employee program.

In reviewing the alternative specimen possibilities it strikes us that use of these additional options in random testing changes the focus of the program from the intent of a random deterrence program to an entrapment intent. After reviewing the proposed changes, we do not intend to recommend the use of alternative specimen procedures within the DOT federal employee program at this time. We feel that these options are not sufficiently supported technically and procedurally. Our specific comments are indicated below. On-site testing and use of instrumented initial test facilities does not provide economies or cost-benefit for our program and could significantly complicate it. We do not intend to recommend any of these alternatives until those processes have matured and federal case law has been established.

There are several proposed changes to the current procedures on urine collection that trouble us and could involve unnecessary complications and difficulties. We are asking HHS, SAMHSA to carefully consider the intent and wording of the proposed changes indicated in these areas.

Specific Comments on NPRM Alternative Specimen NPRM

PREAMBLE

Page 19675 - Center Column, 2nd paragraph: Recommend not using the term "vertex" and replace with "top of the head."

Page 19675 - 3rd Column, 3rd paragraph: States that the role of hair color is a major concern and goes on to explain that there are differences. Why allow the use of an alternative specimen where there are obvious problems. This opens the doors for problems for Federal agencies, their employees and their unions. HHS is the regulatory authority for Federal employee testing, it would seem that the best interest

of the agencies would be compromised by allowing the use of alternative specimens that have disparate results based on hair color.

Page 19676 - Center Column, 2nd paragraph: The following statement is made: "In order to protect Federal workers from incorrect test results..." We believe referring to test results as "incorrect" may create the impression that the test does not detect the presence of marijuana. The test does not provide conclusive evidence that the donor has used illicit drugs. Perhaps it would be better to say "...protect against erroneous conclusions based on test results for marijuana." Using the word "incorrect" gives the impression the testing process was not valid.

The very next sentence states that a urine specimen will need to be collected along with an oral fluid specimen. This requirement to collect two types of specimens provides little benefit to the agency, increases testing costs, and undermines the credibility of the program. If an alternative specimen cannot stand on its own merit then it should not be permitted in the federal employee drug testing program.

Page 19676 - Third Column, 1st full paragraph. HHS states it feels that oral specimen collection and urine specimen collections are not "functionally" different concerning difficulties encountered. The process described seems to involve spitting into a tube container. This conjures images of a potentially messy process. The size of the collection container may be critical, donors could conveniently miss the tube. It seems more practical to use a wide-mouth container that can then be transferred to the tubes and sealed.

Page 19676 - Third Column, 1st Sweat paragraph. States that sweat collection is non-invasive, but the donor must remove part of his/her shirt if the sleeve cannot be rolled up. Some donors, particularly women, may object to removing a blouse if the collector is male. This also requires that the collector make physical contact with the donor. This clearly could become an issue. There would be additional collection costs by requiring the collector and donor to rendezvous twice (at the work site or a clinic) to place and then remove the patch.

Page 19677 - 1st Column top of page. It is not clear what the Department is encouraging research on: cleaning the area where the patch is to be placed or the fact that sweat testing is questionable and needs further research. If it is the latter, then why would we allow a test that is questionable?

Page 19679 3rd Column, Hair paragraph. Hair is recommended for pre-employment tests. Considering the reported length of time drugs may be detectable in hair, this could create a bias against individuals who are applying for jobs and no longer use drugs but had in the past. Depending on the situation Federal agencies may be subject to ADA challenges based on use of this option.

Page 19679- 3rd Column, 3rd paragraph of Sweat Patch. As indicated above, some agencies perform breath or saliva alcohol testing while also collecting urine for drug testing. If the current language referring to section 2.3 remains stating "the Department proposes to prohibit routinely collecting more than one type of specimen from a donor at the same time except when an oral fluid specimen is collected" will mislead agencies into thinking that alcohol testing may not be performed at the same event as collection for drug testing. The department should consider clarifying that associated alcohol testing is not prohibited.

Page 19680 - 1st Column 2nd paragraph. HHS is using an industry recommended quantity for Hair split specimens. How did the Department determine if this was an appropriate amount? Are we relying on industry to recommend standards or was this independently confirmed by the Department?

Page 19680 - 2nd Column - next to the last paragraph. The Department proposes to adopt cutoff concentrations established by the industry working groups (which are not identified) and then asks for comments on the appropriateness of these cutoff concentrations and the ability of laboratories to meet this requirement. We believe the appropriateness and the ability of the laboratories to meet the requirement should have been established prior to publishing it in these proposed changes.

Page 19682- 1st Column, 1st paragraph of Subpart F. HHS is requiring that a different form be used for each type of specimen collected. This has the potential of leading to serious problems with collections. If

the collector does not have the right forms to perform the required collection, no collections will be performed. In the spirit of paperwork reduction, we recommend that there be one or, at most, 2 forms with check boxes to check the type of specimen.

Page 19682 - 1st Column, Subpart G. It is proposed that agencies can only use collection devices that have been cleared by FDA but if FDA has not cleared a device the agency can only use a device that does not affect the specimen collected. Does this mean that if FDA hasn't cleared a collection device the agency must determine if it will affect the specimen collected? We recommend that the Department apply the same methodology that was done with breath and saliva testing devices, the National Highway Traffic Safety Administration maintains a list of approved devices. HHS is putting a burden on Federal agencies who are not equipped to determine what type of collection device will or will not affect a specimen. Since this is an HHS requirement, HHS should tell the agencies what type of collection devices they can use.

Section 2.5 - This section should state how the collector is to weigh the hair to determine the 50 mg amount.

Section 2.5(b). What is meant by a "neat" specimen? No ice?

Section 2.5c. States the sweat patch is worn up to 7 days. The preamble states a minimum of 3 and maximum of 7. This should be restated in this section. Who determines if it should be worn 3 days versus 4 or more days?

Section 3.3 - There have been requests by donors for DNA testing to support the contention that the specimen is not theirs, perhaps specific mention of DNA testing in this section will avoid future misunderstandings.

Section 3.9 - Refers to Tube A for oral specimen. If the donor expected to spit into tubes, are these wide-mouth tubes? Based on the collection procedure described in Section 8.4, the process of spitting into a tube, then having a collector "mix: the specimen and pour into Tube A & B appears tedious and not very practical. Will this be left to the agencies to develop the actual procedures?

Section 3.15 (d) - Discusses the presence of bleach, iodine, fluoride. Does this mean that all certified laboratories will now have the capability and be required to test for these materials?

Section 3.15(g). The word "surfactant" is not a common term. We suggest providing a definition of this term.

Section 3.19(c) - 3.20(c)-3.21(c) Is it possible to determine by appearance that hair, oral fluid, or sweat patches may damage laboratory instruments?

Section 4.2 - Collection training requirements. Most of the testing that collectors perform nationwide is for the DOT regulated industry program. There are stringent training requirement in place in 49 CFR Part 40 that the collectors must adhere to. We understand that HHS is attempting to be more in line with the regulated industry testing requirements, however, a requirement for the collectors to read and understand a document that is, for the most part, not related to collection procedures is an unnecessary requirement. A more appropriate requirement would be to read and understand those portions of the guidelines that pertain to actual collection issues.

Will the train the trainer courses include online courses and CD ROM training? If so, how is it to be documented. How will about the error free mock collections be monitored? Is there a time frame that they must be successfully completed before they must retake the first part of the training course again?

What is the effective date for meeting the collector training requirements for current collectors and for future collectors? With split specimens as a requirement, it would seem that simply adopting the entire 49 CFR Part 40 collector training requirements would be much easier than having a separate but very similar training mandate.

Section 4.4(b) - 49 CFR Part 40 requires that collectors maintain their own training documents, not the company or TPA. The collector must provide the documents upon request. This is another instance where it would be much simpler to incorporate Part 40 verbiage for consistency sake.

Section 5.6 - Indicates that the donor provides the oral sample directly into an appropriate container. Section 7.1 states the collection device for oral fluid is a single-use plastic specimen container and Section 8.3 states the collector will give the donor a clean specimen tube. What is the collection device for oral fluids?

Section 5.7 - As indicated above some donors, particularly women, may object to removing a blouse if the collector is male. This procedure also requires that the collector make physical contact with the donor. Should there be a consent form signed by the donor permitting this physical contact? This clearly could become an issue. There would be additional collection costs by requiring the collector and donor to rendezvous twice (at the work site or a clinic) to place and then to remove the patch for one test.

5.8(c) - This paragraph is stating that mere suspicion that a donor may tamper with or substitute his or her specimen is reason enough for direct observation. More guidance on how the agency might reach this decision would be helpful.

Section 6.1 - We recommend only one or two Custody and Control Form variations (e.g. one for urine and one for all alternative specimens) that includes check boxes for the type of specimen collected.

Section 7.2 - See Preamble comments reference page 19682 above.

Section 8.1 - Why must the collector explain the collection process and then have the donor read the instructions on the back of the CCF? If the collector explains the process and responds to questions from the donor, this should be sufficient. Reading of the back of CCF could become a delaying tactic to begin the test.

Sections 8.2 - 8.4(a)(1) and 8.5(a)(2) are repetitive and can be stated one time in Section 8.1

Section 8.2(3) - Why does the donor have to remove his or her jacket when collecting hair? This same question applies to oral fluid in 8.3(3). Also, what does the collector do if a donor is wearing headgear having religious significance?

Section 8.2(7)- Suggest replacing the word "approximately" with "at a minimum" because in the next sentence specifies if it is less than 1 ½ inches long the width must be increased. The word "approximately" is misleading if the length must be 1 ½ inches long or longer.

Section 8.4(3) - Why does the donor have to empty his or her pockets for a sweat patch collection? The donor will be in the presence of the collector during the entire process.

Section 8.6(b) requires Federal agencies to conduct annual inspections of each collection site. DOT conducts urine collection at the work site and there are well over 1,300 facilities throughout the United States, Alaska, Hawaii, Guam, Puerto Rico and American Samoa where testing occurs on a daily basis. The actual collections occur in rest rooms at each facility. This requirement would entail inspecting every rest room at every facility because we never know what room will be used. This requirement places an unrealistic and unnecessary burden on DOT and any other agency that conducts testing at the work site, to say nothing of the enormous cost impact it would have on the program. We strongly recommend that this be deleted from the final Guidelines. This will create a reason for challenging test results simply because an agency did not inspect the rest room used and stretch agency resources without any matching benefit. Dot is very concerned about the resource implications of this requirement.

Section 12.10(a) - Requires periodic inspection of POCT sites, this is not consistent with the annual requirement in Section 8.6(b). However, we disagree with this inspection requirement as well.

Section 12.25(a) A Federal agency must provide the Secretary a semiannual statistical summary report. Is this requirement in addition to the report that is now submitted to electronically and annually that requires the same information? There is no rationale provided for this increased reporting requirement. We object to the return to a twice a year report. The most recent government-wide consolidated report available is several years old so it does not appear that the information will be available for analysis any earlier than an annual report.

Section 14.2 - Like collectors, MROs should be required to read and understand agency policies and procedures concerning drug testing.

Section 14.2 - What is the effective date for meeting the MRO training requirements for current MROs and for future MROs?

Section 14.3(b) - States that the MRO must cancel all results for specimens that are not collected or tested in accordance with the Guidelines. This could be interpreted in a very rigid manner. What about non-fatal errors that can be corrected? Is the MRO going to check with the collector and the laboratory to ensure that each and every specimen was collected and tested in accordance with Guidelines? The current level of documentation should be all that the MRO typically needs.

Sections 14.4(d), 14.5(d) and 14.6(d) - States that a second collection is ordered by the MRO if there is an invalid result and there is no explanation for the invalid by the donor. If the second collection is also invalid the test is to be canceled by the MRO with no further action.

* First, if I were a donor and I saw this section you can believe I wouldn't have an explanation for an invalid knowing if I can do the same thing again it will be canceled.

* Second, rather than permit no option, it would make more sense to require a urine collection as the second test.

Section 14.7 (b) - -Requiring a recollect of every dilute specimen is unproductive. In FY 03 the DOT federal employee program had 174 dilutes, 3 of which were also positive (positive -dilutes). We have had experience with regulated testing and dilutes and found that the second test is costly in terms of actual expense and resources and rarely results in a non-negative result. We believe this requirement is unwarranted in the federal employee program.

Section 14.7(f) - Rather than canceling the test if the second test produces the same result, why not permit an agency to forward it to a third laboratory for processing? If at that point the result is still the same, then cancel it with no further action required. Has HHS conducted studies to see if the medications listed in this section do, in fact, interfere with a urine specimen?

Section 14.7(g) - Should the recollect of a rejected for testing specimen be collected under direct observation? Also, if the specimen was rejected for testing because it was crushed in transit to the laboratory is a recollection still necessary if the reason for test is not one that requires a negative result, e.g. pre-employment, return-to-duty, etc.?

Section 15.1(b) - We do not agree with the requirement that the donor must request the split in writing. This may not be feasible due to timing constraints and location of donor when he or she is talking to the MRO. It is recommended that this paragraph be modified in such a manner to allow a verbal or written request. Our experience to date with approximately 200 or more split specimen requests has not shown a necessity to complicate and delay the process by a written request

General Comment - If the second laboratory is unable to reconfirm any split can it be sent to a third laboratory or require a recollection under direct observation? If sweat, saliva or hair are the specimens that do not reconfirm, a recollection should be accomplished using urine as the specimen collected.

Section 16.1(c) - As stated earlier, a missing printed name or signature should not be a fatal flaw. On the rare instances when that happens, we have been able to identify the collector and obtain an affidavit.

General Comment - This document was very labor intensive to read due the very similar section headings. This would be a much easier document to read and use if it were divided into sections for each alternative specimen. That way, an agency can go to just the section, urine for example, if there is something they need to look up.

Michael P. Moran
Drug Program Primary Liaison
Substance Abuse Awareness and Testing Office
Department of Transportation

CC: "Faulkner, Don" <Don.Faulkner@ost.dot.gov>, "Cross, Linda" <Linda.Cross@ost.dot.gov>