**Drug Testing Advisory Board**

**Open Session**

**September 14, 2004**

**Agenda Item: Welcome, Opening Remarks.**

DR. BUSH (HHS): We will open this session of the Drug Testing Advisory Board, September 14th. Our plan is to be in open session from 8:30 until 11:15 a.m.

I will stand in for Bob with a few opening remarks. Bob, as I said, is stuck in traffic and can't even gauge when he will be here.

A lot has happened since we all last met. I will just tell you one big thing. We moved. Our phone number has changed, and our fax number has changed, and our email address has changed. Our street address changed. Everything changed.

There is a sheet at the sign-in desk that tells you where we are located, how to find us, how to get information to us, either through U.S. postal mailing address or overnight packages. We have a new main office phone number and a new fax number. Our old email addresses are going to work for the longest time coming. So, we are not going to send that last mail message out quite yet. The most interesting thing about this move, and me sharing the new phone number and the new fax number with you is, our old numbers did not accept a forwarding message. We all have to call in to our old phone number to retrieve those messages, and we don't know how long that is even going to go on, if we are going to have access to that for 30 days, 60 days, or 90 days. It is like a black hole. It is like a major disconnect.

We apologize for that, but we are going to try to put something on our web site with this information. Most people try to find us through the web anyway. Hopefully that will be a good mechanism for the rest of the world to find us. It is kind of ironic. We have so much going on now with the proposal that is out, and implementation of new specimen validity testing coming up. People have questions and, unfortunately, there is a disconnect. We are going to try to recover as much of that as we can. Bear with us, and hopefully we will get a good, solid voice mail system on this new phone number. It is not there yet. We are having difficulty with that also.

Like any move, we are having our challenges. Try to contact us by email, our old email addresses, should you have any difficulty at all, and we will respond immediately to that.

Now that I announced the location of the new building -- 1 Choke Cherry Road, Rockville, Maryland -- this new building is quite beautiful and has good meeting room space. We will easily be able to have all of SAMHSA's advisory board meetings at the new facility. We will be able to start booking rooms and planning meeting events there on October 1. Our plan is to move the next Drug Testing Advisory Board meeting that is in December to the new facility.

Again, for all of you who are here and who have signed in, give us your email address and phone numbers. My most able assistant, Giselle Hersch, emails everybody reminders about where the meeting is, what the sessions are going to be about, and the location. We will let you know in more detail when we select the dates, which

will be the second week in December. That is the way it looks right now. We will decide that later when we actually can physically document the room space.

We will have a public comment session at the end of this meeting. I would appreciate anyone who wishes to make public comments to come see either Walt or me, let us know who you are, identify yourself, so we can allot appropriate time for public commenters.

**Agenda Item: HHS Update.**

DR. BUSH: I will talk to you about how busy we have been from a technical side of things. Recently, the end of August through September 3, there was a joint meeting of the Society of Forensic Toxicologists and the International Association of Forensic Toxicologists, held in Washington, D.C. This was also part of an FBI sponsored workshop symposium. So, we had quite a gathering of international forensic toxicologists to both learn and share information. There were approximately 1,200 registered for that meeting. It was probably the most awesome meeting of technical expertise that I have ever been a part of.

I am happy to say that we were able to make a presentation there. Again, here is a handout that was out front, showing you, documenting where the meeting was, the dates.

SEE ATTACHMENT (1)

I want to call your attention to one page from the meeting abstract book. We put a good bit of time and energy into a study that we entitled, "Confirmation rates of initial drug assays in a group of HHS-certified labs, January 1 through December 31, 2003." This is all federally regulated specimens. The authors were Donna Bush, Mike Baylor, John Irving, John Mitchell and Craig Sutheimer. The abstract is the following page.

I would like to present to you, as a powerpoint presentation, the poster that we presented.

SEE ATTACHMENT (2)

At these scientific meetings there are generally two ways to make a presentation, one from the platform where there is a 15-minute allotted time to present powerpoint slides that document more fully what was stated and summarized in that abstract. The other method of presentation is called a poster, where you are assigned a space, in this case a 4 by 4 feet space, to show pictures, essentially capture the data, however you want to present it, and tell the story in a poster format.

I did not bring that poster, but we did take each part of that poster and prepare it as a powerpoint presentation. The abstract really summarizes the data. We will just go to the first page, actually the second page, of the glossy handout, which is the poster itself, the powerpoint version of the poster.

As the Department of Health and Human Services moved to expand the analytical methods and the approaches to drug detection and the biological matrices allowed as specimens and workplace drug testing programs for federal employees, an in-depth analysis of current practices was initiated. Of particular interest was the specificity

and cross-reactivity currently found in HHS-certified laboratories. The specificity of the immunoassays associated with urine drug testing has long been a subject of discussion among forensic toxicologists. While it has been known that, for some drug classes, immunoassays have very high rates for the confirmation of presumptive positives, it is also recognized that other drug class immunoassays produce a significant number of presumptive positives that fail to confirm, when subjected to confirmatory testing by GCMS, for those drugs identified in the mandatory guidelines. These observations led to an examination of the immunoassays currently used, with the goal of documenting the possible differences in specificities and cross-reactivities of the technologies.

I read that to you because I could not paraphrase it any better than that. A lot of what we hear, and what was behind examination of these technologies are as point of collection testing devices that are used in urine drug testing that are becoming more pervasive in private-sector drug testing is, we hear from laboratory RPs (responsible persons) and lab directors that they get a myriad of calls saying, well, the specimen that you as a laboratory reported back to us as negative, that specimen tested positive here at our work site on a point of collection test. The next statement is, why is your lab wrong. Unfortunately, our drug testing system has been around for so long that people really may forget what a comprehensive testing process goes on in that laboratory.

We have the forensic receipt of the specimen, and that an initial test is performed in that laboratory with FDA-cleared reagents under exquisitely controlled conditions, with instrumented analytical devices, instrument read endpoints, trained technicians and technologists, and a clear knowledge by those of us with a laboratory and drug testing background, that a screen is just that, an initial test is just that, and that, when a specimen tests presumptively positive on that screen, it has to go for more work.

We have told this story time and time again, but it really hits home in private-sector drug testing when people come up with this disconnected result, a screen positive on-site, and then a result from a laboratory who has done further testing through the confirmation testing that has a different result. Not only that, we hear from our laboratories, sometimes, how the screening reagents are working, how the initial test reagents are working, and the confirmation rates that they get when they submit the presumptive positives for mass spectrometry confirmation.

A lot of this is done just to keep an eye on the specificity and the sensitivity of these FDA-cleared reagents. We do validity test cross-over studies when lots change. Lots do differ a little bit. We want to make sure it is a very little bit.

Then, there are just some drug classes, like amphetamines -- we will use that as an example - where the chemical structure of the analytes that we are interested in, the amphetamine and the methamphetamine, are very similar to other compounds in the cough and cold medication aisle in any pharmacy.

The beauty of the mass spectrometry of the confirmation procedure is how we can separate through the chromatography the different compounds that may be interfering, that may be producing this immunoassay result, and then we can fingerprint them. We can separate them by the gas chromatography part, and then fingerprint them by the mass spectrometry part of the procedure. It many times gets lost on people who are not as familiar with testing, and we also wanted to see, how do the different products look compared to each other. In our study, we just included data from 11 SAMHSA-certified laboratories encompassing nearly 4 million specimens tested under federal

mandate during 2003.

It is notable that this number, 4 million, represents between 55 and 60 percent of all federally regulated specimens tested in accordance with the guidelines. The data were obtained from labs using different immunoassay kits, different screening technologies at the front end, all very similar in concept but different in branding and details on how they make their product. These were CEDIA enzyme immunoassay, two different types of enzyme immunoassay, and KIMS technologies as the primary initial tests. Some labs conducted additional screening, additional testing, of the presumptive positives with FPIA, fluorescence polarization immunoassay, as a second initial test. This second initial test, the second screen, becomes very useful for some laboratories, especially in that class of drugs, the amphetamines, where you have a myriad of compounds that may be honestly reacting with the initial screen, and then cross-reacting with it. The FPIA seems to have much more sensitivity and selectivity to identify and move forward the specimens containing methamphetamine and amphetamine.

Once you have all this data, you have to figure out a way to present it. We made tables and graphs, trying to portray this for those who best see things through numbers, and also best see things through histograms.

Because this was an international meeting, we iterated, that we had a regulated industry and a non-regulated industry. So, these are the cutoffs for both the initial test and the confirmation test. Again, a little bit more detail there on the screening assays that the selected laboratories did use.

Here are the results. You do have this in a glossy handout, so we can take a look at it. You can see it on the screen, but probably better on the panel in front of you. I want to show you, we will look at marijuana metabolites confirmation rate first, because marijuana is, and probably will continue to be, America's favorite illegal drug, and that is shown to us by data analysis and evaluation every time we look at it.

In the table, the laboratory which was identified simply by number, 1 through 11, the number of samples or specimens tested by that laboratory, the type of screening assay that they used, the screening presumptive positive rate, four, that laboratory for those samples tested using that assay, and then the number of samples that submitted to confirmation followed by what percentage really did confirm positive, and then the overall total positivity rate using the samples tested as the denominator.

We can go down to the bottom panel where I have a histogram for you to see. We blocked it by type of assay used. CEDIA was used by 2 of the laboratories, which we identified as lab number 7 and lab number 5 and show you, then, through the bar graph the confirmation rate, that overall confirmation rate, using that product in those particular laboratories. There is a space and then we move on to those laboratories that used enzyme immunoassay and there are two different kinds of immunoassay, but here we have the DRI kits that are used here. You can see the positive confirmation rates using that technology. There is a space and then we move on to those laboratories who use KIMS as the screening technology.

There are definitely differences among the technologies. Now, every one of these is a true and confirmed positive. So, the drug is there. It is just taking a look at, under the most controlled conditions, how do screening tests work. How well do they work. How well do they identify the presence of legitimate drug in that specimen.

Early on, when we were pulling this study together, certainly the

laboratories were interested in this also. This is very good information for them, because laboratory systems look at labor hours, reagents, consumables, and instrumentation time. For moving specimens that are identified as presumptive positive on through confirmation.

There are costs to all of that. So, the laboratories were interested from that standpoint, but I found a great deal of interest at the meeting from the reagent manufacturers who were actually very interested to see how their products were functioning in the drug testing laboratories. Some of this was a revelation to a whole bunch of people all around town.

Cocaine. I am going to step up the pace a bit, but I wanted to take my time on that first one to show you how we thought best to present it. Looking at that table again, we have the same laboratories. Obviously, if they are SAMHSA-certified, they are testing for these 5 classes of illegal drugs of abuse, and then moving on through the samples tested, using their technology and their positive confirmation rate, the overall positivity rate. You can see then graphically showing that the cocaine assay, no matter who makes it, really is sensitive and specific in identifying the cocaine metabolites.

Do you have any questions, board members, at the time?

PARTICIPANT: At the bottom of page 3, you are talking about screening assays for EIA-DB, EIA-DRI.

DR. BUSH: The two different manufacturers of that, right.

PARTICIPANT: Then on your tables, for example, for marijuana, you just had the EIA-DRI. I didn't understand.

PARTICIPANT: Only the Dade Behring was used for amphetamines. None of the laboratories chose, on the regulated samples, to use it. They stood with the EIA-DRI, and only a couple of them went with the Dade Behring. I think one of the labs that uses CEDIA actually uses Dade Behring as well. You will notice on the last one the grouping is there.

DR. BUSH: For example, under the assay type, let's just talk about marijuana, because they are all used the same way, all the EIA came from the DRI source for that reagent.

PARTICIPANT: All the laboratories using EIA use the DRI form of it.

DR. BUSH: For that assay. You will see 2 different types of EIA manufacturers of EIA when we get to the amphetamines.

All right, we will move on to phencyclidine analyses, on page 7, and take a look at those tables again. We have a very low positivity rate. There is no doubt about that, and I know that people in certain areas of the country rarely, if ever, see a phencyclidine positive. I am here to tell you that I am from Baltimore, and that is one of Baltimore's favorite illicit drugs. Philadelphia, Los Angeles, St. Louis, there are other cities that see resurgences of this drug from time to time. We need to continue to pay attention to it. I can honestly tell you that there are real, live, honest, federally regulated

drug tests that are positive for phencyclidine. So, it is used.

Even in the regulated industry you wonder, since it is such an unusual drug, it is a drug that produces a feeling of schizophrenia, so why would people go after it. Apparently, some like that.

We had a very low positivity rate. Actually, that positivity rate, we went to two decimal places. The reason we went to two decimal places looking at all of these analyses, wrestling with the idea of statistically significant figures and significant figures on their own, we went to two decimal places because PCP drove us to it. If we didn't use that second decimal place, we would have all zeroes and defeat the purpose of our analysis. That was something else we had to think about.

You see that, in this table, under laboratory 10, you will see that. This is an example of a laboratory that used KIMS as their chosen assay type to analyze 520,295 samples. Then they chose to take their presumptive positives from the KIMS analysis on to testing through the second initial test, FPIA. So, how this table reads, then, of that more than 500,000 samples tested positive by the KIMS test, KIMS identified 281 of them. 281 of them went to FPIA analyses and then, if you move on over to samples submitted to confirmation, you will see that FPIA identified reduced the number, screened out a few more with cross-reactants, possibly dextromethorphan, which is a highly cross-reactive compound here, on to 205 here that went on to confirmation. Even then, the confirmation rate was only about 81 percent.

Trying to show the world in numbers about what screening tests give you. They give you good negative results, and that is their purpose, actually. The intent is always, and has been from the beginning of the development of these guidelines, to have an initial test that is going to give you an accurate and reliable negative result, and have that result quickly reviewed, evaluated and out the door to the medical review officer, rather than identify whatever segment of that population necessarily had to go on to confirmation to confirm or identify the drugs that were present there.

You can see a smattering of performance here across the different types of CEDIA, EIA, DRI type kits, and then KIMS, with the one KIMS used at lab 10, and then screening with the FPIA in addition to that, a second screening.

PARTICIPANT: The RTI folks and everybody, did you look at all the variables that might impact on why the rate is different between the labs using the same test kit? Was it the analyzers?

PARTICIPANT: The big problem is they are not testing the same samples. They are sampling their own patient population. A number of these populations come from dramatically different areas, especially when you go to the amphetamine. There is one amphetamine on the Dade Behring. It is like Miami having cocaine on the money, they probably had methamphetamine on the money. So, some of that is regional. We did not have all the laboratories test all the same samples. Then you could look at this kind of variation and say, okay, maybe with a different analyzer there is a different reaction. A lot of this is probably population.

DR. BUSH: As a follow up to that, if you turn to page 11 on your handout, you will see the acknowledgements to the laboratories who participated in this study. We got six for,

with Barry Sample and the Quest Diagnostics lab system. Then we had Stan Kammerer with Clinical Reference Laboratories, David Kuntz at Northwest Drug Testing, Pat Pizzo at Kroll Lab Specialists, Jennifer Collins at MedTox Laboratories, Stuart Bogima at Advanced Toxicology Network, and Lance Presley and Barbara Rowland at LabOne.

You can see the point that Craig was making about possibly the different specimen donor populations that these populations might have, just based on their sheer location, when you look at their addresses and where they are in their certified lab list. That might be part of the reasons.

Let me go back to page 7, phencyclidine data. What I want to do, let's come down to the histogram. I want to emphasize, you see here, this is a little bit of a divergence, a little lesser confirmation rate, lower confirmation rate here with phencyclidine, when you compare back to the fairly high confirmation rate that we saw with cocaine and with marijuana metabolites. You see, even in a laboratory test system, not all initial test PCP positives go on to confirm, and that is the point.

We want to look at our laboratories and then also, how are we going to look at point of collection testing devices in the future. We all know that is part of what was proposed, in the proposal to revise the mandatory guidelines, April 13, for the future. We have to evaluate, what is life in our laboratory, what is testing life in our laboratory like now, and what can we learn from that and what can industry learn from that to make a better, different system for point of collection testing devices for the future, if that is what is needed.

We will go on to page 8, the next drugs of abuse. Let me see, we have amphetamines. Amphetamines is that class of drugs that has the most and varied number of cross-reactants. We have more laboratories who use a second screen, a second initial test, and I think you can see that here with the data I am showing you. Some use a first initial test, and then take the specimens on to FPIA for further evaluation of those presumptive positives by the first method.

If we just take lab 7 as an example, if that laboratory's total number of samples tested was 288,508, with the CEDIA testing technology, that CEDIA testing technology then identified 1,852 as presumptive positive for an analyte in the amphetamines class of drugs. Those 1,852 presumptive positives by CEDIA technology were taken on to fluorescence polarization immunoassay, FPIA, and then honed that number down, reduced that number, down to 1,055 that went on to confirmation. You see that the confirmation rate is still very low. Even a second initial test has a hard time winnowing down the cross reactants from that first screen. It is just a fact that point of collection testing devices can be no better than this, because these are liquid reagents used under the most controlled conditions.

We are trying to help people with this data understand better how detailed testing technology gets. Let's go to the bottom graph and take a look at the CEDIA. You have got a couple of labs that use CEDIA as the screen and they go on to confirm at a rate of 39 percent or 46 percent. If a lab links CEDIA with a second initial screen of FPIA, then the confirmation rate jumps up to about 69 percent, but still less than what you would like to see, or what we saw with marijuana and cocaine. Similar, then, the same idea going on to EIA with Dade Behring immunoassay kits and KIMS mixed with the FPIA as the second initial test.

We will go to six and take a look at opiates because this is quite a telling

story. That is why I didn't want to forget this one, of all. Looking at that initial test, there were no secondary screens used in these analyses, but you see the number of specimens that screened positive that went on to confirmation, and the confirmation rate being extremely, extremely low, somewhere, looking at the abstract, 17 percent. The lowest rate was 17 percent and the highest rate was 56 percent. There is cross-reactivity going on, with that opiate metabolite screen. The screen is hopefully designed with its eye specifically on calibrated to morphine or codeine, with a good cross-reactivity, then, to morphine, codeine, 6 acetylmorphine. Other opiates, other synthetic opiates, other prescription medications that are not part of the federal drug testing program clearly are what is identified in that opiate screen. When we go on to confirm for morphine, codeine, 6 acetylmorphine, we get very low confirmation rate, because of the nature of the antibodies and the nature of that opiate initial test.

Now we can go to that overall rate, page 9 of your handout, and up there on the screen. Just taking a look by drug now, just by drug. The presumptive positive rates, using the different immunoassay kits for THC, benzoylecgonine, opiates, PCP, and amphetamines. That is the overall presumptive positive rate, screened positive rate. If we turn to the confirmation rate, then, from those screened positives, they are portrayed on that histogram.

The conclusions are, this study evaluated the presumptive positive rates and the confirmation rates for primary initial tests by immunoassay method, as well as paired immunoassay methods, primary initial test plus a second initial tests, from 11 SAMHSA-certified laboratories, each testing unique specimens. As expected, some assays and technologies appear to better identify specimens containing analytes of interest at or above the administrative cutoffs required by the mandatory guidelines for federal work place drug testing programs.

We are planning to write this up as a peer reviewed article, a full fledged article to publish, not just as the abstract that was published at this meeting, but in a journal, likely Journal of Analytical Toxicology since this information was first published at the Society of Forensic Toxicology.

The last conclusion, then, and worthy of thought here, while the study assesses current capabilities of existing technologies from a large population of real federally regulated work place specimens, it also provides information that may be useful in formulating future guidelines by which newer technologies and approaches may be evaluated. Any questions from any of the board members?

PARTICIPANT: I know that these probably included PTs that are submitted by the agencies for the laboratory. You just got the numbers, not like individual sample numbers, to be able to sort those out. Those would be drug specific and probably not have other things like the synthetic opiates and things in them.

DR. BUSH: Right, and that is a very good point, but since we are dealing with laboratory reported results, there is no way for that laboratory to know the identity of the sample or the specimen, sample meaning a PT, specimen meaning a donor specimen. We do not require a huge number, a large percentage, of specimens submitted to be performance testing materials. Looking at the overall number of specimens tested, quite honestly, many of the performance testing specimens submitted by the agency are negatives. They

want to make sure they are identifying the negatives and, oh, by the way, very definitely examining the positives. I think the larger number of specimens that go through performance testing specimens are going to be the negatives. For those reasons, we understand that performance test data is nested within these specimens analyzed, but that is as good as we could get and as fine a detail as we could get from a laboratory report.

PARTICIPANT: It is my understanding that, under secondary contract arrangements through a new contract that we have, through our national lab certification program, we are going to be collecting information from the medical review officer of the process for a fairly large and substantial number of test results that will look in aggregate at the information that it will certainly, to my belief, that it will tease that out. Am I correct on that? That was one of the design issues that was deliberately built in, was to finally, after 14 years, get to a point of being able to differentiate between those QC specimen results that gets beyond what is reported just through the laboratory itself. Is that correct?

DR. BUSH: That is correct. Actually, I understand that that contractual agreement was entered into just within the last few weeks or a month. It will take some time to get that evaluation process into place, and looking ahead down the road to gather data and analyze it. We will have to take some time to get it into place, but we definitely plan to report that here at the advisory board and any other means that we need to get the word out.

PARTICIPANT: Also, along those lines, it might ease your mind to know that the blind PT samples is a very small percent, with a maximum number of samples that go into the labs out of the actual samples. Let's say that is one percent. Seventy five to 80 percent of those are negative. You are talking about a fraction of a fraction of a percent that would be positive that is split between the different type classes. So, it is going to affect those percentages that we are seeing here, if any, at the second decimal place.

DR. BUSH: Right, and that is where PCP as a drug class would be influenced the most, but not for the others.

PARTICIPANT: It is definitely a positive for PCP.

PARTICIPANT: It is a fractional effect in terms of positivity and, if anything, it is enhancing confirmation rates in the sense of being a fortified drug matrix. If anything, confirmation rates may be slightly worse than what the data would represent in terms of the blind QC.

DR. BUSH: Correct, point well taken.

PARTICIPANT: Didn't you at one time look at the overall positivity rate for all labs and all techniques, not just on this study, which is broken down by technique, but just the total positivity number?

PARTICIPANT: I think back around 1992 or 1993.

PARTICIPANT: No, more recently than that, in about the last two years.

DR. BUSH: As part of how we prepare, as part of how the NCLP prepares for inspections of laboratories and the preparation of records to be viewed and examined at those inspections, we do collect some of that non-negative specimen data. We do collect that, but that is as a working part of how we prepare for inspections, and what documents laboratories need to have ready for an inspection.

PARTICIPANT: It might be interesting to compare that number.

PARTICIPANT: We had actual data to represent the numerator. There were assumptions that we had to make in terms of the denominator.

DR. BUSH: That is right.

PARTICIPANT: In terms of the denominator representing the total number of specimens tested, and that was a difficult number for laboratories to accurately provide above and beyond an estimate that had certain assumptions in terms of regularity over a period of time.

DR. BUSH: Honestly, that is why we constructed this study as we did, so that we created the template for the laboratories to fill in the exact number, and ask them so that we would have one consistent denominator and we have not thrown away that macro or that program.

PARTICIPANT: It might be interesting to compare that to this data, when you do the next step, because it will involve some other analytical screening techniques which are not included specifically here.

PARTICIPANT: One thing that is very powerful in your study is that it is a learning opportunity. There are differences by technology and by drug class. One area that we are seeing an upswing and interest, especially in the western states, is the area around amphetamines and the concerns that a number of the governors have, and the issues around the exposure of young people to methamphetamine laboratories and the aftermath in those areas. There is a great deal of concern. It ranges from Nebraska out to the west coast and up and down along those whole area. I would imagine, as time goes on, there is going to be more interest. If you look at the data that is in here and tease it out in your own way, you will find several areas that you can, if you are in the industry, if you are in a lab, you might find some specific hints that would be helpful for the populations that you deal with, or that are part of the process where you try to provide the best quantitation at the lowest price, the highest predictability rate when you do a screen or a confirmation. It is all over the board. In some places in the amphetamine area it is pretty clear that you pay me now or you pay me later. You might get a high screening presumptive rate and a low confirmation rate or vice versa, you get a low screening rate and a fairly high confirmation rate. Some place in the middle is maybe where you want

to be, but that is not true with all the drug classes and it is certainly not true with all the assay types. So, you can't do a summary of this and do it justice, as to the quality of data that was presented or the opportunities to learn from it.

PARTICIPANT: One comment, I am very happy to see that you finally did this. I think within the program you have a tremendous amount of data and information that would be helpful, not only to the labs, but also to the industry and everybody. I really encourage the program to do more in the publishing area than it has done in the past. I think this is really a great start, and I hope that this trend will continue upwards.

DR. BUSH: I will say thank you for that. You know, if we just had a little more time -- isn't that everybody's wish -- to just be able to have more time to do more publication and presentation of this material. Poster number F20, in that same presentation, forensic and drug testing and adulteration poster presentation, Craig Sutheimer, Mike Baylor, John Irving, John Mitchell and I also had a poster on non-regulated specimens, looking at other drug classes. That was not nearly so cut and dried, because of the same laboratories, minus one laboratory -- 10 labs -- looked at different labs that had different screening cutoffs, and a different confirmation cutoff, but still in the effort to harvest that data, too, and get that out there for private-sector and for our knowledge, what is going on out there. Many times we do get questions on it. We also prepared that poster. I am not prepared at this time to present that. Since that is non-regulated, that would be like reading on your own at another time. We plan to publish that also.

MR. STEPHENSON (CHAIR): Let me suggest a couple of things. Number one, the amount of information that you are seeing comes from two processes. One is the ability of the federal government to apply contract resources and funding to do this kind of resources, because we certainly can't do it in house with existing staff. Second, it calls for an ongoing partnership in collaboration with the commercial labs that are out there. Without their voluntary participation and help in doing this kind of work, there is no way that we would ever get this. We are not a big brother in the sense that we could certainly look at this, nor would we, without having that kind of partnership in place. The end result is not to catch or find people to say, aha, here is a deficient technology. It is how to drive changes and improvement in the system over time for everybody's benefit. So, this is a pretty good relationship. If we can keep it up to the point where nobody gets severely dinged by it and damaged as a result of collaboration, there is a good future, and that certainly will apply as we look at the other specimens and alternative technologies that evolve over time. That is the whole nature of the new process that we have established under an existing contract for evaluation and assessment, to do much more of this kind of work, because we realize that we are not just looking at a static environment of urine testing or a small population. We live in a changing world and we live in a place that requires us to have increasing awareness and accountability of what it is we require others to do.

DR. BUSH: I guess for the record, just as follow on to that, we recognized that, when we went to these laboratories and laboratory systems and asked them to participate, everyone is faced with the time and money crunch. Everyone is. We recognized that and did make

sure that, when we asked the laboratories to implement a macro, a program to evaluate their data, we did pay for their computer folks' time. We paid them a small amount of money, just to make sure -- that is just to let you know. It is not like the cost of drug testing is going to go up now because the computer resources were diverted from normal laboratory operations. We did try to write a small check to the labs for their computer time. They were happy for that. I think that made them a little more willing participants, because they were able to do it. I am thinking that is all. We went over time, but I am sure we will make it up later.

**Agenda Item: Department of Transportation Update**

MR. SWART (DOT): I bring greetings from the Secretary of Transportation, Norman Monetta, who wishes a productive DTAB meeting for all of us, and I echo those sentiments. I also bring greetings from our director, John Bobo, who will be here tomorrow, but was unable to attend today because of a commitment to the Federal Aviation Administration and a huge conference they are having in Alexandria.

He did want me to let you know what is new at DOT, and I will certainly do that right now. I am pleased to say that, for the first time in just about 4 years we have a full house at DOT. Like Texas hold 'em, we have 7 staff members, 7 cards, if you will, director, John Bobo, myself, deputy director. We have two senior policy advisors, Mark Snyder, and a new member of our staff, George Ellis. We have a policy advisor, Bohdan Baczara, who came to us from AMTRAK. Everyone knows our administrative staff, Minnie McDonald and Maria Lofton. Again, for the first time in a number of years, we do have a full complement of staff there, and we think we are operating on full cylinders at last.

Some of the things we are doing at DOT, in terms of our publications, we are looking at ways to make the program, at least the part 40 program, a little more understandable to employers and employees. We are developing guides for each of those groups of folks. If you have looked at some of the operating administration regulations, what you see there is that employers are to provide employees with company policies. Those company policies really do not spell out what the heck part 40 is about, and what is going to go on at a collection site, what is going on in laboratories, what MROs are doing, as well as some of the actions that the DOT directs employers to do, if an employee tests positive. We are trying to make something fairly simple, fairly easy to read, so that all employees have a grasp of what will be happening to them as a result of part 40.

Employer GAT is going to be exactly the same way. So many times employers try to wade through our regulations and, even though they are written in plain English, they are still fairly complicated because guys like me write them. So, we hope to have something fairly simple for both employees and employers in the near future.

People are asking us all the time, what happened to the FACA committee and what happened with the best practices report that was going to come out of that for electronic record storage and transmission. I am pleased to say that we are on the verge of finishing that product. Hopefully it will be out in the next 5 months in the Federal Register. Again, it will be just that. It won't be directives to laboratories or medical review officers or people within the scope of our program to do certain things, but it will

present a best practices and some of the really astounding people who are on that FACA committee, some of their best ideas for incorporation of electronic standards for, again, record storage and the transmission of those records.

Someone had mentioned data and Donna, I applaud your efforts, and HHS' efforts to come up with a good use of the data that you have collected throughout the years. We are attempting to do the same thing at DOT. A good first step for us really was taking that MIS form down from 21 -- I don't want to use the word indecipherable -- but 21 forms that were used in all six of the operating administrations, multi-page forms, different forms that were used, and boil that down to a one page, one form fits all within the DOT entity. As soon as we can certify the accuracy of the data that we received from employers on those, we do intend to fully publish that information, so that the public can see what we see in terms of the DOT testing program based upon what employers and third party administrators report to us. Anyway, we had a great response, I think, on the MIS in terms of it being a form that was introduced to the public for the first time and the fact that we did have the ability to put that on line. We had a huge response from entities, companies, and third party administrators, entering data on line. We probably had, within some operating administrations, maybe 90 percent to 95 percent of the employers entering data electronically. So, that was really good for us. So, we are going to be taking a close look at making MIS simpler to use, making it easier for employers to enter the data, and make it easier for us to simplify the accuracy of that data.

We are also looking, with NIDA and other SAMHSA entities, and with our substance abuse professionals, at the fairly close link that we are seeing and that we are hearing about, and other counseling professionals are seeing and hearing about, the close link between depression and substance abuse. What we want to ensure is that, when our substance abuse professionals evaluate an individual who has been identified as having a problem, is that they don't rule out, or they rule in where needed, some help with the person's emotional problems that may include depression, because there is a really close link that is shown to be there, not only by the researchers at NIDA, but also by treatment professionals within some of the professional organizations. If we can enhance an individual's recovery when they return to safety sensitive functions, by introducing a methodology for SAMHSA to use to evaluate the mental status of an individual, and offer that, or provide treatment for that, we think that our return to work agreements will be upheld perhaps a little more than they are being upheld now by the returning worker.

Those are the things that we are working for other than the important things, I am sure, that you are interested in, having to do with the specimen validity testing final rule that HHS has put out, scheduled to go into effect 1 November.

Well, we are concerned about that because we have put pen to paper and hands to keyboard and reviews, and looking at that SVT document every which way we possibly can. We do plan to have a notice of proposed rule making for part 40, with that SVT document, before the end of the year.

You are probably thinking, gosh, what is going to happen 1 November and, if you are not thinking that, let me ask the question for you. Gosh, what is going to happen 1 November? Well, we are staffing right now at DOT, circulating for review within the operating administration, drug and alcohol program managers, an interim final rule on SVT that will bring enough of the standards into place so that there is not a lot of confusion between dueling regulation, part 40, and the HHS regulating for laboratories

and medical review officers when it comes to testing for adulterants, for dilute specimens as well as for substituted specimens.

We hope to have in place by the 1 November, and we are certain that we will have in place a document that harmonizes, insofar as we possibly can, the two regulations, so that there is not a lot of difficulty for laboratories to implement what they have to implement for HHS and to implement what they have to implement for us medical review officers as well. We are working on those two things arduously, and we hope to have the SVT interim final rule on the streets well in enough time for implementation by the 1 November final rule date for HHS.

I want to say here just kindly, first things first. We get asked on occasion, and we know that there are a lot of rumors going around about, gosh, when is DOT going to implement the Health and Human Services notice of proposed rule making on alternative testing. I think the answer is, that is an HHS NPRM on alternative testing. Like you, we are interested in comments to the docket. We are also interested in where HHS is going with this. We have not put pen to paper, we have not put hands to keyboard. We have done nothing but review that document, look at that document, have thoughts about that document. While it is on our radar screen, that is an HHS notice of proposed rule making, and HHS received the docket comments. HHS will answer those docket comments, and we are taking the position that there is nothing for DOT to do with that, other than to watch and wait, just like you are, to see what HHS decides about that.

We do have is our hands full with the publications that we are doing, on the data we are trying to get together, on the SAP look at depression and its link to positive recovery, and looking at getting our specimen validity testing notice of proposed rule making out by the end of the year, inserting a specimen validity testing interim final rule that will go into place, the triggering date for the HHS SBT final rule. Thank you very much.

DR. BUSH: Thank you, Jim. I would like to just take a moment to review how DOT does their process, and I may ask Jim to read in on that in a little bit.

I want to talk about how HHS moves ahead with proposals that we make. I really want to make it very clear that, for us in HHS, putting out those proposed revisions to the mandatory guideline, that is not rule making for us. It is not called rulemaking. Our notice that exists from the very beginning of this program for the drug testing for federal employee work place drug testing programs is not a rule. It never has been a rule. It is a notice in the Federal Register. It is not part of the code of federal regulations and it doesn't have rule characteristics. It was envisioned in this way at the beginning even before I went to this job in 1989, but it doesn't have the characteristics of a rule. So, it is not rulemaking, and we don't call it an NPRM.

Sorry about that, Jim, but I just want to try to kind of clarify this. There are several differences here in just the legal nature of how we, in the federal government, effect, implement, perform the duties in these mandatory guidelines that are very different from how DOT goes about their business of requiring drug free work place in DOT-regulated industries. So, that is just a point I want to make clear. Honestly, that is one point that keeps -- has to keep being said again. It will sink in eventually. I am sure it will sink in eventually. The other thing is that this proposed revision to the mandatory guideline is just that. This is a proposal. We have to come out with a final notice. There

are over 2,000 comments that have been made. It is going to take a while. This isn't going to be implemented like real soon because it just physically can't happen.

Back to that rulemaking issue, ours is a notice in the Federal Register that affects federal employees in their workplace, and it is different from how you guys do business. Do you want to pick that up a little bit, Jim, how you have to post this ANPRM and the alphabet soup for us?

MR. SWART: There are several ways that DOT can do a variety of things that perhaps other federal agencies cannot. While HHS publishes guidelines that have regulatory meaning and effect, we have guidelines that do not appear in the Federal Register. What we can do, and what we have done for several years is, if we are on the verge of wanting to introduce regulation but we are not in the stage where we can produce a notice of proposed rule making, because our notices of proposed rule making, while they are not at all complete documents, they basically show where we want to go with a particular regulation. If we are just on the verge of a thought or an idea related to where we desire to go, and we want public comment before we head in a direction, we will issue what is known as an ANPRM, an advanced notice of proposed rule making. In that ANPRM we will not be very specific at all in terms of any language that we might have in a regulation, but we will ask the public, what do you think, where do you want to go with this. From that ANPRM, we will then develop what is called a notice of proposed rulemaking, which is almost written as if it is a complete document. We will pose questions in that notice of proposed rule making in areas where we really don't necessarily understand totally, getting the public's comments, directing the public's comments on some of those issues. Then, from that notice of proposed rulemaking will come a final rule that will be basically the regulation that must be implemented.

So, these are fairly long procedures, fairly long processes. Again, they are written by us. It takes us time to do those kinds of things. It takes us time to wade through the comments that we get and answer those comments. Now, what we can do and what we have done before is introduce an interim final rule, which basically tells people where we are headed now, and those are done on an emergency basis, like SVT interim final rule that we are getting ready to do. We will take comments to that interim final rule for a 30-day period. So, it is not as if we are going to be introducing this specimen validity testing interim final rule, and not offering an opportunity for the public and interested parties to comment. Again, you are operating under a different regulatory situation than we are, and at some point we, at DOT, will begin to understand that.

**Agenda Item: Nuclear Regulatory Commission Update**

MR. MC CUNE (NRC): I also bring greetings from the Nuclear Regulatory Commission Chairman Diaz and Commissioners McGaffigan and Merrifield.

I would like to mention a couple of quick points here. In the interests of time, I will be brief. I would first like to address where NRC is from the perspective of the previous conversation regarding guidance in HHS and policy on the part of the DOT. As many of you know, in the NRC we do have the responsibility for publishing policy that is incumbent, primarily, on our contractors. That is a big area of distinction that I think is important to keep in mind. My responsibility, as the drug and alcohol program

manager at the NRC, has responsibilities for licensees, contractors, and a new term that we have come up with to address some other officials covered by a drug testing program, other entities, but not federal employees in the NRC. In fact, the program that deals with federal employees in the NRC largely follows HHS guidelines. So, that is an important distinction to keep in mind when you are thinking about the NRC.

When last we met in June, I think it was presented that we had gotten direction from the commission to combine our drug and alcohol portions of Part 26, which is our proposed rule on drug and alcohol testing, with another provision that covers fatigue. Largely because we have a pre-existing program for drug and alcohol testing, the changes that we are proposing in part 26 from that perspective are relatively minor. While I won't go into it in great detail, the philosophy of the NRC is, from a consequence perspective, someone who is overly tired or fatigued at work can have the same negative consequences as somebody who is under the influence of drugs or alcohol. So, the commission directed us to combine the fatigue portion of our Part 26 with our drug and alcohol provisions, and gave us a suspense in May, I believe, of December of 2005 to get that proposed rule up to the commissioners, so that they could publish if for public comment.

Due to a number of things -- I think pressure from the industry as well as some bright thinking in the fact that our rule had been going on for years and years for some good reason, the commission also gave us some other guidance about a month ago, truncating that schedule until June 2005, roughly cutting six months off our schedule to get the proposed rule up to them so that they could review it for public comment. That has done a number of things, chiefly caused us to look at a schedule whereby we would only have one additional public meeting, and that starts in about 20 minutes in Rockville. I will tell you that the public meeting scope in Rockville is on only the fatigue provisions. It is interesting to note, to us at the NRC, that while originally, for all government agencies who were responsible for coming up with drug and alcohol testing programs, there was a perceived need. There were a lot of machinations that went on to develop the original policy. We are now going through that in the NRC with respect to fatigue. While it is not within the scope of this body, I will tell you that there is no short amount of industry interest in being encumbered with shorter work hour controls, especially on the part of the unions, and some of the other groups who have a great interest in maximizing the earning potential, rightfully, of their constituents.

Without going into a lot of the details of some of the minor changes, I will say, in the drug and alcohol portions that we have envisioned and incorporated into the draft final rule since June, I will mention one thing that we felt was rather important. The industry felt that it was very important, I think largely from the proximity of the MROs to the licensee facilities, to add responsibilities to the MROs to act as substance abuse professionals or experts. Many of you may be aware of this issue. I can tell you, after having attended MRO certification training in Boston in July, and speaking to the course manager as well as a number of the physicians, the average physician does not feel comfortable calling themselves a substance abuse official or expert because they just plain don't have the training for that. So, that is one thing that we have elected not to incorporate into the draft final rule, that being the equivalency, if you will, of an MRO with a substance abuse official.

I mentioned that we have got a public meeting today. Our schedule should

have a new draft public rule up on our NRC web site, open to the public, within two weeks. I would encourage you to go to the public section at www.nrc.gov and take a look at that. We are one of the only other government agencies that is attempting to regulate work hour controls for licensees, contractors in this particular case, and we would welcome any comments that you have in that area.

Again, we appreciate the opportunity to participate in this body, with our brothers and sisters from DHHS, DOT, as well as the board, the public and the industry, and we look forward to continued participation in the months and years to come. Thank you.

MR. STEPHENSON: Thank you very much. I think the issue around fatigue is one that will be interesting. I know a number of years ago there was a congressionally mandated study that the Department of Transportation has undertaken to look at the impact of certain testing procedures on I think the interstate transportation primarily. Is that correct? That was a 6 state study and I think it wound up with about five.

MR. SWART: It was a federal motor carrier safety administration study, but their hours of service, there are regulations within many of the operating administrations.

MR. STEPHENSON: There is some precedent that is there, but in that testing area, one of the things that they found as a proxy for fatigue was presence of caffeine. It was just interesting that it was one of the things that came up that was a total side bar. It was not expected. I think that was one of the first times we started to see some of the over-the-counter ephedrine type products that were frequently available at the truck stops that were being used, in some cases, in very large amounts by people as a way to counter some of the tiredness and so on. If you turn to them, I am sure they will be able to share some of that.

At this time we are going to talk about public comments. There is going to be a presentation by Donna Bush and Mike Baylor (RTI).

**Agenda Item: Discussion of Public Comments Submitted for the Revised and Proposed Changes to the Mandatory Guidelines for Federal Work Place Drug Testing Programs**

DR. BUSH: I would like to review a couple of things that happened. One of them is that, on April 13, SAMHSA and the Department of Health and Human Services published the revised mandatory guidelines for federal work place drug testing programs with specimen validity testing as the big issue addressed there.

SEE ATTACHMENT (3)

Final specimen validity testing requirements were defined, with an effective date of November 1, 2004. The creatinine concentration criteria to finding a substituted specimen was proposed at a creatinine concentration less than two milligrams per deciliter. This was the only issue open for public comment, the public comment period being 60 days. Thirteen comments were received, and not all of them were on the

creatinine criteria.

The second thing that happened was a notice of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs that was also published, sequentially to the first one, on April 13, 2004, in the Federal Register. Now many proposals were made in this document, using alternative specimens for drug testing, specimen validity testing for each type of specimen, point of collection testing. Cutoffs were established, proposed for alternative specimens. Cutoff changes for some urine drug tests were also proposed. All issues in that document were open for public comment, the public comment period being 90 days. We received comments from 285 commenters but, when one examined those 285 comments, one found that there really were more than 2,000 different comments. We received some comments that were one page emotional outbursts. We had some that were 100 page dissertations on many different topics, with a lot of technical merit raised in them.

All of these comments are available on our website (www.drugfreeworkplace.gov or workplace.samhsa.gov).

We will just look at the major issues that were brought up from those public comments on the proposed revisions to the mandatory guidelines for federal work place drug testing programs.

For oral fluid, people brought up issues concerning the definition of the term, oral fluid. as well as discussion about the collection of oral fluid, concerns about spitting versus oral fluid collected on a collection device was talked about and questioned, required volume of specimen. It questioned determining the volume of collected specimen and how to split the specimen into two. It brought up issues concerning examination of the oral cavity as well as the wait time in the collection site before the actual oral fluid collection proceeded. It questioned the allowable reasons for testing using oral fluid, recommended using return to duty and follow up kinds of testing for oral fluid. One of the questions that was clearly brought up in the preamble and asked for public comment directly on the issue concerned the detection of marijuana using oral fluid. It has to do with requiring the collection and testing of a urine specimen with each oral fluid specimen, and this hinged on the presence of marijuana, parent THC, in oral fluid, and the reason that it is present there. It is because it is a contaminant, or is it the result of active marijuana use. There was definitely discussion on that.

There was some discussion on detection of drug metabolites versus parent drug. Questions were raised concerning the proposed oral fluid specimen validity testing. Many questioned the need for specimen validity testing, since they are observed collections by their very nature, and questioned the appropriateness of testing for IGG and other specimen validity testing characteristics.

For hair, we got many comments -- well, several comments, stating that programs in use in the private-sector now allow the use of body hair. In the case of either male pattern baldness or shortness of head hair or lack thereof or otherwise, be it stylized or just by the very nature of the donor, allowed the use of body hair. That comment came in. The secretary, as you recall, in the preamble and through the document, did speak directly to the use of head hair and head hair only. Many questioned the effect of hair color on drug concentrations and recognized higher detection levels for some drug users than others based on hair color. Contamination from environmental exposure was brought up, and effectiveness of decontamination procedures to address that

environmental exposure were raised. Collection of head hair required the amount of the hair collected and the percent split between A and B, and then how does the collector assess the proper amount. Many questioned the need for hair specimen validity testing since, in fact, that collection is observed, and questioned the appropriateness of the validity test described in the proposed guidelines and other validity testing issues around hair. Discussion came in on the confirmatory test cutoff concentrations for THCA, the marijuana metabolite that would be measured in here.

Sweat, environmental exposure issues were raised, privacy issues with application and wearing of a patch, should it be obvious to others, and privacy issues surrounding that. Length of time to wear a patch, guidelines proposed three to seven days, and others suggested different time windows to us. Sweat specimens validity testing, there were questions about testing for lactic acid as a characteristic.

General issues concerning all matrices. Issues concerning fairness to the individuals testing using different matrices, trying to compare drug detection times amongst the different matrices, and the relationship of the cut off concentrations between the matrices, those issues were raised. Apparently, some want each and every specimen test to be uniform.

Guidance for federal agencies on selection of the appropriate matrix, collection procedures and the proposed guidelines lack sufficient detail, it was told to us.

There were some specific testing issues concerning testing of specimens for 6-acetylmorphine by immunoassay, and the requirement for a confirmed positive morphine to report 6-acetylmorphine itself. Also, there was information on the need for a separate immunoassay to test for MDMA.

Collections, use of one versus multiple federal custody and control forms, matrix specific kind of custody control form questions came in on that, one type of form versus a multitude of forms. There are procedural differences between collections for the different specimens, some instructions in the proposed guideline are the same for all matrices, but not applicable to all.

Standardized training of collectors and collector trainers, and documentation of the training was brought up to us.

Problematic collections such as paruresis, shy bladder, dry mouth, allergic reaction to the sweat patch..

I expected some comments, in addition to paruresis, dry mouth and allergic reaction to sweat patch, possibly on the amount of head hair that a person has, either naturally or by hair style.

Authorization for the collection of alternative matrix, how are we going to do that, additional guidance needed for problematic collections. We knew it wasn't a complete document to begin with. We certainly wanted the feedback, and we got it.

Some people discussed with us annual inspections of collection sites by federal agencies. For the instrumented initial test facility, some questioned the need for IITFs based on the cost and the turn-around time, and what type of IITF report does that facility send out, and to whom, and tests performed in the certified laboratory on IITF tested specimens - want more definition on that.

Point of collection testing, discussion came back to us on the approval process for point of collection testing devices to be accepted for federal work place drug testing applications. Discussion on the approval by the lot number of the device and

submission of manufacturer validation records versus HHS testing of devices. We got comments back on that.

Training of testers and tester trainers, and then the documentation of that training, comments on that, and what validity tests are to be performed at point of collection test sites. The quality assurance process, questions sending 10 percent of negative specimens to a certified laboratory. To whom does the laboratory report the results and what follow up actions would be taken. Reporting point of collection testing negative specimens to federal agencies instead of MROs, that was brought up to us, and require that quality control testing was discussed with us.

Point of collection testing site inspections were discussed with us, relationship between the point of collection device manufacturer and the testers and the certified labs.

We have always talked about relationships among testing parties, and the proposed guidelines allow these entities to freely enter into any relationship, and we got some comments back on that.

Concerning medical review officers, we got comments on the relationship between the MROs and point of collection testing manufacturers and the testers themselves, and the need for MRO training organizations to be approved by the secretary.

We were open to comment on everything, and we pretty much got comment on everything to the tune of more than 2,000 issues raised to us and, needless to say, that needs a database to handle and to try to appropriate the comment, after it is received, to the section of the guidelines to which it applies. All of that is going on, and we are working those comments. That is really about all I wanted to say, just to review with you that we are working on it, and the big picture issues, certainly. This doesn't do justice to all 2,000 of the comments but, for the sake of this open session, just to let you know where we are.

MR. BAYLOR (RTI): In conclusion, of the 285 comments, six could be clearly associated to federal agencies. Three additional submissions could be identified to federal employees.

Of the seven union responses, three of those seven unions appeared to be associated with federal employee unions, that issued comments.

I think oral fluid was one of the major themes you find. If you look at that subgroup of federal employee comments, the issues around oral fluid and the issues concerning annual inspections and the potential cost to the agency to perform such.

MR. STEPHENSON: About a dozen out of the 285, is that what you are saying, were specifically related to federal agencies, or federal agency-related employees.

MS. CHILDS (Board Member): Any sense of how the responses to these were compared to the numbers and variety of responses when the alternative specimens were first proposed.

MR. STEPHENSON: That was an internal sharing process that was done on the internet as an opportunity to further the dialogue. It was not a proposal that was put forward with an opportunity for structured response that we would have to deal with under the

regulations. It was more or less an extended set of notes that had been put on the website that told us what we had just gone through and the sharing process that we just had, and gave a chance for people who hadn't been at a particular meeting to get a sense of what was being submitted by the working groups, and to help the dialogue. We really needed that. I don't think we could even be where we are now if we hadn't used that process. It was absolutely essential. The working groups were essential.

At the point that we began this whole process of actually crafting the real notice, we had to go into our own silo. We had to go silent, and we had to stop many of the activities that were related around the ongoing updates and what people were still continuing to learn, and the thing that we were still experiencing from the voluntary PT programs that were going on. None of that could be addressed or responded to in the context of while we were writing the proposed rule or revisions. The issue for us is, the public comments during this process were the first time that many of the old, established partners, as well as other interested parties who hadn't come to our meetings were having a chance to really have their input. We really wanted to make sure that this was a full and open process for everyone. I don't think you really can compare the two. Certainly, there will be a certain extension of where we were with that first set of working group drafts, but there is a whole group of folks who have never had input or process. What is interesting is that those that the Guidelines are directly aimed at, we got about a dozen. That is interesting.

Either we explained it very well or something else, and I don't need to go there. I think the thing is, typically in the things that directly impact the federal agencies, when you take the time to go out and share it with the agencies themselves, which we did in two meetings, and we actually walked through the exact proposed revisions in meetings with all the people that are responsible for the drug program coordination effort in the federal agencies, we made a very deliberate outreach to them two times. That may well have answered many of the issues.

MR. BAYLOR: I would just add that, even though we received 2,000 comments, I am not sure what percent of the document there were no comments on at all. I think it is a significant amount, and I like that part of it, because we don't have to revise those. Those stay the same, basically. If you look at this summary here, and you group comments together on a given issue, you know, you are talking maybe a dozen kind of major issues and then a number of minor ones, and the rest of the document is pretty good. I think, you know, that supports what Bob just said, that the process, the working group process, the previous drafts, the comments that were submitted were all taken into consideration in developing this document. I feel really good about it, that we really have something that is not that far off from what the final document is going to look like. Therefore, this process of coming up with the final notice, I am hoping it is a relatively short period of time.

MR. STEPHENSON: I think one of the things, also, is that you are hearing two different sets of numbers. You are hearing a dozen comments or 285.

These are commenters. The commenters are raising issues that number in the 2,000s. Many of them are the same thing being said by multiple voices. So, they are clustered around these given areas. We have to at least account for the issues that range

up to 2,000, and aggregate them and then address them as groups in the response.

We can't be arbitrary, capricious, and not address a comment that has been raised by someone, even if that is the only one person out of 285, or if it is only one voice out of the 2,000 comments and issues that we have seen. We still have to go through a process of vetting and so on, because there are oftentimes -- sometimes in the past Mike has been the lone sentinel who has called our attention to something that no one else has seen or addressed. We have to read all of these with that kind of understanding and attention. It is what we are expected to do.

DR. BROWN (Board Member): Can you remind me of the next step in the process? After these comments are batched and vetted, what is next.

MR. STEPHENSON: I hope in the closed session will be some dialogue with the members of the Drug Testing Advisory Board, around some of the science issues and so forth. From that, we will distill out those issues, and we will begin the process of public discussion around some of the other issues. If we have all of the answers that are simply waiting to be crafted, that is fine. If, in some of these areas, we don't have the definitive answers, we may need to do a little bit more exploration, either through the contract or through outreach, maybe additional review of the science or the standards. There is still a lot of information that is out there. We are constantly challenged by the fact that we have a public comment period that closes, as if the world stops informing us of what is going on as of a certain date. That isn't the nature of the way peer reviewed public literature appears, and it is not the way we learn about it. That is the very nature of why we changed the process on SVT testing, and that one single number.

Given where we are, we feel comfortable that we are going to wade through all of these comments, make sure they are properly aggregated and accounted for in total, and then begin to craft the writing of the proposed final comments that address and respond to what we have heard from the public.

Then the members of the board will have that shared with them internally and will discuss that within the board, to craft what we would propose to be a final. Again, we go silent to the outside world until such time as that document has been legally reviewed, shared with our federal agency partners to the degree that it is necessary within our Office of Management and Budget and department procedures, it has passed legal muster across a number of areas, and scientific muster across multiple agencies within the department that we have to have internal clearance performed with. Then it will come forward as a final notice. At that time it will have been looked at by the Office of National Drug Control Policy, the Office of Management and Budget, certainly cleared initially by the department. It will have passed legal muster and scientific review. So, that is the due diligence process that we will follow on this over time.

DR. BUSH: That is exactly what happened with the original guidelines that were put forth as proposals, I think, in 1987, and then published in the Federal Register as a final notice for the first time April 11, 1988. Then, after all of that happens, after the paperwork is done, then a laboratory certification program has to be set up, and we have to train inspectors, and we have to have the inspection checklist and guidance document, we have to have performance testing specimens, and all of that will have to then come

after this paperwork process of developing the final notice.

MR. SWART: Are we going to also allow our contractor, RTI, to also be proactive in some of the comments that were suggested or requested that we change the cutoffs, to look into the future PT sets to include these new cutoffs?

MR. STEPHENSON: That is a contract issue that has been the nature of what has been going on, even with the SVT issues. During the time when we were preparing the proposed revisions to include alternative specimens, we continued with the work. In fact, under a revision to our contract, they expanded the resources and established new specific tasks around the areas of alternative specimen technologies. We recognize that we need to aggressively and continuously address the performance testing, the issues, the development of proficiency challenges, the blind specimens that would be distributed, and to make sure that they are as like the real world as we can provide it. That is where we had some leadership that happened around hair testing, to a limited degree around oral fluid, but we still have to do this with a lot more detail and precision. So, that work will continue on a daily basis. To the degree that there are partners in this process, they do the technical work, but we still have to provide the directions and the standards and the priorities of which work will be done first. We do have sufficient funding, an d contract capacity to provide and support the development of the technical details, inspection standards, training of inspectors and so on, to cover all of these areas. That has been crafted into the current contract instrument that we have that supports this area, and it was put in place literally a year before we had this notice that came out. So, it is staged, and is now in operation.

MR. STEPHENSON: At this stage, are there any issues that the members of the board would like to bring to the attention of the group? Are there any comments on any of the topics that we have covered?

At this time, we have had two individuals that have identified an interest in making a public comment. Since there are two, if you can limit your comments to about 7 to 10 minutes each, that should provide enough time for the two presenters to do what they want. The order in how they registered, the first being Melissa Handler.

DR. BUSH: I am going to ask that you use the microphone, because that helps with the transcription and also for the audio here.

**Agenda Item: Public Comments**

MS. HANDLER: My name is Melissa Handler. I represent the International Paruresis Association as a legal consultant. IPA is a non-profit organization that provides therapeutic treatment, education, advocacy and support for people with paruresis.

Paruresis is a social phobia more commonly known as shy bladder syndrome: the difficulty or inability of individuals to urinate in a public rest room facility, or even in their own homes, if other people are nearby. According to a 1997 Harvard University Medical School study, an estimated seven percent -- 17 million -- of the nation's population experiences some form of anxiety when using a rest room away

from home. Of these, one to two million are paruretics who experience such anxiety at all times. Many of these people face employment difficulties, not because they are drug users, but simply because they are unable to submit a urinalysis under the current drug testing regulations. We appreciate the fact that HHS has promulgated new rules that have allowed for alternative testing. However, they do not take into account people who suffer from paruresis and, therefore, are unable to produce urine samples. As our 44-page rebuttal indicates, there must be provisions included in the new regulations that allow for alternative testing in lieu of urine testing for people with paruresis. Almost 50 percent of the 285 public comments on the regulations concern the issue of shy bladder. HHS must rise to the occasion and change the rules to deal with the problem for once and for all.

Thank you very much for the opportunity to speak on behalf of this issue, which is of great concern to numerous people with paruresis, struggling to obtain or maintain a place in the work force. Thank you very much.

I put a copy of the testimony outside, if any of you want to take a look at it. Thank you very much.

MR. J. J. SMITH: I will try to be brief. I think the panel needs to fine tune notification and publication of these meetings. In mid-August, I contacted SAMHSA's public affairs office, seeking more information no this meeting, and this is what I was provided, and there is nothing on there that says that the meeting is closed at any time. I only found out that the meeting was closed on Wednesday, and that it closed this afternoon yesterday, when I made several phone calls to try to get a copy of an agenda. Giselle Hersch told me that the meeting was closed, that it closed at 11:00 o'clock today. I think the panel needs to fine tune how to get this information out to members of the public who might want to attend. Thank you.

MR. STEPHENSON: You have raised an interesting point, and it is one that I will own here on behalf of the government. It is easy to explain why something doesn't happen. It is more of a challenge to try to do what is right and to hold a meeting, despite the fact that some administrative things did not happen the way they should have. There were many factors that came together during this time period. The bottom line is, I made the determination that we needed to continue to hold this meeting today because there was an expectation from many of the people who routinely come to these sessions, that are well established in advance because of booking of the hotels and so on.

J.J. is right. There was no Federal Register notice that got into the paper on it. More important, the issues around the topics for the closed session have to pass legal muster and have to be documented and approved by our office of general counsel and the department prior to even having the Federal Register notice published.

Not excuses, but facts. We have had a compression of our office of general counsel staff availability. Our whole agency has moved from one building into a whole new building and staged over the last month, such that people were put into boxes, all of the things, the working documents, were physically moved from one building and then unpacked. We had parts of our groups that, as we started the move, we had to delay a little bit, and I take ownership of the fact that I am supposed to be the hands on guy in charge of all of this. I have had divided attention because I am also an acting deputy center director for one of the centers. When I came back and asked for the details on the

Federal Register notice and the clearance for the agenda and the closed sessions, we found that it had been transmitted to the people who were supposed to clear it back in August, and that we didn't have it back.

I was faced with a decision. Do we cancel the meeting, eat the cost of the hotel for the people who have either come in to visit with us from the public, not to hold the public session, not to hold the closed session, or to try to work through, with the office of general counsel and others to make sure that, in fact, it could happen. I chose to engage the third part, and we were successful in having legal review of the issues, and we will be publishing a Federal Register notice after the fact, discussing this meeting and why it was not done in advance. Hopefully that will be the only time we have to resort to that. Fair comment, good catch, and we own this, and hopefully we will not repeat it.

There were no other comments made.

A motion to close the open session was made and seconded. Meeting was adjourned at 11:00 a.m.

Attachments:

(1) Joint Meeting of SOFT and TIAFT – Abstract for Poster F19
(2) Confirmation Rates of Initial Drug Assays in a Group of HHS-Certified Laboratories, January 01 – December 31, 2003 – I: Federally Regulated Specimens
(3) Revisions to Mandatory Guidelines

# Joint Meeting of SOFT and TIAFT

## Program and Abstracts

August 30 – September 3, 2004
JW Marriott Hotel
Washington, DC, USA

**GLOBAL PARTNERS for JUSTICE and HEALTH**

ATTACHMENT D

**FUDT & Adulteration**
**Poster Presentation**
**Session A**
Wednesday, September 1st
Russell/Hart/Cannon

**Presenters must be at their posters from 9:00 – 10:30 a.m.**

*Moderators: David Kuntz, PhD and Anya Pierce, PhD*

| | | |
|---|---|---|
| **8:00 a.m. – 12:00 p.m.** | **F14** | **Automated Approach to Non-Negative Specimen List (NNSL) Production and Application for SAMHSA-Certified Laboratories**<br>*W.N. Bennett and A. Wu** |
| **8:00 a.m. – 12:00 p.m.** | **F15** | **Method Validation for the Analysis of Amphetamine, Methamphetamine, MDA and MDMA in Urine**<br>*M.Park, S. Choi, E. Kim, M. Lim*, M. Pyo, and H. Chung* |
| **8:00 a.m. – 12:00 p.m.** | **F16** | **Urinary Excretion of Morphine and Codeine Following the Administration of Single and Multiple-Dose of Brown Mixture**<br>*D. Lin, H. Liu*, H. Ho, C. Wang, and R.H. Liu* |
| **8:00 a.m. – 12:00 p.m.** | **F17** | **A Modified Method for the Liquid-Liquid Extraction and GC/MS Analysis of Methadone from Human Urine in a CAP-FUDT Certified Drug Testing Laboratory**<br>*J. Lavelle, B. Brunelli, E. A'Zary*, and J. Keller* |
| **8:00 a.m. – 12:00 p.m.** | **F18** | **A Rapid LC/MS Method for the Determination of Methamphetamine/Dimethylamphetamine and Their Metabolites in Urine – A Study of the Current Situation in Hong Kong**<br>*W.C. Cheng*, and V.K. Mok* |
| **8:00 a.m. – 12:00 p.m.** | **F19** | **Confirmation Rates of Initial Drug Assays in a Group of HHS-Certified Laboratories: January 01 Through December 31, 2003 – I: Federally Regulated Specimens**<br>*D.M. Bush *, M.R. Baylor, J. Irving, J.M. Mitchell, and C.A. Sutheimer* |
| **8:00 a.m. – 12:00 p.m.** | **F20** | **Confirmation Rates of Initial Drug Assays in a Group of HHS-Certified Laboratories on On-Regulated Specimens: January 01 Through December 31, 2003 – II: Non-Regulated Specimens**<br>*C.A. Sutheimer*, M.R. Baylor, J. Irving, J.M. Mitchell, and D.M. Bush* |
| **8:00 a.m. – 12:00 p.m.** | **F21** | **Determination of Benzodiazepines in Human Urine Using Solid-Phase Extraction and High Performance Liquid Chromatography Electrospray Ionisation Tandem Mass Spectrometry**<br>*S. Hegstad*, E.L. Oiestad, U. Johansen, and A.S. Christophersen* |
| **8:00 a.m. – 12:00 p.m.** | **F22** | **Use of Compounds Altering Vigilance Performance: Preliminary Results of Prevalence in Haulage Drivers in the Nord-Pas-De-Calais Region (France)**<br>*L. Labat, B. Dehon, M. Lhermitte** |

# CONFIRMATION RATES OF INITIAL DRUG ASSAYS IN A GROUP OF HHS-CERTIFIED LABORATORIES, JANUARY 01 THROUGH DECEMBER 31, 2003
## I: FEDERALLY REGULATED SPECIMENS

Donna M. Bush[1*], Michael R. Baylor[2], John Irving[2], John M. Mitchell[2], Craig A. Sutheimer[2]: [1]Division of Workplace Programs, CSAP, SAMHSA, Rockville, MD, USA; [2]RTI International, Research Triangle Park, NC, USA

As the U.S. Department of Health and Human Services (HHS) moved to expand the analytical methods, the approaches to drug detection, and the biological matrices allowed as specimens in the workplace drug testing program for Federal employees, an in-depth analysis of current practices was initiated. Of particular interest was the specificity and cross-reactivity of the immunoassays currently found in HHS-certified laboratories. The specificity of the immunoassays associated with urine drug testing has long been a subject of discussion among forensic toxicologists. While it has been known that some drug class immunoassays have very high rates for the confirmation of presumptive positives, it is also recognized that other drug class immunoassays produce a significant number of presumptive positives that fail to confirm when subjected to confirmatory testing by GC/MS. These observations led to an examination of the immunoassays currently in use with the goal of documenting the possible differences in specificities and cross-reactivities of the technologies.

The study included data from 11 HHS-certified laboratories encompassing nearly 4 million specimens tested under Federal mandate during 2003. These specimens represented between 55 to 60% of all federally regulated specimens tested in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 Fed. Reg. 29908-29931, June 9, 1994 and 63 Fed. Reg. 63483-63484, November 13, 1998) during 2003. The data were obtained from laboratories that used CEDIA, EIA and KIMS technologies as a primary initial test. Some laboratories conducted additional screening of presumptive positives with FPIA as a second initial test. Summaries of specimen testing and confirmation rates are presented in the tables below. The confirmation rates are expressed as percent of the presumptive positives confirmed by GC/MS for each drug class. The mean, lowest and highest laboratory confirmation rate for each drug class are also provided.

| | Amphetamines | BZE | Opiates | PCP | THC-COOH |
|---|---|---|---|---|---|
| Specimens Tested | 3,939,614 | 3,946,445 | 3,937,611 | 3,937,611 | 3,946,445 |
| Presumptive Positives | 21,577 | 23,570 | 21,586 | 1,772 | 54,578 |
| [illegible] | 11,715 | 22,920 | 6,550 | 1,229 | 48,458 |

| Initial Test Assay Confirmation Rates | Amphetamines (1st/2nd Test) | BZE | Opiates | PCP | THC-COOH |
|---|---|---|---|---|---|
| [illegible] | 51.9%/82.8% | 98.1% | 30.2% | 69.7% | 91.0% |
| [illegible] | 37.4%/81.3% | 91.1% | 17.3% | 51.6% | 73.0% |
| [illegible] | 77.8%/84.3% | 99.9% | 55.9% | 91.0% | 98.8% |

This study evaluated the presumptive positive rates and the confirmation rates for primary initial tests by immunoassay method as well as paired immunoassay methods (primary initial test plus second initial test). The results were examined with consideration of assay cross-reactivity and specificity. As expected, some assays and technologies appear to better identify specimens containing analytes of interest at or above the administrative cutoffs required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs. While the study assesses current capabilities of existing technologies from a large population of "real" federally regulated workplace specimens, it also provides information that may be useful in formulating future guidelines by which newer technologies and approaches may be evaluated.

Keywords: HHS-certified laboratories, Immunoassay confirmation rates, calendar year 2003

FBI/SOFT/TIAFT 2004

# Confirmation Rates of Initial Drug Assays in a Group of HHS-Certified Laboratories

## January 01 – December 31, 2003 - I: Federally Regulated Specimens

Donna M. Bush[1], Michael R. Baylor[2], John Irving[2], John M. Mitchell[2], and Craig A. Sutheimer[2]

[1]DWP, SAMHSA, Rockville, MD, USA • [2]RTI International, Research Triangle Park, NC, USA

ATTACHMENT (2)

## STUDY RATIONALE

- As the U.S. Department of Health and Human Services (HHS) moved to expand the analytical methods, the approaches to drug detection, and the biological matrices allowed as specimens in the workplace drug testing program for Federal employees, an in-depth analysis of current practices was initiated.
- Of particular interest was the specificity and cross-reactivity of the immunoassays currently found in HHS-certified laboratories. The specificity of the immunoassays associated with urine drug testing has long been a subject of discussion among forensic toxicologists.
- While it has been known that some drug class immunoassays have very high rates for the confirmation of presumptive positives, it is also recognized that other drug class immunoassays produce a significant number of presumptive positives that fail to confirm when subjected to confirmatory testing by GC/MS for those drugs identified in the Mandatory Guidelines.
- These observations led to an examination of the immunoassays currently in use with the goal of documenting the possible differences in specificities and cross-reactivities of the technologies.

## STUDY DESIGN

- The study included data from 11 HHS-certified laboratories encompassing nearly 4 million specimens tested under Federal mandate during 2003.
- These specimens represented between 55% and 60% of all federally regulated specimens tested in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 Fed. Reg. 29908-29931, June 9, 1994, and 63 Fed. Reg. 63483-63484, November 13, 1998) during 2003.
- The data were obtained from laboratories that used CEDIA, EIA and KIMS technologies as a primary initial test.
- Some laboratories conducted additional screening of presumptive positives with FPIA as a second initial test.
- Tabular and graphical summaries of specimen testing and confirmation rates are presented. Presumptive positive rates are expressed as the ratio of the number of specimens determined to be presumptively positive and the number of specimens tested multiplied by 100. The confirmation rates are expressed as the ratio of the number of specimens confirmed positive and the number of specimens submitted to confirmation (presumptive positives) multiplied by 100. The overall confirmation rates (without and with a secondary screen), as well as the lowest and highest laboratory confirmation rate for each drug class are also presented.

### HHS Cutoffs and Analytes

| | Initial Test (ng/mL) | Confirmation Test (ng/mL) |
|---|---|---|
| Marijuana Metabolites | 50 | |
| CarboxyTHC | | 15 |
| Cocaine Metabolites | 300 | |
| Benzoylecgonine | | 150 |
| Opiate Metabolites | 2000 | |
| Codeine | | 2000 |
| Morphine | | 2000 |
| 6-AM | | 10 |
| Phencyclidine | 25 | |
| Phencyclidine | | 25 |
| Amphetamines | 1000 | |
| Amphetamine | | 500 |
| Methamphetamine | | 500 |

# SCREENING ANALYSES

## Screening Assays

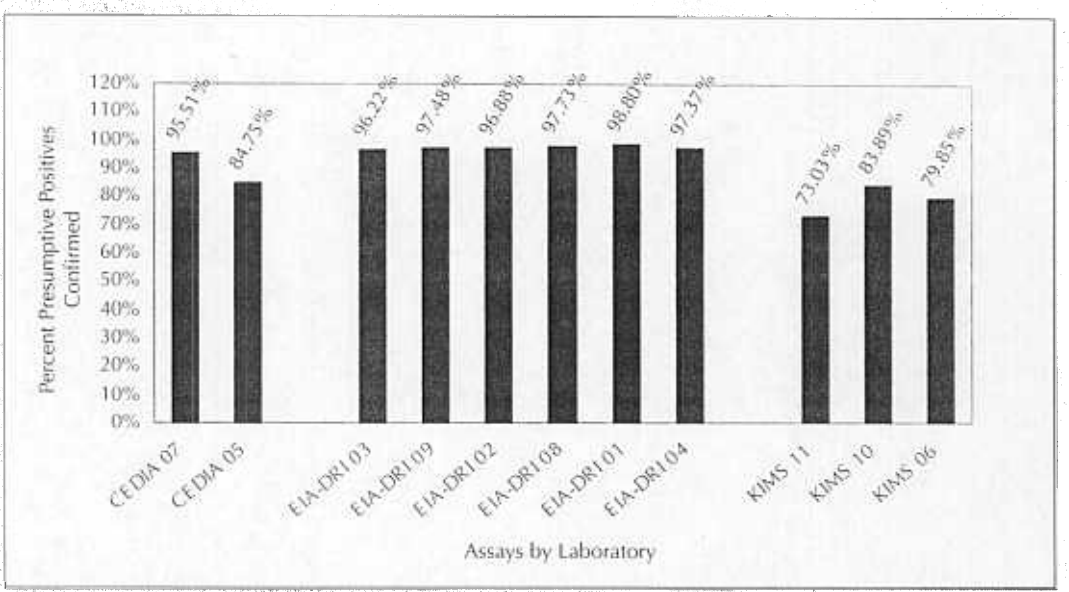
- CEDIA [Marijuana Metabolites, Cocaine Metabolites, Opiate Metabolites, Phencyclidine, Amphetamines]; CEDIA + FPIA [Amphetamines];
- EIA-DB [Amphetamines]; EIA-DRI [Marijuana Metabolites, Cocaine Metabolites, Opiate Metabolites, Phencyclidine];
- KIMS [Marijuana Metabolites, Cocaine Metabolites, Opiate Metabolites, Phencyclidine, Amphetamines]; KIMS + FPIA [Phencyclidine, Amphetamines]

# RESULTS

## Marijuana Metabolite(s) Analyses

| | Initial and Secondary Screening Assay | | | Confirmation Assay | | |
|---|---|---|---|---|---|---|
| Laboratory: | Samples Tested | Assay Type | Screening Presumptive Positive Rate | Samples Submitted to Confirmation | Confirmation Rate | Positivity Rate |
| 03 | 385561 | EIA-DRI | 1.50% | 5795 | 96.22% | 1.45% |
| 09 | 170007 | EIA-DRI | 1.29% | 2186 | 97.48% | 1.25% |
| 02 | 219594 | EIA-DRI | 1.53% | 3363 | 96.88% | 1.48% |
| 08 | 199080 | EIA-DRI | 1.31% | 2604 | 97.73% | 1.28% |
| 01 | 256642 | EIA-DRI | 1.37% | 3505 | 98.80% | 1.35% |
| 11 | 344146 | KIMS | 1.37% | 4702 | 73.03% | 1.00% |
| 07 | 288508 | CEDIA | 1.38% | 3984 | 95.51% | 1.32% |
| 10 | 520295 | KIMS | 1.30% | 6755 | 83.89% | 1.09% |
| 04 | 332792 | EIA-DRI | 1.51% | 5024 | 97.37% | 1.47% |
| 05 | 462022 | CEDIA | 1.96% | 9049 | 84.75% | 1.66% |
| 06 | 660848 | KIMS | 1.21% | 7975 | 79.85% | 0.96% |

## Marijuana Metabolite(s) Confirmation Rates

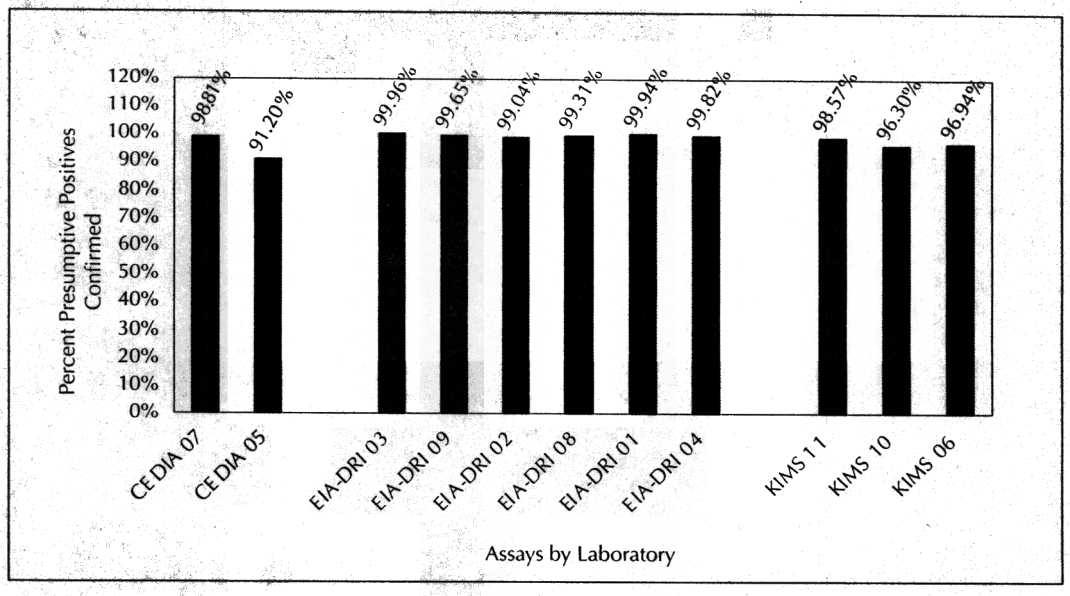


## RESULTS *Continued*

### Cocaine Metabolite(s) Analyses

| | Initial and Secondary Screening Assay | | | Confirmation Assay | | |
|---|---|---|---|---|---|---|
| Laboratory: | Samples Tested | Assay Type | Screening Presumptive Positive Rate | Samples Submitted to Confirmation | Confirmation Rate | Positivity Rate |
| 03 | 385561 | EIA-DRI | 0.62% | 2376 | 99.96% | 0.62% |
| 09 | 170007 | EIA-DRI | 0.67% | 1134 | 99.65% | 0.66% |
| 02 | 219594 | EIA-DRI | 0.76% | 1669 | 99.04% | 0.75% |
| 08 | 199080 | EIA-DRI | 0.36% | 721 | 99.31% | 0.36% |
| 01 | 256642 | EIA-DRI | 0.68% | 1750 | 99.94% | 0.68% |
| 11 | 344146 | KIMS | 0.39% | 1331 | 98.57% | 0.38% |
| 07 | 288508 | CEDIA | 0.76% | 2186 | 98.81% | 0.75% |
| 10 | 520295 | KIMS | 0.61% | 3163 | 96.30% | 0.59% |
| 04 | 332792 | EIA-DRI | 0.50% | 1656 | 99.82% | 0.50% |
| 05 | 462022 | CEDIA | 0.83% | 3851 | 91.20% | 0.76% |
| 06 | 660848 | KIMS | 0.59% | 3886 | 96.94% | 0.57% |

### Cocaine Metabolite(s) Confirmation Rates

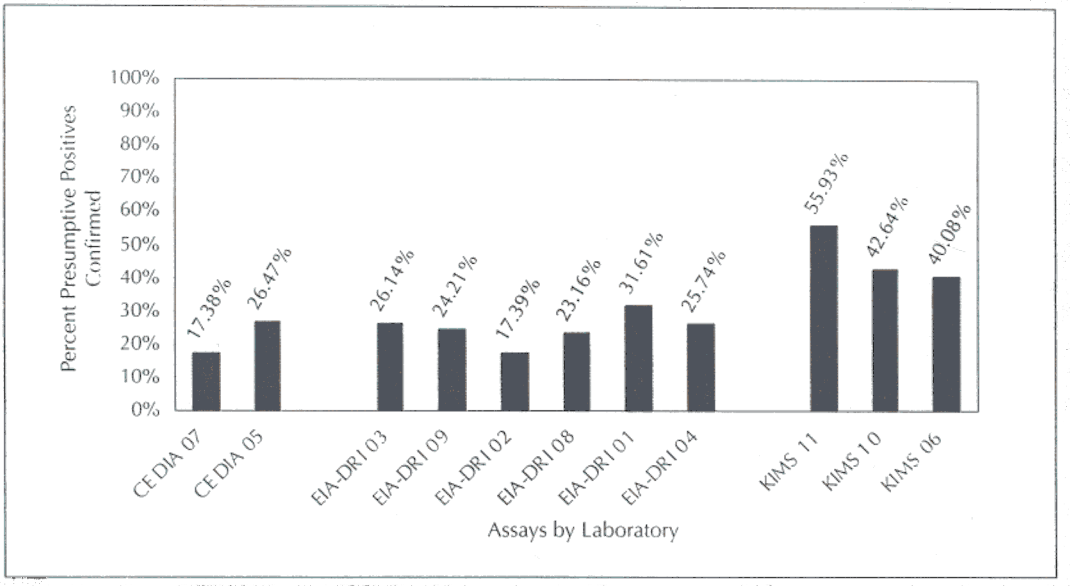


## RESULTS *Continued*

### Opiate Metabolite(s) Analyses

| | Initial and Secondary Screening Assay | | | Confirmation Assay | | |
|---|---|---|---|---|---|---|
| Laboratory: | Samples Tested | Assay Type | Screening Presumptive Positive Rate | Samples Submitted to Confirmation | Confirmation Rate | Positivity Rate |
| 03 | 385561 | EIA-DRI | 0.69% | 2651 | 26.14% | 0.18% |
| 09 | 170007 | EIA-DRI | 0.67% | 1132 | 24.21% | 0.16% |
| 02 | 219594 | EIA-DRI | 0.64% | 1415 | 17.39% | 0.11% |
| 08 | 199080 | EIA-DRI | 0.82% | 1641 | 23.16% | 0.19% |
| 01 | 256642 | EIA-DRI | 0.64% | 1645 | 31.61% | 0.20% |
| 11 | 335312 | KIMS | 0.43% | 1450 | 55.93% | 0.24% |
| 07 | 288508 | CEDIA | 0.66% | 1916 | 17.38% | 0.12% |
| 10 | 520295 | KIMS | 0.41% | 2132 | 42.64% | 0.17% |
| 04 | 332792 | EIA-DRI | 0.64% | 2141 | 25.74% | 0.17% |
| 05 | 462022 | CEDIA | 0.67% | 3087 | 26.47% | 0.18% |
| 06 | 660848 | KIMS | 0.38% | 2525 | 40.08% | 0.15% |

### Opiate Metabolite(s) Confirmation Rates

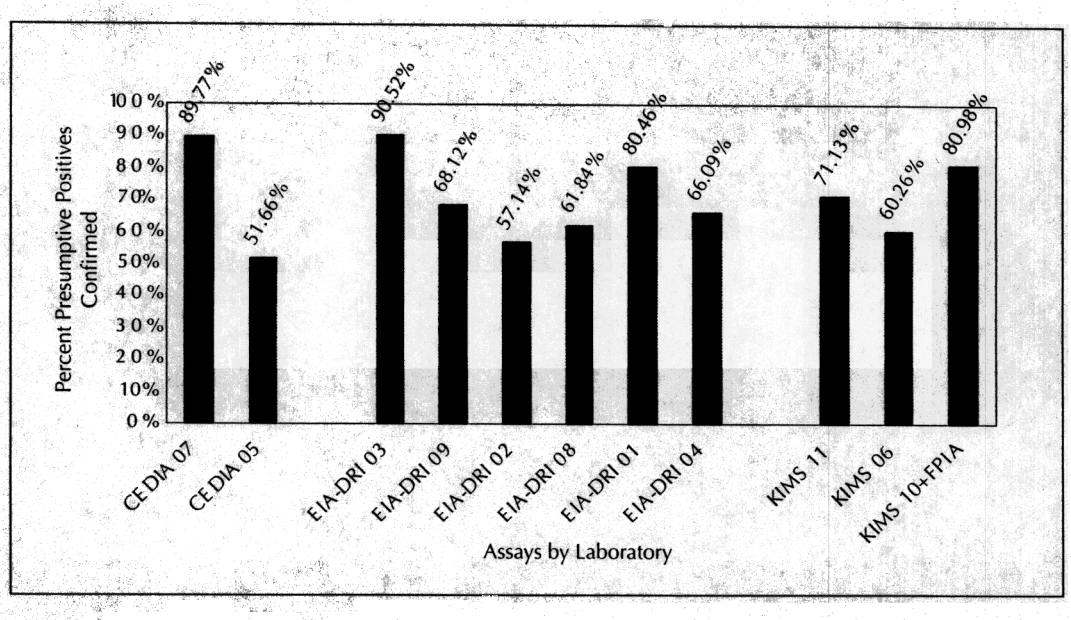


## RESULTS *Continued*

### Phencyclidine Analyses

| | Initial and Secondary Screening Assay | | | Confirmation Assay | | |
|---|---|---|---|---|---|---|
| Laboratory: | Samples Tested | Assay Type | Screening Presumptive Positive Rate | Samples Submitted to Confirmation | Confirmation Rate | Positivity Rate |
| 03 | 385561 | EIA-DRI | 0.03% | 116 | 90.52% | 0.03% |
| 09 | 170007 | EIA-DRI | 0.04% | 69 | 68.12% | 0.03% |
| 02 | 219594 | EIA-DRI | 0.03% | 70 | 57.14% | 0.02% |
| 08 | 199080 | EIA-DRI | 0.04% | 76 | 61.84% | 0.02% |
| 01 | 256642 | EIA-DRI | 0.09% | 220 | 80.46% | 0.07% |
| 11 | 335312 | KIMS | 0.07% | 239 | 71.13% | 0.05% |
| 07 | 288508 | CEDIA | 0.03% | 88 | 89.77% | 0.03% |
| 10 | 520295 | KIMS | 0.05% | | | |
| | 281 | FPIA | 0.04% | 205 | 80.98% | 0.03% |
| 04 | 332792 | EIA-DRI | 0.03% | 115 | 66.09% | 0.02% |
| 05 | 462022 | CEDIA | 0.06% | 271 | 51.66% | 0.03% |
| 06 | 660848 | KIMS | 0.05% | 307 | 60.26% | 0.03% |

### Phencyclidine Confirmation Rates

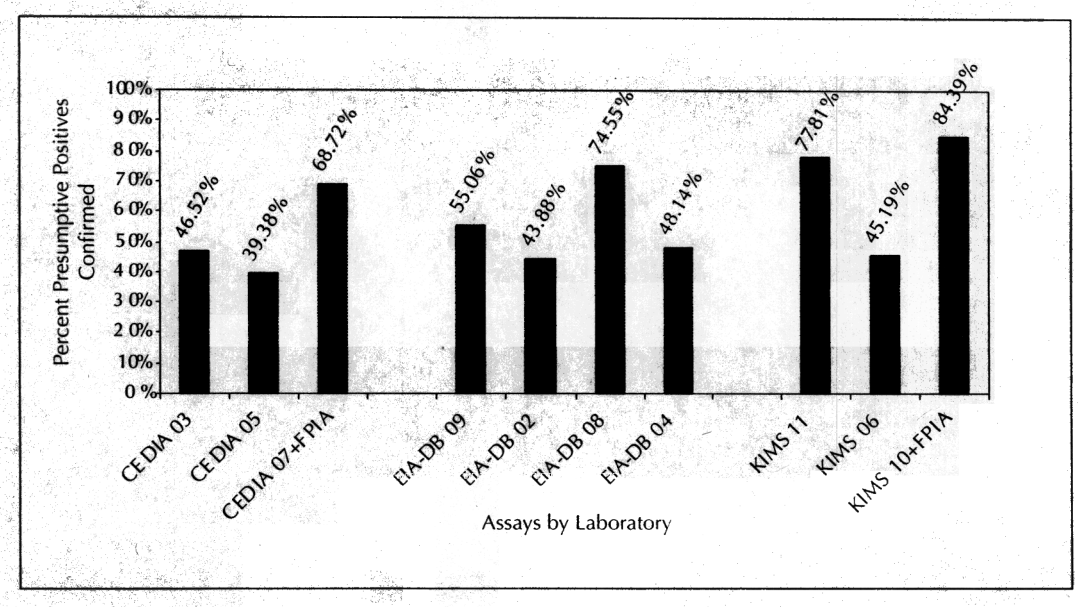


## RESULTS *Continued*

### Amphetamine(s) Analyses

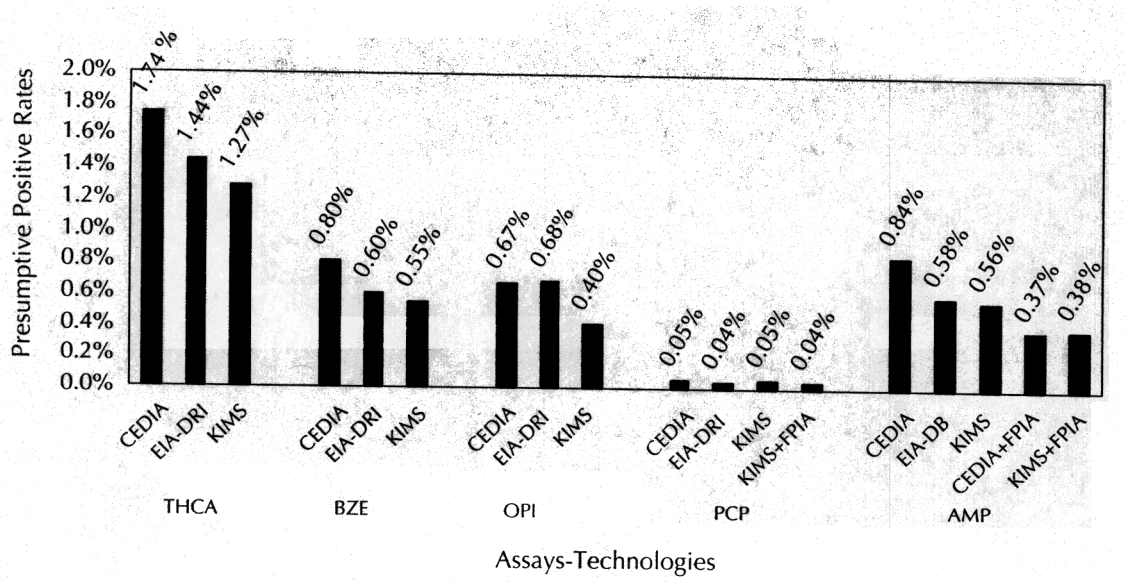
| | Initial and Secondary Screening Assay | | | Confirmation Assay | | |
|---|---|---|---|---|---|---|
| Laboratory: | Samples Tested | Assay Type | Screening Presumptive Positive Rate | Samples Submitted to Confirmation | Confirmation Rate | Positivity Rate |
| 03 | 385561 | CEDIA | 0.76% | 2915 | 46.52% | 0.35% |
| 09 | 170007 | EIA-DB | 0.63% | 1068 | 55.06% | 0.35% |
| 02 | 219594 | EIA-DB | 0.52% | 1144 | 43.88% | 0.23% |
| 08 | 199080 | EIA-DB | 0.87% | 1725 | 74.55% | 0.65% |
| 01 | ----- | EIA-DB | ----- | ----- | ----- | ----- |
| 11 | 337315 | KIMS | 0.42% | 1424 | 77.81% | 0.33% |
| 07 | 288508 | CEDIA | 0.64% | | | |
| | 1852 | FPIA | 0.37% | 1055 | 68.72% | 0.25% |
| 10 | 520295 | KIMS | 0.51% | | | |
| | 2628 | FPIA | 0.38% | 1979 | 84.39% | 0.32% |
| 04 | 332792 | EIA-DB | 0.42% | 1396 | 48.14% | 0.20% |
| 05 | 462022 | CEDIA | 0.91% | 4182 | 39.38% | 0.36% |
| 06 | 660848 | KIMS | 0.63% | 4140 | 45.19% | 0.28% |

### Amphetamine(s) Confirmation Rates



# OVERALL RATE

## Overall Presumptive Positive Rates

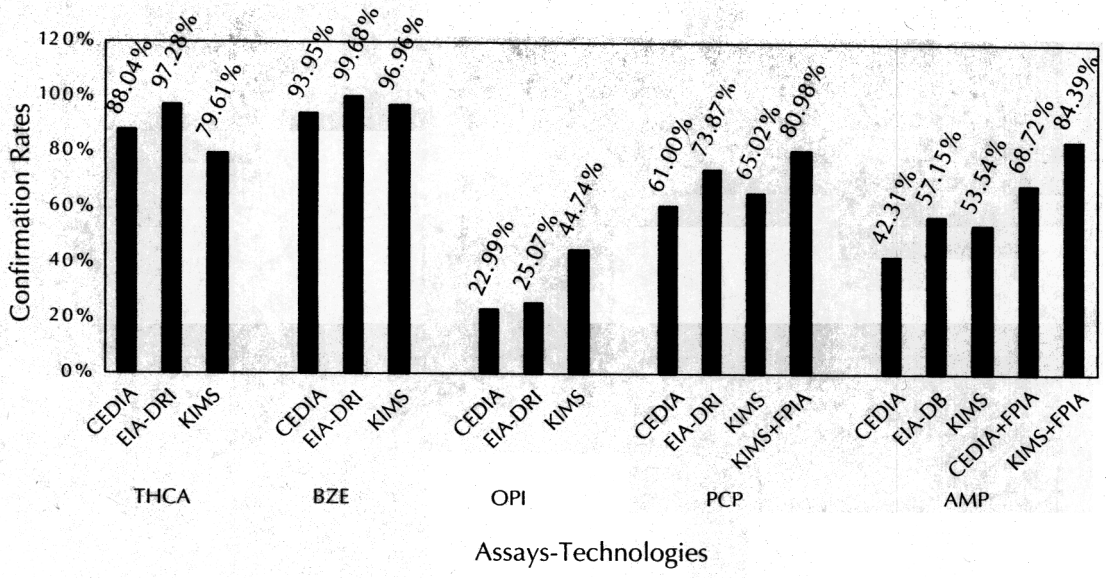



## Overall Assay Confirmation and Range Data

| | THCA | BZE | OPI | PCP | AMP |
|---|---|---|---|---|---|
| OVERALL without Secondary Screen | 88.84% | 97.26% | 30.12% | 67.85% | 50.18% |
| Overall with Secondary Screen | ----- | ----- | ----- | 80.98% | 78.94% |
| LOW without Secondary Screen | 73.03% | 91.20% | 17.38% | 51.66% | 39.38% |
| Low with Secondary Screen | ----- | ----- | ----- | 80.98% | 68.72% |
| HIGH without Secondary Screen | 98.80% | 99.96% | 55.93% | 90.52% | 77.81% |
| High with Secondary Screen | ----- | ----- | ----- | 80.98% | 84.39% |

## OVERALL RATE *Continued*

### Overall Confirmation Rates




## CONCLUSIONS

- This study evaluated the presumptive positive rates and the confirmation rates for primary initial tests by immunoassay method as well as paired immunoassay methods (primary initial test plus second initial test) from 11 HHS-certified laboratories, each testing unique specimens.
- As expected, some assays and technologies appear to better identify specimens containing analytes of interest at or above the administrative cutoffs required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs.
- One-way ANOVA analysis of monthly laboratory confirmation rates by initial test showed:
  - No difference between PCP immunoassays
  - Difference between THCA, BZE, OPI and AMP immunoassays
- Probability plots of monthly laboratory confirmation rates by initial test showed:
  - Overlap of PCP immunoassays
  - Overlap and separation of BZE, OPI and AMP immunoassays
  - Separation of THCA immunoassays
- While the study assesses current capabilities of existing technologies from a large population of "real" federally regulated workplace specimens, it also provides information that may be useful in formulating future guidelines by which newer technologies and approaches may be evaluated.

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*Workplace Drug Testing*
*Division of Workplace Programs*
*Center for Substance Abuse Prevention,*
*SAMHSA*

Open Session, DTAB
September 14, 2004

## Revisions to Mandatory Guidelines

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## One.....

- Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, Specimen Validity Testing (69 FR 19644), April 13, 2004
- Final SVT requirements defined
- Effective date November 1, 2004
- Creatinine concentration criterion defining a Substituted Specimen was proposed as <2 mg/dL
- This was the only issue open for public comment; 60 days
- 13 comments received, not all on the creatinine criterion

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## Two.....

- Notice of Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19673), April 13, 2004
- Many proposals made on using alternative specimens for drug testing, SVT for each type of specimen; point of collection testing; cutoffs established for alternative specimens; cutoff changes for some urine drug tests
- All issues open for public comment; 90 days
- 285 commenters responded with more than 2,000 comments

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All comments available on our website:
www.drugfreeworkplace.gov
OR
workplace.samhsa.gov

Major Issues from Public Comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs

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## Oral Fluid

- Definition and collection of "oral fluid"
  - Definition of "oral fluid"
  - Collection method: "spitting" versus collection device
  - Required volume of specimen
  - Determining volume of collected and split specimens and method of splitting into A and B specimens
- Examination of oral cavity and wait time before collection
- Allowable reasons for testing using oral fluid
  - Recommend allowing return-to-duty and follow-up testing

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## Oral Fluid

- Detection of marijuana use using oral fluid
  - Requiring collection and testing of a urine with each oral fluid specimen
  - Detection of metabolite versus parent drug
- Oral fluid specimen validity testing
  - Need for SVT (oral fluid collections are observed)
  - Appropriateness of testing for IgG and other SVT

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ATTACHMENT (3)

## Hair

- Allowing the use of body hair
- Effect of hair color on drug levels
  - Higher detection levels for some drug users
- Contamination from environmental exposure
  - Environmental exposure
  - Effectiveness of decontamination procedures to address environmental exposure
- Collection
  - Required amount of hair and percentage split between A and B specimens
  - Collector assessment of proper amount

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## Hair

- Hair specimen validity testing
  - Need for SVT (hair collections are observed)
  - Appropriateness of validity tests described in proposed Guidelines and other SVT
- Confirmatory test cutoff concentration for THCA

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## Sweat

- Environmental exposure
- Privacy issues with application and wearing of a patch
- Length of time to wear a patch
  - Guidelines propose 3 to 7 days
- Sweat specimen validity testing
  - Appropriateness of testing for lactic acid and other SVT

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## General: All Matrices

- Fairness to the individuals tested using different matrices
  - Drug detection times
  - Relationship of cutoff values between matrices
- Guidance for Federal agencies on selection of appropriate matrix
- Collection procedures in the proposed Guidelines lack sufficient detail

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## Technical Issues

- Testing of specimens for 6-acetylmorphine by immunoassay and the requirement for a confirmed positive morphine to report 6-AM
- Request for information on need for a separate immunoassay to test for MDMA

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## Collections

- Use of one versus multiple Federal custody and control forms (i.e., matrix-specific)
- Procedural differences between collections for the different matrices
  - Some instructions in the proposed Guidelines are the same for all matrices, but not applicable to all
- Standardized training of collectors and collector trainers and documentation of training

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## Collections

- Problematic collections (e.g., paruresis, dry mouth, allergic reaction to sweat patch)
  - Authorization for the collection of an alternate matrix
  - Additional guidance needed for problematic collections
- Annual inspections of collection sites by Federal agencies

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## IITF

- Question the need for IITFs based on cost and turnaround time
- What type of test result does an IITF report
- Tests performed in the certified laboratory on IITF-tested specimens

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## POCT

- Approval process for POCT device to be accepted for Federal testing
  - Approval by lot of device
  - Submission of manufacturer validation records versus HHS testing of devices
- Training of testers and tester trainers and documentation of training
- What validity tests are to be performed at POCT sites

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## POCT

- QA process: sending 10% of negative specimens to a certified laboratory
  - To whom does the laboratory report the results
  - Follow-up actions
- Reporting POCT-negative specimens to Federal agencies instead of MROs
- Required QC testing

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## POCT

- POCT site inspections
- Relationships between POCT device manufacturers/testers and certified laboratories
  - Proposed Guidelines allow these entities "to freely enter into any relationship"

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## Medical Review Officers

- Relationships between MROs and POCT manufacturers/testers
  - Proposed Guidelines prohibit MROs from any relationship with these entities
- Need for MRO training organizations to be approved by the Secretary

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