FR Doc # 04-7984
Public Comment 8400043

Federal Register Vol. 69, No. 71/April 13, 2004

Reference: Docket 04-7984

The following general comments and opinions are related to proposed revisions to mandatory guidelines for the Federal Drug Testing Program published on April 13, 2004.

1. Logic for extension of the program to "added specimens" Specific to page 19675 Section Alternative Specimens:

   Comment: The logic for the proposed change as stated is that the "***Addition of these specimens to the Federal Workplace Program would compliment urine drug testing and aid in combating the threat from industries devoted to suborning drug testing through adulteration, substitution and dilution.***"

   The out growth of this logic is to develop an ever increasing and complex industry of drug testing, chemical detection, and physiologic nuance analysis that will further inflate the cost of health care, insurance and government. This is being done by setting into place a massive system of testing, monitoring and oversight which includes new matrices and testing designed to overcome alleged deficiencies of urine drug testing. All of this is unnecessary and preventable. Accurate and reliable detection of drug and or drug metabolites in a defined specimen (e.g. urine) is the goal of and in the purview of the Forensic Toxicologist***, the determination of physiological nuance and specimen validity is not***. The distinction of this problem in the sole focus on the presence or absence of drug in a urine specimen has a much more appropriate, cost effective, and logical solution.

   a. Improve and upgrade collection site requirements by requiring that real time presumptive SVT (e.g. temperature, color, order, dipstick-colormetric pH, nitrites, oxidants, surfactants, specific gravity, etc.) testing be performed on an aliquot of specimen at the time of collection.
   b. A presumptive positive in any of the aforementioned contexts necessitates a "canceled test" and an on-site ***immediate observed recollection*** (e.g. use of a non-confrontational 1-way mirror system etc.). If the program precipitates firing personnel for 'cheating' (e.g. adulteration, substitution etc.) as opposed to putting confirmed positive drug abusers into rehabilitation, then ***IT SHOULD BE ABLE WHEN NECESSARY TO DEAL WITH OBSERVED COLLECTIONS PRIOR TO FIRING SOMEONE!!***
   c. This approach applies incident by incident, collection by collection, solely based upon the presumptive validity testing of the specimen at the time of collection.
   d. By definition, this process would accuse no one of cheating, and would defeat any adulteration, substitution process, at minimal cost and with greatest effectiveness.
   e. The remaining issue of "dilution" could be handled in one of two ways. Firstly, an increased frequency of random testing and/or lowered screening and confirmation limits in ***drug testing of the specimen*** could be invoked, or
   f. Secondly, this is perhaps the one case where a logical argument for the co-collection of a ***hair and/or oral fluid specimen*** (in the latter context using an appropriately approved FDA device to insure consistency decorum of collection***)*** and testing it/them in addition to the observed urine collected specimen would be of value.

   The out growth of appropriately applied logic allows for ***reduced costs*** and the proper application of Forensic Toxicology to the issues ***of evidence handling and drug analysis*** (not esoteric open-ended searches for chemical chicanery)***.***

   It is important to recognize that the real issue here is ***collection validity not specimen validity. This is a collection site problem with a simple, final and cost effective solution. Proper urine collection obviates the need for many if not all of proposals listed in this document. This is not rocket science nor should it become as costly and complicated as putting men into space!!!***

2. Page 19675 Hair:

General comment: the use of the hair specimen is specific to issues related to "history" of drug use/abuse. Unless this becomes a mandated issue in the current drug testing program and by definition testing protocols with requisite accuracy and precision can be generally applied, in my view it has currently very limited utility. For that reason, I would argue (and urge) that it should be applied only by organizations that have demonstrated accuracy, precision and PT competence, and only to those circumstances in which ***as discussed above (No. 1)*** urine specimen dilution is an issue. Until or unless the program mandates a uniform change to generally applied criteria of historic use, the only logical issue of application becomes that dealing with urine dilution.

3. Page 19676 Oral Fluid:

   General Comment: If urine specimens are properly collected as noted in (No. 1) above then there is no direct applicability of this specimen in the currently defined federal program.

   One area where it may be of value is for on scene in cases of for-cause testing and/or 'incident' testing. Collecting multiple specimens in this case, for qualitative evaluation an oral fluid specimen in collaboration with a urine sample would be of value. It is my further belief, however, that in all for-cause or 'incident' collection scenarios, an adequate and appropriate blood specimen should also required and collected for analysis ASAP following the event in question.

   This would only apply in cases where "appropriate" (as discussed in (No. 1) above) collection site procedures are unavailable. Additionally, it is also my belief that collection of oral fluid in these circumstances is best done in a standardized manner using FDA approved collection devices.

4. Page 19676 Sweat:

   General Comment: If urine specimens are properly collected as noted in (No. 1) above there is no applicability of this specimen in the currently defined federal program.

5. Pages 19677-78 and Subpart I: sections 9.5-9.21, Subpart L & M Instrumental Initial Test Facility (IITF) and Point of Care Testing (POCT):

   Comment: Since these methods would be applied in testing circumstances for the same purpose that screening methods in NLCP accredited laboratories perform, these methods must submit to the exact same test performance requirements. To report results (e.g. 'negatives'), using IITF and POCT devices, not only should all appropriate program performance requirements be met, they should also meet and pass the exact same PT specimen criteria, challenges and requirements that HHS accredited laboratories face. To do less, ***regardless*** of FDA device acceptability creates a multi-class system of specimen testing that is forensically unacceptable for individuals being tested under uniform program expectations. In this regard, it is possible that litigation will force the program to the lowest common testing and performance denominator. If this concept is unappreciated, then all one needs to do is consider POCT device issues applied in the context of clinical care (e.g. Titus, Karen, "Clinicians on POC-read this and weep", *CAP Today,* Vol.18 (5), 2004 pages 1, 90-96.)

   In the context of the current proposed revisions, whether a specimen tests positive or negative truly will depend on where it was tested and what type of device was used. Therefore under the current proposals by definition all testing is not equal. These devices should not be substitutes for HHS Certified Laboratory testing, and a 'negative' should be a 'negative' regardless of the initial test method applied.

6. Page 19679; Subpart B Specimens Major Change:

   Comment: Paragraph 1 this sets up a legally indefensible circumstance. You cannot give elements of the government free choice in employee evaluation. E.g. The people at DOT can not chose urine testing for conditions of employment, while NRC uses a Hair testing. Different windows of time relative to drug abuse, are being evaluated, and thereby result in the application of different hiring/evaluation criteria. Is historic or more recent drug abuse of more concern? Why can an historic drug abuser receive employment in one agency, while person with a more recent drug use practice may get a job in another? The basic specimen

selection, when and if a matrix is tested must have consistent criteria applied. This is a program issue not an agency issue. Litigation, follows inconsistent application of employment practices.

7. Page 19679; Urine:

   Comment: Once again the point is clearly made that although urine testing can and is effectively utilized for all aspects of drug abuse evaluation, it is because of adulteration and substitution that "***...urine drug testing may be least suited for pre-employment".*** The simple and cost-effective answer to this problem is proper specimen collection as noted in (No. 1) above, done properly the necessity of the majority of these proposed revisions are obviated

8. General Comment: If we must go forward with alternative specimen matrices. Then go forward for the right reasons and with the following in mind:

   The majority of changes in these proposed revisions generally apply to the specifics of the testing involved with the added specimens and to lessor extent new devices. I have already discussed my issues with the application of new testing devices in above commentary (No. 5). The remainder of this discussion will address the proposed revisions specific to alternative matrices. Like many aspects of science, the criteria set forth tends to reflect the general capabilities of the methods applied. Currently for alternative matrices, this is based upon a relatively small 'n' of experience and application sites. The distinctions applied here revolve around the fact that urine drug testing still represents the greatest area of application and experience. Far greater numbers of laboratories and personnel have experience with sample preparation, analyses and PT testing in urine drug testing then any of the other matrices put forward alone or in total.

   It is not, however, necessarily inappropriate to expand testing into new areas. Each of the new matrices put forward has potentially useful facets in drug testing. These are areas of utility ***in addition*** *to* those provided by ***a properly collected and performed urine drug test.*** They revolve around issues of drug abuse history e.g. longer time windows (Hair), follow-ups following re-habilitation (sweat patches) and sorting out recent use from historic use (oral fluid). These are all elements that perhaps should be added as program mandates and laboratories and methods become more sophisticated and able to produce reliable data and PT performance. Adding larger numbers of testing facilities and/or experience bases to this process ***in the contexts noted,*** will by definition, ultimately define what technology and testing limits best apply. Until this process occurs in a larger context, the true 'practical' limits of testing in these matrices remains to be defined. The best use of the new matrices (and for that matter new testing devices) is in support of the existing urine 'gold standard' provided by reliable testing performed in HHS Certified Laboratories. To the extent that testing on the additional matrices would be of value, the minutia provided to govern this consequence is consistent with program expectations for the testing of urine specimens. I find no fault with program expectations in these areas, other then that which will be corrected through changes dictated by experience.

   These 'newer' matrices applications ***should not***, however, be put forward as an answer to urine specimen validity. This is illogical and will lead to increased legal challenge. The most logical and practical answer to the collection validity issue has and will always be to focus on proper criteria of specimen collection. Its time to grow up, this is the 21st Century post 9/11 world and we as a civilization are sophisticated enough to be able to deal with an observed collection when and if indicated. For once and for all, let us deal with the collection issue in the most straight forward and logical manner and finally turn the page on urine specimen validity.

[Signed]

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