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Public Comment 8400042

We gratefully acknowledge and applaud Ken Edgell's comments , and have used his framework to add our own. The sections bolded and italicized include our additional comments to this already eloquently written document.

Respectfully,

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General:

The state-of-the-science for alternative specimen testing is not ready to be proposed for use in workplace testing conducted by the Federal government. It is recommended that until answers can be provided to the numerous and substantive questions asked by HHS, that this document be withdrawn as a proposed rule. At best, this document that acknowledges the "serious concerns," "suspected limitations," "known limitations," incorrect results," and ""conflicting studies" currently afflicting alternative specimen technologies, might be suitable as an advanced notice of proposed revision, but it does not meet the standards required for a notice of proposed revision.

Workplace drug testing must continue to meet the "gold standard" that the testing of urine specimens has offered for the past two decades. People lose their jobs when a single test says that they are drug users. Alternative specimens do not offer the reliability that a single-point test needs. Today, results from alternative specimen testing offers no more than "additional information," such as the information a physician might gain from a diagnostic clinical test. Alternative specimen testing does not provide gold-standard reliability. Commenting on the proposed rule is akin to commenting on pure speculation; there are too many things that the public needs to be assured of before the public can provide the government with meaningful comments. HHS must spend the time to do the work science requires before this actually meets the standards to be "proposed" for use.

As further comments are provided, references will be made at places where the state-of-the-science is so insufficient that it would be impossible to provide meaningful comments.

PREAMBLE

Background and Program History:

HHS almost completely omits any acknowledgement of the Department of Transportation's (DOT) drug testing program. DOT's program affects approximately 12,000,000 safety-sensitive workers across the country. The program accounts for approximately 7,000,000 tests per year. It's "where the rubber meets the road." To make matters worse, the Omnibus Transportation Employee Testing Act of 1990 (OTETA) requires DOT to "...develop requirements that, for laboratories and testing procedures for controlled substances, incorporate the Department Health and Human Services scientific and technical guidelines dated April 11, 1988, and any

amendments to those guidelines, including mandatory guidelines..." 49 U.S.C. 45104(2).

The Federal drug-testing program affects approximately 1,000,000 government employees and accounts for approximately 200,000 tests per year. If and when alternative specimen technology becomes a reality, the pressure will be on the DOT to use it – not the government. DOT's testing accounts for 20% of all drug testing; the non-regulated industry makes up the other 80%. Additionally, the non-regulated segment of workplace drug testing, follows the DOT procedures. Employers do not ask laboratories for an "HHS-like test." They ask for a "DOT-like test." Even the Federal Custody and Control Form has become known as the "DOT form."

It is time for HHS to recognize that the DOT program is regulated drug testing; the Federal program is barely a drop in the bucket.

Had HHS kept DOT in mind, this proposal would have given HHS a great opportunity to develop a "ONE-Government" document, adopting the procedures and format of DOT's 49 CFR Part 40. This proposal acknowledges Federal agencies and their safety- and security-sensitive employees, as well as laboratories and other testing service providers. HHS does not acknowledge that the proposal would affect participants in the DOT program. However, as everyone else knows, HHS rules and decisions have a profound effect on DOT. If Congress stated that the Mandatory Guidelines and any amendments to the guidelines would apply to the DOT agency-regulated industries covered by the Omnibus Act, how can HHS choose to ignore their leadership role and the responsibility that goes along with it? The charge Congress placed on DOT is serious – so is the omission of the DOT program by HHS.

Because the statute requires that DOT "incorporate" the HHS Guidelines, as amended, the draft NPRM, if made final, would impose on DOT a non-discretionary duty to change its regulations to be consistent with HHS' requirements. While DOT has always interpreted this statutory mandate to permit some differences in detail between the HHS and DOT testing rules, it is clear that the major provisions of the HHS proposals (e.g., use of oral fluid, hair, and sweat testing, and reliance on point-of-collection testing) would necessarily have to be made part of the DOT program. HHS cannot properly ignore this relationship, and HHS should have consequently provided an analysis of not only the economic impact of the proposals on Federal agencies and their employees testing service providers but also on the much larger universe of DOT-regulated employers and their employees and testing service providers. HHS states that the effect of the proposal would be to authorize, rather than mandate, specific additional forms of testing. This does not, however, eliminate HHS' responsibility to estimate the costs of these alternatives, to consider the larger industry and the DOT procedures that are used day-in and day-out.

The federal government is not going to implement racially-biased hair testing, or begin an oral fluid program where they still have to collect urine for America's most abused drug, or wait a week to get the results of a sweat testing, or cough up the money to build IITFs. They will not do so because of the flaws and reliability issues inherent to the proposed methodologies. No one is going to put pressure on them to do so, because there is so little money to be made on Federal volume. However, this is not the case for DOT, and the non-regulated industry that patterns itself after the DOT. That's where the money is to be made, and that's why HHS must consider the full picture in everything it does for drug testing. Like it or not, you are the leader in this area. You cannot pretend that you are only leading the few; you have the "900-pound guerilla" in tow as well. This document does not appear to have been written in collaboration with the Federal regulators at DOT. This document needs to be withdrawn as a proposed rule until this collaboration takes place (**Reason #1**.)

The Added Specimens -- Major Change:

The movement to recognize alternative specimen technology began at HHS in 1997. One would think that seven years is long enough to define the problem, assign the work, do the studies, and

get the questions answered. Had it not been for the general slowness of government, uncooperative nature of the test manufacturers ("they'd sooner share a toothbrush than data"), and a little thing called "specimen validity testing," more might have been accomplished. However -- there was, and -- it wasn't.

HHS credits the Drug Testing Advisory Board (DTAB) evaluating "the information submitted by the industry representatives...since 1997." This is off the mark and DTAB would probably qualify the statement by adding that the industry did submit data, but that the original plan was to create "focus groups" of DTAB members to verify the industry-submitted data (see DTAB minutes, Sep. 6, 2000). The focus groups materialized. As a result, cutoffs, for example, were proposed as the result of industry working group recommendations rather than true scientific studies. It needs to be determined, probably by experiment, how the specimen cutoffs interrelate. This is important regardless of whether commercial methods can achieve such cutoffs. It is also a huge body of work that will take a lot of time and money to answer.

The interrelationship of cutoffs is very important in any workplace arena, but especially so for the Federal government. An applicant or employee having a Federal hair test in Kansas City cannot be judged any differently than an applicant or employee in Atlanta who takes a Federal urine test or an applicant or employee in Seattle who takes a Federal oral fluid test. Otherwise, the entire testing program is imperiled because it becomes subject to justified charges that its operation is wholly arbitrary. This is a very real problem in a program that is frequently involved in litigation. The Federal government will demand equivalency for the testing of its employees – and so would any responsible employer, regulated or non-regulated. The interrelationship of cutoffs for the different specimens is a basic question of science that is still virgin territory within HHS. (This is **Reason #2** why this proposal should be withdrawn.)

The interrelationship of test results can manifest itself in other ways: Today, urine testing is the only testing authorized by the government. Therefore, when a Federal employee contests a positive test in court by offering a negative hair test as "proof" that he is not a drug user, the court will ignore the hair test. If this proposal becomes a rule, all specimens will be on the same footing. Now imagine the same scenario as above, but with both tests recognized by the government. What would the court be expected to do? Most likely, dismiss the case and tell the government that they look foolish and to go home and not come back until they can decide what is positive and what is negative.

At his point in time, the government recognizes a single specimen (urine) for drug testing. Even with only one specimen to worry about, the program has suffered a few bumps and bruises over the past few years. Proposing multiple specimens for recognition requires more work by the government than it is currently staffed to handle. Each specimen not only brings its own issues, but also its interrelationships with the other specimens. The degree-of-difficulty is exponential, not linear. This is higher math, and the government has failed the test in presenting its case for using alternative specimens. Meaningful data from peer-reviewed studies addressing the subject of specimen-interrelationship needs to be made available to the public in order for the public comments to be anything more than guesswork. Simply relying on self-serving, off-point scientific articles, or proprietary industry data submitted for an FDA clearance process, or marketing material from manufacturers of alternative specimen tests is not good enough. Until HHS can explain to the public what the testing of a particular specimen means – in the context of the relationship to other specimens from the same individual in the same time frame -- this proposal should be withdrawn.

HHS concedes another set of problem with alternative specimens by pointing out "three serious concerns" that were revealed through the results of government-sponsored proficiency testing: (1) labs are not able to accurately test for all drugs; (2) some drugs are more difficult to detect than others; and, (3) those drugs that are difficult to detect varies by the type of specimen being tested. The solution recommended by HHS is: "That means that special awareness will be required to select the most appropriate type of specimen to be collected from a specific donor, when use of a specific drug is suspected." This is confusing and not supported anywhere in the rule text. One might think that the government is asking that whoever orders a drug test first become a drug-

recognition expert before ordering a drug test. Should one also survey their geographical region to determine the drug-of-choice most prevalent in the area before ordering a pre-employment test. What happens with an out-of-state applicant? HHS has left the reader to figure this one out alone. Making this type of recommendation is preposterous – it shows that little is actually known about alternative testing methodologies, but of that that is known, a lot of it isn't so good.

The "three serious concerns" are scientific laboratory issues to which HHS has offered they be solved by the Federal agency (or DOT employer) conducting the test. HHS then adds, "This public comment period is intended to provide an opportunity for all interested parties to review the testing criteria and associated specimen-specific procedures, to be sure that required performance is achievable and sustainable when implemented. (emphasis added)" This is certainly a task that needs to be done, but by HHS, prior to proposing these alternative specimens for use, not by the public. HHS must validate the testing criteria. HHS must validate that the laboratory performance is achievable, and when achieved is sustainable in a court of law. These are not jobs for the public.

One final point on this issue: Proposals to change government rules do not contain "serious concerns." Use of this phrase is acknowledgment by HHS that the testing of these alternative specimens is so new that even the most competent laboratories in the country are still struggling with the scientific and technical challenges required. Certainly HHS would not let laboratories set their own standards for alternative specimens. All that would accomplish is to set up a repeat of the litigation problems that were experienced with urine specimen validity testing. Before proposing the use of these new specimens, HHS should articulate how it will meet these challenges for each specimen. Until scientific evidence is presented that the testing criteria can produce achievable and sustainable results, this document should be withdrawn as a proposal (**Reason #3**). Gathering the type of information that HHS is asking for (above) is suited to an advanced notice of proposed revision (ANPRM), as previously mentioned. (A novel idea would be to separate each alternative specimen into its own ANPRM, rather than to keep them tied together. That way if one does show merit it will not be encumbered by the others.)

The type of information required is going to take more than 90 days to obtain, which brings up another issue -- the length of comment period: HHS predicted that the comment period would be "about 120 days" (see DTAB minutes, Dec. 4, 2001). For a rule so different and so complex, 180 days seemed more reasonable. Nevertheless, why did HHS shorten the comment period? When the government makes a statement of one intention (e.g., 120-day comment period is predicted) and then significantly changes that position (e.g., shortening rather than lengthening the comment period), the public deserves an explanation.

Alternative Specimens:

Hair –

The racial bias issue for hair testing is an absolute deal breaker. "Federal government" and "racial bias" are terms that simply cannot walk hand-in-hand. To propose a test method with such an issue hanging over it is unfathomable. Why would the government want initiate the "digging up of old bones?"

HHS offers some fifteen references documents on the testing of hair. Twelve of the fifteen references contain cautions regarding interpreting hair-test results with respect to the color of hair. Three of the fifteen references refute the problem of racial bias in hair, not with test results of different hair colors, but with comparative statistics showing similar positive rates for other specimen types, suggesting simply that people with black hair use more drugs than people with light hair. One of the HHS references (ref. No 3: Huestis and Cone) provide a range of information in Chapter 11 of the Handbook on "Alternative Testing Matrices." The chapter covers similar areas for saliva, sweat, and hair, except that their section on hair contains a heading not found for any other matrices discussed – "Racial Effects and Possible Bias." Under this sub-

section, the authors reference three additional papers by R. Joseph et al. affirming the issue, which are not included in the HHS references.

For those studies that administered drugs to individuals and then did subsequent testing, racial bias is defined as the situation where more drug is deposited into darker hair vs. lighter, given equal dosing. For those studies that did not administer any drugs, but rather made statistical inferences of data, racial bias is defined as a statistically significant difference between whites and blacks in the relative rate of positive detections, comparing hair-test results with urine-test results. HHS, in particular, mentions a study by Hoffman (1999), who statistically compared test results for a group of police candidates who received both urine and hair tests. The author cautions: "It should be noted that the conclusions to be drawn from our analysis are quite limited, because of the nature of the available data." The point is – more data are needed.

Specific data from the literature regarding dose of the drug of interest versus drug concentration in the specimen and drug detection time has not been compiled for each drug and specimen and in relation to specific alternative specimen variables (variables might include types of hair, pH of oral fluid, and volume of sweat). Hair has a unique issue with racial bias, but all of the alternative specimens have issues that need to be answered before they are proposed for use by the Federal agencies or anyone else. Government generated data that can assure the public that each alternative specimen meets the gold-standard threshold are lacking. Make this **Reason #4** why this document is not ready for proposed-rule status.

Read the reference papers. Anyone who has tested hair that has been soaked in drugs, or administered drugs to animals or people and then tested that hair, acknowledges the fact that dark hair concentrates more drug than light hair. It is also critical to look at the publication date of the references. The more recent papers are more emphatic that racial bias exists.

In a later section of the preamble ("Issues of Special Interest"), HHS provides their summary of the these reference articles, saying "some studies purport that a drug user with dark hair is more likely to test positive because a drug is more likely to be deposited in black hair as compared to blond hair while other studies refute these findings (emphasis added)." This summation by the government makes it sound like there is an equal split on the scientific opinions toward the racial bias issue. That is not true. Implying so is a very disappointing "bias of a different color."

The variability of drug incorporation along racial lines has been observed by 12 of the 15 reference sources. Those who have not observed the problem are sources closely associated with the hair-testing industry. Does HHS really believe that this is a "toss up?" Be assured the Federal government, nor any reasonable-thinking employer, will never touch hair testing unless science can resolve this issue. Why would the government want to give credibility to a test so flawed that is does not treat people equally? This reason alone (**Reason #5**) is sufficient to warrant this proposal is withdrawn.

On the subject of when to use a hair test, HHS proposes to use hair testing for return-to-duty and follow-up testing. Think about this: 1.5 inches of hair represents a time period of about 90 days. It is likely that the worker will complete his substance abuse education or treatment and be eligible to return to the workplace within 90 days. A return-to-duty hair test should produce a positive from the initial use. Hair testing should not be proposed for return-to-duty and follow-up testing.

Oral fluid --

HHS confesses that oral fluid testing produces "incorrect test results for marijuana." That is a very emphatic statement (which is later repeated). The solution that HHS proposes is that for Federal agencies who want to test for America's most abused drug -- and still want to use oral fluid -- that they must also a collect urine specimen. Why would anyone want to do that? Science has come up against a barrier for oral fluid testing that HHS is proposing to resolve with policy that

will double the cost and double the time of a drug test. Only the Federal government could propose such a procedure.

I would think that the oral fluid industry would want to sue you. I would also think that any employers using oral fluid tests would want to sue the oral fluid manufacturers.

HHS informs us that they will revise the Guidelines "when science is available to differentiate between actual use and environmental contamination." There is a better solution: withdraw this proposal until science can resolve this issue by detecting the metabolized drug (**Reason #6**). People are going to be losing their jobs after positive drug tests. Those doing the firing must be assured that the positive test came from actual drug use and not passive inhalation or some other source of external contamination.

Sweat –

The sweat patch has limited use (return-to-duty and follow-up), a limited number of commercially available devices (1 or 2), and can create either physical (rash) or mental harm (stigmatize) to the wearer. To make matters worse, possible external contamination on the skin before the patch is applied requires the collector wash the donor before applying the patch. This is a list of reasons that make it obvious why the Federal agencies will not beat a path to the sweat-patch door. What is not so obvious is why the sweat patch was proposed for use by the Federal government in the first place. Was it just a slow day, or were you just doing this to appease one manufacturer?

IITF –

Why is this being proposed? Who is asking for these facilities? The preamble doesn't give any insight. HHS does reference the NRC's use of similar urine-based facilities, saying: "the Department has learned a great deal from them." What does that mean? Does this mean, for example, that if you sent in a team of NLCP inspectors to an NRC facility, that the NRC facility would prove to be equal to the screening portion of an HHS-certified laboratory? Or does it mean that if the NRC had to obtain approval from the NLCP to operate their facilities, the NRC would find it cost-prohibitive to do so? Have laboratories indicated that they would like to save courier costs by building and staffing regional screening laboratories? That doesn't seem like a good trade-off, and HHS does predict that it is "unlikely that that the total number of laboratories and laboratory "like" facilities will increase." The question remains: Why you are proposing IITFs?

The preamble does not articulate a rationale for several of the proposals. For example, the preamble could state or cite either a policy rationale or any scientific basis for the major changes the document proposes.

The use of an IITF necessarily involves a further transmittal of a urine specimen and associated paperwork for non-negative specimens (i.e., collection site to IITF to laboratory for confirmation testing to MRO). HHS has not addressed the potential problem of additional administrative error, chain of custody problems, or loss of specimens or paperwork created by introducing this additional step. In addition, DOT and HHS have been careful, under the current rules, not to permit or encourage reporting of negative results to an employer before non-negative results, since employers and other employees could make inferences about screening test results solely from the timing of the reports. Adding a separate step for the IITF-laboratory transfer makes preventing such inferences all the harder. But HHS does not propose any steps to mitigate the problem its proposal could create.

POCT –

Point-of-collection testing (POCT) present a dilemma for HHS: Laboratories have to meet one standard, HHS proposes to have POCT meet a lower one. On the other hand, if the requirements need to be equivalent to the front-end of a laboratory, POCTs will never work.

If the Point of Care tests and IITF will be the same as a laboratory immunoassay, shouldn't the immunoassay be validated in the same way as the laboratory must using the standard NLCP method validation protocol (see EH Taylor and P Pizzo "Evaluation of the Drug Check 9 On-Site Immunoassay Test Cup According to a Standardized Method Validation Protocol" J. Anal. Toxicology Vol. 28 pp190-197 (2004) This could be performed by the manufacturer or distributor and data submitted to SAMHSA or NLCP. In addition, we support the need to submit cups to SAMHSA or NLCP for evaluation to support the claims in the evaluation. This will make it clear to the manufacturers exactly what studies are required. Would each POC manufacturer be subject to inspection similar to a lab?

Use of HHS-approved POCT devices – whatever the quality controls proposed for the devices themselves – necessarily relies on the existence of well-trained and qualified POCT testers. The draft does not contain specific training requirements for POCT testers sufficient for them to be trained to do the job. For example, HHS would need to develop material comparable to those DOT established for urine collectors or a model course such as DOT prescribes for breath alcohol technicians (BATs) in the alcohol testing program, who play a role analogous to that of the POCT collector.

This raises a major policy issue. It is generally acknowledged that, in the present urine-testing program, collectors are the "weakest link." To propose a new form of testing that would put the entire program into the hands of the weakest link is to knowingly introduce the probability of additional extensive errors in the drug-testing program. This would be a problem for testing Federal workers, it is even more of an issue in the DOT universe, which is far more extensive, and involves training far more people.

HHS provides two reference papers that report "little difference in the performance of devices was observed between tests conducted by laboratory technicians and laymen." However, on close examination while one paper had the error rate for both the same, the laymen caused ten times more false positives as the technicians. The other paper had laymen errors at three times the technicians – but the laymen were law enforcement officers conducting roadside testing. Point being – it is highly possible that law enforcement officers, with their training and knowledge that tests must stand up in court, may be more reliable than weakest-link urine collectors (who may be more reliable than employers wanting to do it themselves).

HHS clearly states that it does not expect a POCT device to perform perfectly. In fact, a device need be only accurate on 80% of its challenges to be certified. Stated directly, HHS believes a POCT device is acceptable if it is only right 8 out of 10 times. In §12.12, however, any device error is considered a failure. Every failure has a HHS requirement to be investigated in order to determine if the device should be suspended or disqualified from Federal testing (see §12.13).

A reliability rate of 80% has never before been acceptable in any Federal-testing program. HHS' counter-argument that specimens testing incorrectly positive on the POCT device will be resolved when the employee's specimen is sent on to the laboratory fails to take into account that the employee and the employer become at least anxious and probably upset waiting another day or more for the final laboratory report to clear the employee. That employee could end up being stigmatized by the false perception that he/she is actually using drugs and the eventual laboratory negative only represents that the employee was somehow able to 'beat the test.' HHS must establish criteria which limit to a much greater degree the number of 'acceptable' errors a POCT device can be permitted to make, both false positives and false negatives. If POCTs are going to substitute for laboratory-based drug screenings, then POCTs should be judged on the same scale

as the screening sections of laboratories.

Generally, the POCT subpart of the proposed HHS NPRM provides no requirements for how POCT devices or device lots are to be validated or how they are to be verified as to the accuracy of their day-to-day performance out in the field. POCT devices are usually self-contained units with a limited shelf life that grant the collector the opportunity to test a single employee. Nothing is built into any currently marketed POCT device that demonstrates that the device is performing accurately. Some POCT devices contain a 'control,' but in fact it only measures whether the device is working at all (a much different assessment).

In the proposed HHS regulations, no true controls are required to be run with the devices each day to support the likely accuracy of a particular employee's test, so no assurance can be offered that any particular device is performing properly. HHS only assesses a POCT device brand when it originally certifies it. HHS then relies on the device manufacturer to inform HHS if there has been a change to the device or a problem is uncovered by an Agency that causes HHS to reassess whether the device is to remain certified. HHS instead relies on the laboratory as its backup in the case of false positive POCT readings and is content to remain virtually unaware in the case where a particular device starts to produce false negatives. In its certification process, HHS contemplates no continued evaluation of a device brand as it starts to head towards the end of its shelf life.

The rationale for permitting laboratories to have any and all relationships with POCT device manufacturers and POCT testers, while not permitting such relationships with MROs, needs to be fully explained. It would seem that a laboratory may have at least an appearance of conflict of interest since they (the laboratories) are the first line responsibility for detecting problems in a device in which they had a financial interest. ***Section § 13.19 describes the relationship that is prohibited between MRO and Lab / IITF / POC. What is the rational with a conflict of interest of the MRO and POC tester? Typically the vast majority of tests will be done at an occupational medicine clinic that has the collection and doctor (MRO) at the same location and most of the tests (approximately 95% will be negative). These tests have to be read in approximately 5 min and it would be impossible to "send it out for reading" since the time frame for reading will have past. It seems counterproductive to have to send the Urine to another site for (reading / interpretation) or a laboratory simply because of conflict of interest – this will waste time and defeat the purpose of the POC test. Since the test will be confirmed at a SAMHSA certified lab (where the MRO has no financial interest), isn't this sufficient to create a barrier. Also, if the MRO has to review 5% of the negatives from the laboratory, what is going to be the MRO role ie "gatekeeper" in the process.***

It is the laboratory, after all, that must confirm all POCT screen positive test results and must test a percentage of the negative test results. Either the device has the problem or the tester does. Laboratories with such relationships stand to gain if they mask such problems. The HHS position on the relationships between MROs and POCT testers will potentially cause problems at medical clinics if POCT testers can not work for clinics where MROs are employed. Similar concerns apply to IITFs. HHS needs at least to more fully examine its position on laboratories and MROs relationships with POCTS and IITFs.

Other issues:

In §12.16, Training is required for POCT tester. Is this training similar to BAT Model or Urine Collector model? Will each POC Tester required to attend course similar to the Breath Alcohol Model? It will be very difficult to demonstrate proficiency via internet / CD with the requirement of mock tests / situations.

In §12.13, If an error occurs, the federal agency must immediately notify the secretary. What constitutes an error?

If one out of ten negative specimens are sent to the lab, what happens if the lab determines that a donor is Positive?

Manner of Presentation and Use of Plain Language –

HHS is to be commended for moving to the plain-language, question-answer format that "other Federal agencies" received very positive feedback from the public after using. HHS must be alluding to the DOT's Part 40 in this passage, because nowhere else in HHS has plain language been used (e.g., HIPAA rule). Maybe this will start a new trend.

Plain language is a great idea from HHS, but adopting the DOT Part 40 in full context is a better one. The government should develop one set of procedures that the administrators of workplace programs can follow. Begin by using the procedures set forth by DOT as a model. The DOT procedures are "tried and true" and are already being used on a national basis. Using the DOT Part 40 as the starting point, HHS would then add the scientific standards necessary for conducting a drug test. How simple and unique: a single set of procedures coming out of the Federal government. Better yet, make a joint announcement that HHS and DOT plan to work hand-in-hand to develop a "ONE Government" set of procedures for workplace testing. The public would love you!

HHS Contractor –

The contractor that HHS uses to maintain the laboratory inspection program has a very important role and performs it quite well. HHS uses the contractor for routine bi-annual inspections as well as "special" inspections stemming from particular issues might suggest a problem systemic to all HHS-laboratories. Such a problem occurred about three years ago when HHS discovered that several laboratories had not followed HHS guidance documents implementing specimen validity testing. A special inspection revealed that one laboratory had not followed HHS program documents, was being managed by an individual with bogus credentials, and was possibly guilty of falsifying documents -- a breech of the basic fundamentals of forensic drug testing. After being detected, the laboratory implemented corrective actions to correct their misdeeds and continued with business as normal. Their license was not revoked; they were not suspended. The basis for HHS not doing what many were expecting (maybe even the laboratory in question) was that the laboratory was no longer being an "imminent harm" to its customers to warrant suspension (see § 9.3(k)). This in-action caused HHS to lose a lot of credibility.

It is recommended that HHS drop this language from its rule. There are certain parts of the line that defines forensic drug testing that if laboratories cross, a simple promise of "we won't do that anymore" is not a sufficient correction. The actions of the laboratory in question caused all laboratories irreparable harm; it put "blood in the water" for the entire industry. Think about it, how many people (HHS included) use the term "gold standard" very much any more?

The laboratories, and their clients, pay a lot of money to operate under the HHS certification banner. When HHS inspectors find a laboratory falsifying information, that laboratory should be suspended. "Imminent harm" should apply to errors from test procedures, implemented in good faith, which can be corrected by such ways as changing the science or repairing a machine. Honesty is the basic principal of forensic testing. When a laboratory is found to be dishonest, suspension and revocation should be immediate. In the future, should the contractor present HHS with evidence that a laboratory is falsifying information, HHS should revoke that laboratory's certification. Else it is HHS that is doing "imminent harm" to the rest of the program.

Subpart B – Specimens

Much of this section deals with the windows of detection for the various specimens and how (§ 2.2, reason-for-test chart) the specimens should be used. But in providing this information, HHS "wants

to make it very clear to agencies that there is no requirement that they use hair, saliva, or sweat...(emphasis added)." This is probably very good advice presented in "government code" for regulatory compliance purposes.

The probability for different specimens to detect drug use has not been statistically evaluated or compared to each other. Until HHS can assure each agency that there is equivalence-of-deterrence capability for each specimen, by reason-for-test, agencies should not use them. (**Reason #7** for withdrawing this proposal.) Likewise, most studies on human variations and differences regarding alternative specimens have been done in few subjects with limited doses and, therefore, the applicability to the general drug abusing population still needs to be properly evaluated. Studies need to be conducted with more subjects and a wider range of doses. A huge, but rather basic, question needs to be answered: what are the differences seen between a casual and regular user? The government does not know the answer. And, yes, agencies should not use — much less, be required to use -- alternative specimens until they can be given the answer. (**Reason #8** for withdrawal.)

Subpart C – Drug and Validity Tests

TBD

Subpart K – Laboratory

Confirmatory drugs tests have been conducted exclusively with GC/MS since the outset of the Guidelines in 1988. There were other instruments at the time HHS chose GC/MS, but HHS did not authorize them. The proposal changes 16 years of operation in four sentences. GC/MS is what the term "gold standard" references. Changing gold standard should be done with more than four sentences, just out of respect for the standard if nothing else. For example, HHS could include the "assessment of a DTAB working group that has studied newer instrumentation and technologies."

The ability for Federally certified laboratories to use the newest test strategies is important, and in fact may be essential with the new specimen matrices, but should make its case based on the data it has. After all, HHS has signified this change as a "major change."

Validity tests are a significant part of drug testing. This includes alternative specimen testing. The people who are drug tested are very innovative people. Some of them will cheat. The analytical and quality control requirements for validity testing are not developed. HHS says that they have proposed the same requirements for each specimen, but "information may become available during the comment period to suggest that requirement for each type of specimen should be different." This is another example of knowing so little about the specimens being proposed. This is an advanced notice type of question.

The rule test on this subject requires using "appropriate calibrators and controls." That sounds like urine validity all over again. Do not leave this up to the laboratories to figure out on their own. While quite capable to do so, the laboratories should have like processes. That includes specific boundaries for calibrators and controls associated with some specific cutoff.

HHS writes "the Department reiterates the specific analytical requirements to conduct each validity test for a urine specimen and proposes the specific analytical requirements to conduct each validity test for head hair, oral fluid, and sweat patch specimen collected. The Department believes these requirements will ensure that the validity test results reported by a laboratory are scientifically supportable." The requirements for urine are very specific; the requirements for the alternative specimens are vague. Actually, they seem to be left up to each laboratory to develop on its own. Where is the scientifically supportability in that? That sounds more like the-laboratory-takes-each-test-to-court supportability.

(Reason # 9 for withdrawing this document.) The differences between the development of this proposal for validity testing is night-and-day different for urine compared with the alternative specimens. If fact it is so different that HHS has nothing to propose in these areas for alternative specimens, other than they believe that the laboratories will attain scientifically supportable results. (What does "scientifically supportable" mean anyway. HHS should define *after* they withdraw this proposal.)

(Reason # 10 for withdrawing this document) Although the number of labs available for alternative testing are growing, the business conflicts between them limit the access of the employee to due process. An example is the practice of Psychemedics to require an exclusive relationship with their "distributors" that creates a "monopoly" that a company may use only their laboratory for hair testing (see attached pdf file). This limits the rights of the employee to have a split sample tested if the MRO is doing business with that lab. The guidelines will have to address that if they want the testing to be widely available enough to have an impact.

Electronic Technology –

Despite years of controversy over requirements for electronic transmission, storage, and security of laboratory and MRO results, HHS does not offer recommended changes to address these issues. Barely is electronic technology mentioned. It is time for HHS to develop procedures for electronic signatures and electronic custody and control forms that can be used to send specimens to laboratories. Specimens can still be documented and controlled in a manner suitable to maintain forensic defensibility of the specimen and results. It is long over due for HHS to begin work on this. OMB has required it, but HHS has ignored it.

Comments on Draft Regulatory Text

This is an area where collaboration between HHS and DOT is absolutely required. There should be no difference in the definitions. This is an area where policy and science can get together and agree on wording. The laboratories and the courts, for two, would love it.

§1.5 – The definition of "adulteration" does not directly address HHS' pH adulteration criteria.

A "confirmatory drug test" is a second "analytical procedure," whereas a "confirmatory validity test" is simply a second "test." The distinction is confusing, and appears to suggest that, in the case of a validity test, the second procedure can simply be a repeat of the first one, using the same methodology. If so, this creates a substantive problem in terms of convincing decision makers that the validity testing process is itself scientifically valid (i.e., because two separate analytic procedures are not used). This certainly is a problem that HHS is aware of, with DOT having already encountered in litigation. If there is a reason for this distinction, it needs to be explained in the preamble.

A "dilute" specimen is one with "less than normal" physiological constituents. What is normal? What is the scientific basis for this definition? The definition is vague and has no specific tie to the creatinine concentration and specific gravity criteria for dilution or oral fluid (also potentially subject to dilution).

The definition of an "invalid result" is incomplete. There can be scientifically supportable, but not actionable, results that fall into this category (e.g., an inconsistent creatinine and specific gravity result, or an invalid pH or nitrite).

A "non-negative result" also includes an invalid test?

The definition of "post-accident" test may give the erroneous impression that Federal testing is permitted after any job-related accident (as opposed to a qualifying event defined in other Federal regulations).

There is a definition of something called a "sample," as distinct from a "specimen." The term sample is applied in certain situations but not others. The preamble does not explain the rationale for using one term on some occasion and the other on other occasions (see Table of Contents for Subpart E). The result is unnecessary confusion. Absent some compelling legal or scientific reason, it is probably better to stick with the well-known "specimen" term throughout.

The definitions of "specimen" and "split specimen" would permit material to be subdivided, concurrently collected, or consist of two specimens collected almost simultaneously. The OTETA specifically requires specimens to be "subdivided," and does not provide for concurrent collection or almost simultaneous collection. Consequently, there is inconsistency between HHS' proposed definition and the DOT statute.

"Substituted" raises the issue, noted above, of what "normal" means. Also, this definition appears to fit within the definition of "adulterated", and requires more specific content to differentiate it.

§ 2.2 – The reasons for the assignments of particular types of tests to particular specimens are not well explained and, in some cases, do not make sense (e.g., hair test for return-to-duty and follow-up, oral fluid for pre-employment). Also, how will a laboratory handle a known problem? Will the laboratory have to reject an incorrect specimen? As an example, hair is not recommended for post-accident or for-cause. An employee comes in for a post accident collection. The agency/client has selected hair as their main choice for drug testing. The collector inadvertently collects a hair sample, which is not suitable for post-accident. Should the sample be considered acceptable and tested or should the laboratory cancel the test and ask for a proper specimen to be collected? If the specimen is tested, the results would not be relevant to the period of time in question. If the sample is re-collected there is no way to assure the specimen would be collected in a timely manner.

§2.3 – The mechanism for seeking permission from the Federal agency in real world situations is very unclear; the rule reads as if the decision is being made in real-time. This would be most difficult to do in any workplace setting, but especially so in the case of the DOT program. Also, Federal agencies might justifiably want the flexibility to mix and match specimen types. This option has not been developed.

§2.4 – This section prohibits more than one type of specimen from being collected at the same time, rather than for the same test. This imprecise drafting could lead to problems in practice. For example, it could lead to employers believing they were prohibited from having random alcohol and drug tests on the same occasion at the same collection site, a common practice in the DOT program.

§2.5 – It is not clear how the approximately 100 mg/sample for hair is to be measured at the collection site. How much deviation from this approximation is permitted before it brings the validity of the collection into question? The minimum 3-day wearing time for a sweat patch is not mentioned. Note also that the text in §2.5(c) says "up to" 7 days. The scientific, technical, and policy implications of shorter periods, apparently left to the employer's discretion, are not clear and HHS does not discuss them.

§3.1(c) – There is no information provided here on how validity tests on non-urine specimens should be conducted. This is the kind of uncertainty that has been a chronic problem in urine validity testing in the absence of specific HHS instructions to laboratories.

To make it practical to implement §3.2(c), HHS will need to publish a list of the methods that have been validated at the various laboratories. HHS will need to publish laboratory capabilities on a routine frequency (e.g., as part of the regular, currently certified laboratory listing).

3.2(a) HHS proposes to allow an agency to test for "any Schedule I or II drug of the Controlled Substances Act (other than the drugs listed in section 3.1, or when used pursuant to a valid prescription or when used as otherwise by law)." As written, this paragraph is confusing. Does this mean that the agency must determine *before* deciding to test for a drug whether the employee had a valid medical reason for using that drug?

In addition, this section requires the agency to request additional testing on a case-by-case basis, since "a justification to test a specific specimen for the drug" must accompany such a request. Is there any time limit on when such a request must be made? What would such a procedure require?

§3.3 – This section should, like DOT's Part 40, specifically preclude DNA testing or other identity testing of employees' specimens.

§3.4 – 3.7 – The alternative specimen cutoffs were proposed as the result of industry working group recommendations rather than true scientific studies. It needs to be determined, probably by experiment, how the specimen cutoffs interrelate. This is important regardless of whether commercial methods can achieve such cutoffs. The cutoffs for urine specimens have changed, however there is no basis for these particular proposals to change cutoffs stated in the preamble. It is also essential that the cutoffs for different specimens be equivalent.

Also, the proposed HHS NPRM describes hair sample cutoffs which involve significant additional scientific criteria never before seen in Federal regulations (benzoylecgonine/cocaine ratios, cocaethylene concentrations, and norcocaine concentrations) without explanation of either their scientific importance or technical acceptance (3.4). HHS has never before tested for parent cocaine, cocaethylene, or norcocaine, nor is it clear what the standards or cutoffs for these new analytes are to be.

§3.8 - Some terms (digestion test, dye test) are unclear and unexplained, as are the purposes of using the various kinds of tests. It is likewise unclear what additional validity tests would be used for unconventional coloring of hair that is seen in today's society. In fact, this section provides no information about what validity tests would be used in any situation. This is significant, since in employee challenges to validity testing results, the scientific persuasiveness of the tests chosen is a key consideration. This point applies to all the validity testing sections, and is further evidence of the unreadiness of the document for issuance.

§3.8(a)(5)(i) - There is a reference to abnormal physical characteristics. How will it be determined when there are abnormal characteristics, like "different types of head hair?" Is visual inspection sufficient? If so, how would people be trained to make the appropriate distinctions? Alternatively, is microscopic analysis required? What are the typologies involved, and are they scientifically accepted?

§§3.9 – 3.10 – As in the previous section, the meaning, purpose, and rationale of the various steps are unstated, either in the rule or the preamble. How was the minimum IgG concentration (less than .01 mcg/mL) scientifically determined? What is the purpose of this test (unexplained)? Why is the pH of oral fluid not considered? What are the relevant differences between secretors and non-secretors, for this purpose? None of these issues are addressed. They apply to lactic acid as well. There could also be medical or dietary issues that affect the physical characteristics of oral fluid.

§3.11 - The proposed HHS NPRM requires validity testing for "one or more oxidizing adulterants" (3.11), but gives no guidance on whether a laboratory is free to pick one, two, or even all from the

list provided by HHS in the regulations. This gives inappropriate discretion to the laboratory because an employee of Agency A could be tested for chromium VI, nitrites, pyridine, and halogens, and an employee for Agency B could be tested for nitrites only. Obviously, the employee of Agency B is much more likely to escape detection for an attempt to beat the test through adulteration.

Since Federal agencies are not expert in what adulterating agents they should be testing for, agencies should instead rely on HHS to tell them and the laboratories exactly what constitutes mandatory adulterant testing and what specific oxidizing adulterants must be tested for. This becomes an even more critical concern because a Federal agency could employ multiple laboratories, with each of their applicants or employees being subject to different standards depending on to which laboratory their specimen are sent. For example, agencies that hire Quest or LabCorp will likely have their specimens sent to any of the laboratories in that particular system. Under the current HHS regulation, each laboratory in the Quest or LabCorp system could test for different oxidizing adulterants. Thus, applicants and employees within the same agency would be treated differently.

§3.12 – "Concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present." The meaning of this sentence is unclear. The same point applies in following two sections. It might be clearer to say something like "equal to or greater than the cutoff concentration for the analyte of interest."

§3.15 – Unlike the preceding sections, this section provides some specificity about adulterants and tests for them. The fact that it has so many specifics makes the preceding sections look deficient. Are all specimens being treated equally?

§3.16 – 3.17 – There are no provisions for reporting a hair or sweat specimen substituted. Substitution of hair or sweat patches is a very conceivable response of persons trying to beat the test, and this potential problem should not be ignored. How are collectors to determine if someone is wearing a convincing wig? Substitute, look-alike (with ID numbers faithfully duplicated) sweat patches also appear well within the capability of "beat the test" entrepreneurs.

The basis for the oral fluid IgG concentration is unclear and not explained in the preamble. Also, in §3.16, is the IgG concentration scientifically sustainable? HHS should cite the scientific literature supporting this value.

§3.18 – There should be a section on dilute saliva specimens. A false tooth filled with tap water, that mixes with oral fluid when it is bitten by the donor during a collection, may create a dilute specimen.

§3.19(d) – Change "reasons" to "results." Same comment at §3.20(d).

4.1 (b) - HHS proposes to prohibit the immediate supervisor of an employee from collecting a specimen from that employee unless no other collector is available. Allowing an immediate supervisor to serve as an employee's collector should be allowed only in post-accident and reasonable suspicion testing, where the need to conduct a test cannot be foreseen. For scheduled forms of testing (e.g., random, follow-up, pre-employment, etc.), the employer should be required to plan sufficiently ahead to ensure that a collector other than an immediate supervisor is available.

§4.1(c) - This sentence appears to be attempting to parallel DOT's Part 40, but misses the mark. Try: "You must not act as the collector for the employee being tested if you work for a HHS-certified laboratory (e.g., as a technician or accessioner) and could link the employee with a particular specimen, drug testing result, or laboratory report." It could be problematic in the context of POCT, where the collector always knows at least the screening test result.

§4.2(a) - The requirement that collectors read and understand the Guidelines is overbroad. It would be sufficient if they read and understand the portions of the portions of the Guidelines pertinent to their function.

§4.2 – 4.3 – What is an "established organization" for this purpose? Does HHS intend to establish a list? These sections are also unclear on who, if anyone, monitors or approves a train the trainer course.

§4.4(b) – This would make collection site, employer etc. maintain collector records, a significant paperwork burden. Suggest following Part 40, which simply tells collector to keep his own training records, and is better in this respect.

§5.1 – This section needs considerably more detail on the requirements for a collection site for all media, as DOT's Part 40 does for urine. This section does not address "monitored" collections, as that term is used in Part 40, and "monitored" collections are certainly used within the Federal agency programs.

§5.2 – The text omits restricting employees from access to contaminants and chemicals in the collection area. This should be added here and in §5.4.

§5.3 – The 2-year collection site record retention requirement is significantly greater than that in Part 40 (30 days), which will have a PRA impact.

§5.4(a)(6) - This leaves out important details that have served the DOT program quite well -- Part 40's provisions for standard kits. §5.4(b) assumes tamper-evident packaging for other specimens, but this does not appear to be required in the proposal. Suggest proposing standard kits.

§5.5 – The meaning of privacy in this situation is unclear. It should be specified. This point also applies to §5.7.

§5.8(c) - A reason for collecting under direct observation is that the agency believes the donor may tamper with or substitute the specimen. This appears to say that mere suspicion of bad intent is enough to require an invasion of normal privacy. This is unacceptable from both a policy and legal point of view.

§6.1 – It would be better to have a single Federal CCF with check-boxes to indicate the specimen collected. In any case, HHS needs to actually propose its various forms as part of the proposal.

§7.2(a)(2) – As noted above, it is unclear how a Federal agency or DOT-regulated employer would determine whether a device affects a specimen.

§7.2(b) – It is suggested that HHS rely solely on FDA-approved devices.

§8.1(a) - To avoid difficulties in the collection process in unionized environments, it would be helpful for HHS to very specifically spell out what is required for collector identification.

§8.2 - 8.4(a)(1) and §8.5(a)(2) use a lot of identical language and can more conveniently be placed in §8.1. These sections offer a "free pass" to many employees who may wish to avoid testing. If the employee conveniently forgets or loses his ID, and knows the time or place of the test makes it unlikely that someone from his employer can show up to identify him, he won't be tested. The same repetition point applies to (a)(2) [(a)(3) in §8.5)]. This section assumes there will be an assigned arrival time, which is frequently not the case in any workplace program.

§8.2 – If one is clipping head hair, it makes sense to remove the hat, but why the jacket? However, HHS should specify how collectors are to deal with headgear that employees may have religious reasons for not wanting to remove (e.g., as frequently worn by some Jews, Muslims, or Sikhs). Also, as noted above, there is provision for wigs or punk-style multicolored hair, or for dealing with someone with a buzz cut, or thinning hair. The width of the sample collected to meet the 100 mg requirement might be wide enough to create a bad hair week. Employees will justifiably object. The section makes a welcome exception for lice, but what about other scalp conditions that might reasonably give a collector pause about touching an employee's head?

Also, the section says that the 100 mg requirement "must" be met. What happens if it doesn't? How are collectors to measure it? Is there a "shy scalp" problem that would cancel a test for an insufficient specimen? What happens if the root ends extend in instead of out, or are placed in the envelope facing the wrong direction? If the donor recently had a hair cut, this could easily happen. What about hair that curls so both ends touch? Is this a fatal or correctable flaw? All this intricacy seems well designed to trip up collectors, who we know are easily confused.

Introducing scissors into the testing process (for hair testing) poses problems. An angry employee could seize them and use them as a weapon. A clumsy collector could injure an employer, leading to personal injury lawsuits.

§8.3 – This section seems unprepared for an obvious way of adulterating or substituting an oral fluid specimen, by concealing a capsule with some substance in the employee's mouth, or even in a hollowed-out tooth.

Just how does the collector "confirm" with the donor that he has had nothing in his mouth for the past 10 minutes? Does this provision assume that subjects always tell the truth, or that the collector will constantly watch the employee for 10 minutes? What is the scientific basis for selecting 10 minutes, as opposed to some other time period? If the 10-minute period is necessary, perhaps it would be more prudent to require the waiting period in all cases rather than just when the employee admitted having something in his mouth, or perhaps having the employee wash his mouth with water would be quicker and surer.

What happens if the donor and collector both don't keep the tube in view all the time (this question has come up in urine testing litigation, and HHS should make its view clear here)? HHS should probably specify a wide-mouth collection container, to minimize accidental or deliberate "mis-spitting."

§8.3(8) - Why is mixing necessary, and what does the collector mix the specimen with? There may be a reasonable explanation; if so, it should be stated.

§8.3(15) - HHS refers only to the transfer of the split oral fluid specimen via the Federal CCF. What about the primary specimen? This language is used for all specimens. HHS should speak in terms of "primary and split specimens" in all cases – it is plain language.

§8.4 – The section on adulteration of sweat patches seems to parallel that for urine and some other specimens, but this does not make a great deal of sense. What could someone conceal in his pocket to adulterate a sweat patch? The more real danger, which this section does not address, is the potential ability of the employee to switch the patch sometime during the up to seven days he or she is supposed to be wearing it. As noted above, even if there is a number printed on the patch, a clever entrepreneur will no doubt figure out how to replicate numbers on the substitute patch he overnight couriers to the employee. The draft says the collector should check to see if the donor tampered with the patches. How? Are patches tamper-evident (e.g., do they leave a purple stain on the person's skin if removed, properly or improperly)?

Also, the instruction in §8.4(a)(5) that the donor cleanse the area where the patch is going to go could be problematic if the area is hard to reach, like parts of a person's back. We also wonder how this procedure deals with people with unusually dense body hair -- both from the point of view of contact between patch and skin and the possibility of pain and injury to the employee upon removal of the patch. Does HHS contemplate a requirement that the affected area be shaved to be free of hair? If so, what procedures would be used to ensure the safety of the collector and employee?

HHS acknowledges that "on rare occasions, the sweat patch can produce an allergic reaction similar to that for other adhesive bandage products. When this occurs, the donor shall return to the collection site and the collector must remove the sweat patch and then request permission from the Federal agency to collect another type of specimen." What if the donor immediately notifies the collector of such an allergy, before the patch is applied in the first place? Does the collector contact the Federal agency? Does the collector try the patches anyway to see what happens? What if the reaction is severe – is the collector trained to deal with the medical implications of this (anaphylactic shock, swelling, etc)? What if the collection site is closed when the allergic reaction occurs or the donor has traveled to another city or state? Would removal of the patches by a doctor, clinic, hospital, constitute a refusal? What happens if the employee returns late to the collection site (e.g., a truck driver whose job takes him to the other coast)? Is this a refusal? What happens if the collector fails to remove the patches within several minutes? Is this a fatal or correctable flaw? Must a doctor verify an allergic reaction by the employee (analogous to the shy bladder evaluation)?

In this and parallel sections, there are references to specimens being "appropriately safeguarded." HHS should clarify what kinds of safeguards are appropriate.

There is an apparently incomplete sentence in §8.4(a)(13): Suggest replacing "as having been" with "was." This same change should be made at §8.3(a)(13). In both places, "in accordance with Federal procedures" should be added.

§8.5(10)(ii) – HHS is developing a new "shy bladder" procedure here. Why? This is a prime example of how simple things could be if HHS had just used the procedure that the whole country uses – the DOT procedure. Why reinvent the wheel? There are significant differences with respect to the size of the glasses of water and time intervals involved. The reasons for these differences are not stated. Also, it appears that the new specimen can be 30 rather than 45 mL. Why? Later, in §8.5(19), HHS says that Bottle A alone must have 30 mL. The reason for this deviation from the typical 45 mL specimen volume is unclear and unexplained. If 30 mL is enough to send to the laboratory on the second attempt, why would one use the shy bladder procedure at all if the first attempt had produced 30 – 44 mL? The DOT shy bladder process is missing, with only a vague note to contact the appropriate authority for guidance.

This section needs to be more specific: when does a "shy bladder" procedure start; collector should document CCF; how long will it last: what happens if sufficient urine is not obtained. Without a limited time period, and an explanation of when the clock is deemed to have started, an employee could delay indefinitely providing a specimen without concern about the stalling being characterized as a refusal attempt. DOT has already been through this. They have already written it out for HHS in Part 40. Please consider using it. Doing so will save you time and the public money.

Generally, this section departs from the "Plain style" organization of the document and falls into the "too many subsections" trap of the current rule, which makes it so hard to follow.

§8.5(24) - The concurrence of a higher-level supervisor is often not possible in any workplace-testing program, and this includes the Federal government. This is a responsibility that the collector can handle. ***Allowing the agency or employer to select an opposite gender collector for a***

direct observation is unacceptable in all workplaces. There must be a same gender collector in all direct observation collections. This is a sexual harassment alert to HHS!

This section also provides no description of the role and limitations of the "observer". The proposal is not clear on who is qualified to be an observer, whether this person can handle specimens, or whether he or she must be documented on the CCF.

§8.6 - The proposal requires each agency to inspect each collection site at which specimens are collected for that agency. As noted above, the inspection requirement is a potentially very burdensome provision (there are currently hundreds of collection sites in the Federal Agency testing system and thousands if the DOT and the NRC are included), the costs of which HHS has not made any attempt to estimate.

If it is decided to include an inspection element, once its costs are estimated, the requirement should focus on specimen collectors. Collectors are the risk element in these regulations, not the collection sites, as such. The agency should be asked by HHS to employ such specific evaluation techniques as mock collections where the collector is asked to perform a collection for the Federal inspector. The content of what is to be included in a mock collection must be described by HHS either in this document or in a separate document.

Also, in the DOT and TSA federal employee testing program almost 20,000 random and 1,000 follow-up tests, collected in perhaps a thousand separate locations, were performed in FY 2003 at DOT/TSA work sites (e.g., airport restrooms), not in clinics or at certified collection sites. The sites used were public lavatories closed for the urine collection purpose. It is administratively impossible as well as valueless to perform annual inspections of these sites. This requirement seems to relate to programs that use dedicated collection sites. This is not the case in the majority of Federal testing. This same point applies to the DOT regulated industries program.

§9.1 – This material does not belong in regulatory text, and should be relocated into the preamble.

§9.2 - Although the Standards Council of Canada voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) in 1998, laboratories accredited under that program have continued to be certified for transportation workplace testing under DOT authority, while the responsibility for conducting quarterly performance testing and periodic on-site inspections has been transferred to HHS' National Laboratory Certification Program (NLCP). This section should be amended to make clear that Canadian and other foreign laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as United States laboratories do.

§9.2(a) – This section asserts HHS' authority to review the results of specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies.

The scope of this provision is unclear: is it an indirect reference to the DOT program? If so, it is a tacit admission that the Guidelines do, in fact, impact implementation of the DOT program. If not, it is hard to determine what it does cover. A private employer, not regulated by the Federal government, does not test under the Guidelines' jurisdiction, even if the same procedures are used. However, the breadth of this assertion could result in burdensome impositions on laboratories, which would have to maintain records in non-regulated programs the same way that they do for the Federal employee and DOT programs.

§9.3(k) – The term "imminent harm" has limited HHS' ability to suspend laboratories even for serious problems (e.g., substitution-related mistakes that led to some 300 cancellations of tests and a $400,000 civil judgment against one laboratory). HHS' ability to impose sanctions should not be limited just because the laboratory fires an offending employee and promises to do better in the

future. It is strongly suggested to eliminate the term or finding a less limiting substitute.

§9.9 – Urine testers are challenged for nitrite, creatinine, pH and specific gravity. However, §9.6 (for oral fluid) does not address challenges for IgG, abnormal physical characteristic proficiency, nor even mentions pH at all. §9.7 (for sweat patches) omit lactic acid challenges and abnormal physical characteristic proficiency. §9.8 (for hair) does not mention challenges for digestion or dye testing accuracy, or abnormal physical characteristic proficiency. These appear to be oversights, and apply to the next three sections (§9.10-§9.12, HHS-certified laboratories; §9.14-§9.16, applicant IITFS; §9.18-§9.20, HHS-certified IITFs) for each alternative specimen being tested. Without inclusion of the missing validity testing PTs, urine testing is subject to a higher standard.

The proposal does not include substituted samples in the proficiency testing (PT) requirements for oral fluid applicant laboratory and incumbent laboratory testing, although both sample dilution and substitution could still be an important issue with oral fluids. Also, with oral fluids, HHS does not establish a "no-false positive" substitution criteria for laboratories like it does for adulterated PT samples sent as proficiency tests (PTs). (See also §9.13(a)(6)).

§9.22 - This section would prescribe two inspectors. But elsewhere HHS says one inspector may be sufficient. This should be clarified. In addition, this section and §9.23 do not fully deal with the potential impact of an audit of IITFs, applicant laboratories, and incumbent HHS-certified laboratories when any of these entities are testing more than one specimen matrix.

Even though the audit for each type of specimen can theoretically be conducted concurrently, either HHS will have to dramatically increase the number of inspectors assigned to a laboratory analyzing multiple matrices, or dramatically increase the length of time a normal group of inspectors will have to be in residence for each audit. The inspection costs for multiple matrix laboratories could skyrocket. In addition, HHS will need to retrain a number of its inspectors to be able to evaluate sample types and test technologies for which they have no experience. This will also be a high cost item.

§10.1(c) - The change to 1 percent for blind samples is unexplained. What is the basis for HHS' belief that this is adequate? Particularly with respect to newer methods (other than laboratory testing of urine specimens), which are untested in the field in the Federal employee or DOT programs, a higher percentage (e.g., 5%) might be safer, at least initially.

§11.1(d) – How long must the obsolete procedures be retained? This is a PRA issue and not addressed in the PRA estimate.

§11.3(b) – The RP's qualifications are expressed as concerning "biological" specimens. This may be too general. The same individual may be well qualified with respect to urine but not saliva or hair, for example.

§11.10 – Testing a POCT specimen in the same manner, means re-doing the screening test. What does this say about our confidence in the accuracy of POCTs? What is the consequence if the laboratory comes to a different result from the POCT?

§11.12(a) – HHS should clarify what constitutes an "appropriate detector."

§11.12(d) – What is a "second initial test"? Could there be uncertainty with the first initial test? Why would a laboratory conduct a second initial test? This should be discussed in the preamble.

§11.13 – The laboratory must demonstrate and document various things for "each initial test." Does this mean each testing method (e,g, drugs, adulterants, etc.)? It should be clarified.

§11.14 - The proposal seems to reduce the calibrator requirements for an initial drug test. The

Guidelines require "A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff." The proposal seems to lessen this requirement. Please explain the reason.

§11.15 - HHS has failed to make the case in the preamble why a change from the GC/MS "gold standard" is necessary. There is no discussion of acceptance in the scientific community of these proposed methods for drugs of abuse testing, why some of these new test technologies are essential for alternative specimens, and whether these technologies produce test results that are scientifically sound and legally defensible equivalent to GC/MS.

§11.18 - §11.21 – "Appropriate calibrators and cutoffs" is in appropriate. HHS needs to provide specific direction in this area. It is HHS' responsibility to state what the appropriate calibrators and controls are. Do not leave this up to individual laboratories to determine.

§11.21 – The definition of "confirmatory validity test," used in this section, means a second test, but not necessarily a different analytic method.

§11.22 - §11.25 – These sections are not similar, but should be. There seem to be very detailed procedures, but barely any detail at all for the alternative specimens. In fact, it appears that the laboratories will develop their own procedures. This is unacceptable. HHS must provide the detail for alternative specimens like they have provided for urine.

Terms like "compound of interest" are unclear and unexplained.

§11.27(c) - HHS states that only in cases where an employee's oral fluid test result is positive for marijuana, the laboratory should not report the result to the MRO but should test the employee's primary urine specimen for marijuana and report that result instead. HHS does not provide instruction on what to do if the urine specimen did not accompany the oral fluid.

§11.29(g)(10) – This talks about interference with GCMS runs but omits consideration of what might happen with the other confirmation methods that the draft would otherwise permit. Much of this section duplicates §3.15.

§11.32 – The language on statistical reports does not describe whether a separate statistical report would be required for different types of specimens or for the drugs (MDMA and related substances) added in the proposal.

§11.34 – This is another area where collaboration with DOT would have helped. HHS should include additional specificity found in DOT rules on this point.

§12.1(a) – (b) and 12.3 – Again, this is language that belongs in the preamble rather than the regulatory text. (In fact, it duplicates some of the preamble language on FR p. 19648.)

§12.5 – 100 devices seems like a small number for proper evaluation of devices. At least, HHS should allow itself discretion to review more devices where the situation warrants.

§12.6 – The proposal appears not to require a POCT device to be able to detect specimen substitution or to be certified by HHS in any real-world environment. Validity is mentioned in general, but not substitution, creatinine, or IgG, specifically. There is no explanation of why these issues are not important to HHS.

§12.8 and §12.10 - §12.11 – As discussed in the preamble comments, the application of these requirements in the context of the DOT program are highly problematical, and HHS has made no attempt to evaluate the burdens (even for the Federal agency program itself). How frequent, for

example, must a "periodic" inspection be, and who is qualified to conduct it? Why should agencies, as opposed to HHS, develop a POCT procedures manual?

§12.12 – Why is a false positive not also a failure (e.g., POCT records a specimen as exceeding screening cutoff, and lab determines that specimen is below the screening cutoff)?

§12.16 – Again, the record-keeping burden is placed on the employer rather than the tester, which is a mistake. Also, it should be specified that POCT collectors are qualified only with respect to the particular device they have trained to operate (like BATs in the DOT alcohol testing program).

§12.17 – What is the consequence if a POCT tester or site conducts POCTs without satisfying the minimum requirements? Is this a fatal or correctable flaw?

§12.18(e) – All specimens should be submitted for analysis. The result from the oral fluid specimen needs to be verified to have any validity. Generally, this section again raises the question of why, given the apparent gaps in certainty about the accuracy of oral fluid testing, HHS should propose allowing its use at all.

This section should also contain instructions to POCT collectors on how to dispose properly of urine specimens.

Generally, this section is complicated to read, and individual steps in the process should be spelled out more clearly.

§12.19 – If the tests don't work out accurately, as in the alcohol testing "dry runs," the POCT devices (from the lot, at least) shouldn't be used for testing until they do.

§12.21 – §12.22 – After a POCT test, a positive screening test result is sent to a lab and a negative report is sent to the MRO. These sections slide by one of the main policy questions concerning POCT testing, which is whether the positive screening result should be provided to the employer and whether the employer should then be allowed to stand the employee down. The proposal must grapple with this issue. In addition, there is a timing issue: the employer will be aware of a screen negative result before a screen positive/confirm negative result from the laboratory, resulting in a possible inference of misconduct by an employee who has not violated any rule.

§12.24(b)(3) - Upon written request, each POCT tester is required to provide a donor with copies of his or her resume or curriculum vitae. This seems overly burdensome. The guidelines do not require POCT testers to have positive education and experience requirements (the way they do RPs). This resume / curriculum vitae is overkill, especially when documentation of POCT training should suffice. ***On the other hand, would an employer want to go to court with a POCT tester with limited credentials or an RP with a formal resume? The HHS needs to address the issue of training in light of court challenges.***

§12.26 – The POCT site operation prohibition for MROs means that doctors' offices are effectively precluded from being POCT testing sites. This prohibition **is** overly broad. ***The MRO conflict of interest is designed to prevent the MRO from not reporting an error by the laboratory. How does this apply to the POCT? If the test is negative, the MRO really has no role. If the test is positive, it is confirmed by the lab. As long as the MRO has no financial interest in the lab, how does this compromise the integrity of the POCT? If there are quality control issues with the POCT, make it the lab responsibility to report it. The MRO should be free to choose whichever device works in his environment and in which he/she has confidence. The MRO is free to choose the lab, so why not this?***

§12.27 – The proposal would permit a range of relationships between POCT manufacturers and laboratories. However, given that laboratories are supposed to check the quality and accuracy of POCT devices in operation, would not at least some relationships (e.g., joint ownership, marketing partnership) raise substantial questions about conflict of interest or its appearance?

§13.15 – There should be procedures specified for the transfer of non-negatives from the IITF to the laboratory.

§13.17(d) – An IITF employee must be made available to testify in a proceeding against a Federal employee. For proceedings brought by employees as well as proceedings brought against them (e.g., a suit for unjust termination)? Does the same requirement apply in proceedings involving transportation employers' workers? Who has the right to make such a request? The employee? The employer? The arbitrator or hearing officer? Is this responsibility on the part of the IITF without limit? An employee who wishes to challenge his or her positive, adulterated, or negative test result often does so by making vague allegations about the quality of the procedures used in his or her test. Historically, DOT has taken the position that testing personnel should be required to testify only if the employee can identify a credible challenge to the integrity or accuracy of the testing procedures used in the employee's test, and that such testimony need not be in person, and can be done by telephone. (Comment also applies at §11.32 re. laboratory personnel and at §12.26 re. POCT personnel.)

§13.19 – 13.20 - It is the laboratory, not the MRO, who will primarily be overseeing the IITF. Therefore, the greater possibility of conflict of interest is with laboratory-IITF relationships, not MRO-IITF relationships. These provisions place conflict of interest-related prohibitions on the latter, not the former. This seems backwards.

§14.1 – This is an area that screams for collaboration with DOT. DOT MROs who have completed ASAM, ACOEM, or AAMRO courses before HHS approves them under this draft should not have to re-certify because their training occurred before HHS approval of the courses. There may be a need for retraining for MROs if all the proposals go into effect, but this would not be a function of HHS approval of courses.

HHS's review of MRO testing entities will be "objective," but nowhere is it indicated what the objective review criteria will be or who will develop the criteria. Absent such explicit criteria, the review would inevitably become subjective.

The absence of the requirement that an MRO be knowledgeable about controlled substance abuse disorders is a glaring oversight. Not only is it in conflict with Part 40, but is a dis-service to those employees who have to deal with a health care professional who does not understand the disease. Many times, the first interaction of the employee with a health care professional is with the MRO and it therefore sets the tone for future interactions with people who are struggling with a shame- based illness. It behooves the MRO to be knowledgeable about the disease to be able to address the employee at least as just another sick individual, and at best as a struggling soul who needs help. A compassionate interaction can be the difference between someone who reaches out for more help and someone who dives further into their self-destructive behavior. Further, the MRO must interact with the SAP and needs to know the process from their perspective.

§14.3 – This section is much less detailed than, and differs from, the DOT MRO sections. HHS should use Part 40 as a model and specifically define all fatal flaws and correctable flaws.

Is a hair sample subject to being rejected if it comes from a source other than the head (e.g., underarms)?

§14.4(b) – The legitimate medical explanation burden on the employee is harder in the hair context – how is the employee to document or remember what happened months ago? How is the MRO to know whether a prescription obtained 30 days before the test explains a result that might indicate drug use 90 days before the test?

If there is a legitimate medical explanation for the hair test invalid result, the MRO cancels the test. If there isn't such an explanation, the MRO also cancels the test, the only difference being a retest (should it be a different specimen?) is ordered. If the same result occurs, this is the end of the process. What does an agency do if they need a negative result to put a worker to work? Do two invalids equal one negative? Same point occurs in §§14.5 – 6.

§14.7(d) – The MRO is subject to the usual special instructions for handling a urine positive for opiates, but there are no parallel instructions concerning opiate positives resulting from the other types of specimens. This oversight should be remedied.

§14.7(f) – If an IITF finds an invalid, it need not go to confirmation testing to see if a valid result can be obtained, but just goes straight to the MRO? This is not good policy.

If a donor provides a valid prescription that explains the invalid result, a second specimen is collected under direct observation. This is contrary to Part 40. If it is to be the procedure, why even interview? The donor will rarely (once, in my experience) admit to tampering the sample, and it gives the donor a heads up that another test is coming.
I recommend that no interview be required and another sample be collected immediately under direct observation for all cases of invalid tests.

§14.7(g) – This section would require direct observation recollections in all cases where a laboratory rejected a specimen for testing. This is an expansion of the use of direct observation testing for which there is no good policy rationale. Rejected-for-testing can occur through no fault of the donor.

§14.10 - Many C/TPAs have one or two people conducting the random selection draws, collecting the specimen, and verifying the test result. Also, some employers have employees who conduct the collections. Permitting some of these people to be POCTs could lead to confidentiality problems. These problems are more important to address than the MRO-POCT relationships on which the HHS concentrates more attention. Confidentiality issues could arise on screening tests that are positive and have not completed the confirmation process at an HHS certified laboratory.

§15.1 – Requiring the employee to request a test of the split specimen in writing is unnecessary. This places an unreasonable burden on employees in many situations in the Federal program ,not to mention the transportation industries. If the split is lost, then the original test is cancelled (HHS forgets to say this), and the ensuing test, in the urine context, must be under direct observation.

§15.2(c) – Why does this section apply "for urine only?" The second laboratory must, rather than should, conduct the same validity tests as on a primary specimen ("should" is a word for guidance, not rules).

§§15.3 and 5 - These sections appear identical, and could be combined. Ditto for §§15.10 and 12.

§15.13 – This is a very long, complicated section that should be presented in a more understandable way. A chart would be a good idea.

The use of the word "and" is confusing in these questions. What HHS means is that if the specimen fails to reconfirm, but tests for something else (adulterant), then subsequent actions occur.

§16.3(c) - There is no basis or rationale for the one percent threshold in this paragraph. As noted in the comments on the preamble, it is unclear how an MRO – who sees only a fraction of the output of a collector or laboratory – could know when this one percent threshold is reached. Also, stating a hopeful "expectation" in the second sentence is not a regulatory requirement, and as such should be in the preamble, if it is not too hollow to put anywhere.

§16.4 – This section includes what are, in fact if not name, additional correctable flaws. Not clear why they are separated from §16.2. In (c), not clear if there are any consequences if MRO does not obtain the statement.

Subpart Q – While there is nothing objectionable about this set of procedures, HHS should make it clear that these procedures do not in any pre-empt or interfere with DOT's ability to take PIE action against a laboratory that violates DOT rules, as currently specified in Part 40.