**SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION**

# DRUG TESTING ADVISORY BOARD

**June 2, 2009**

**One Choke Cherry Road**
**Rockville, MD**

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## Proceedings

### Call to Order

DR. BUSH: My name is Donna Bush and I am the Designated Federal Official for SAMHSA's Drug Testing Advisory Board (DTAB). At this time, I call this meeting to order.

This is an open session of the Drug Testing Advisory Board. Some attendees are physically present in the Substance Abuse and Mental Health Services Administration (SAMHSA) Sugarloaf Meeting Room while many of you listening and/or viewing remotely. At this time, I'd like to turn the meeting over to Erica Harbison of Research Triangle Institute (RTI) who will advise you on the web instructions for this meeting. Erica?

MS. HARBISON: Hello, and welcome to today's meeting. My name is Erica Harbison, and I will explain a few things about the room in which you are meeting. Your screen is broken into several different sections, called "pods". Each of the pods will provide a different function for you throughout the meeting. Most of the presentations will be shown through our shared pods, which are the largest pods that take up the most of your screen. The attendees list pod, which displays a list of everyone in the room with us today, including those who are calling in but will not be viewing the presentations in the room. At the top of the attendees list, which is on the left hand side of your screen, there is a "My Status" drop-down arrow. Now, if everyone would go to the top of their attendees list and click on the “My Status” drop-down arrow and select the green check mark. This will let me know that you can hear my voice, and that you are having no problems thus far. These “My Status” options are a great way to communicate with us. For example, there is a "Stepped Away" status that lets us know an attendee has

temporarily stepped away from the room, and the "Raise My Hand" status, which lets us know that you have a question. I would also like to mention the chat pod, which is on the right hand side of your screen. The chat pod allows you to submit a question to us at any time concerning either technical problems or pertaining to the material. There is a white bar at the bottom of the chat pod. You simply take your cursor and click in the white bar. This will allow you to begin typing your question, and then you hit "Enter" to send your message. All questions submitted pertaining to the material given will be held until the allotted discussion time when the meeting host will prompt you know it is your turn to talk to the group. There is also a timer pod that will help us keep on track with the agenda today. Again, if you do have any technical problems, or any questions pertaining to the material, please feel free to submit those in the chat pod on the right hand side of your screen.

DR. BUSH: Thank you Erica.

Out of respect for people who are calling to hear one particular presentation, we will attempt to stay on time. If we finish one presentation early, we will wait until the time given on the agenda to begin the next presentation. The American Academy of Forensic Sciences, when they convene their meeting, adheres to the agenda times so attendees can plan their schedules accordingly. If we go over a couple minutes, that will be okay. But we will try to control the time on this significantly, out of necessity and respect.

For public comments, there is a sign-up sheet at the registration desk in back of the room. There will be two public comment sessions for this meeting. The one today is from 4:00 until closing at 4:30 pm Eastern Daylight Time (EDT). Tomorrow, there will be another half-hour public comment time from 12:30 until 1:00 pm EDT.

Several people have already informed me by email that they wish to make public comments. I have requested that the two individuals who wish to comment on the custody and control form presentation on tomorrow's agenda to please wait until tomorrow to make their comments. Another individual has asked to make a public comment today at 4:00 pm. In addition, there are three others.

If you wish to make a public comment, and you have not already notified me, please email me at donna.bush@samhsa.gov. I will check my email until about 3:15 or 3:30 pm, so if you wish to make a public comment today, please let me know by then if I don't already know who you are.

Regarding our Drug Testing Advisory Board members, Bob Stephenson is present in the SAMHSA meeting room. Attending remotely are: Dr. Louis Baxter, Dr. James Bourland, Dr. Larry Bowers, Dr. Jennifer Collins, Lisa Moak, Dr. Nipper, Barbara Rowland, and Dr. Turk. Drs. Estape and Courtney Harper are not in attendance today.

Bob. I'll turn it over to you.

**Welcome and Introductions**

MR. STEPHENSON: Good morning. I want to welcome everybody, both here in the room and those attending remotely through the internet and phone connections, today on behalf of the Director of the Center of Substance Abuse Prevention (CSAP) in SAMHSA, Frances Harding, and on behalf of the Acting Agency Administrator, Admiral Eric Broderick. They have both previously been available to give their greetings personally, but that is not possible today. Both of them have greatly supported and helped foster the publication of the Mandatory Guidelines that came out last fall, and

they understand the nature of what this group and the task that is at hand.

**Implementation of Web-based and Telephonic Meeting Technologies for DTAB Meetings**

MR. STEPHENSON: A reason this meeting was conducted as web-based was to progress on the revisions to the Mandatory Guidelines implementation work that has to be completed in the remaining 11-months before the effective date. The meeting today is important because it is the first to really engage the new technologies and flexibilities in an open session. We have successfully used this technology internally for contractor site visits for over a year. Also, we used it in a closed session of the Drug Testing Advisory Board, so most of the members of the Board have prior experience with these remote technologies. We have used the same technology to address national lab certification laboratory issues and related tasks, which typically are short-notice with quick-turnaround times. This interactive approach, which allows us to share documents, has served us well. This flexibility is valuable to facilitate participation, not only by the members of the DTAB, but also for the public, especially in these tight economy times and with the looming threat of H1N1. I calculated that what we saved at least $5000 in travel costs for the DTAB members alone, and permitted at least one member to participate who otherwise could not have. For instance, one presenter from Department of Defense (DoD) is in the field and will be calling in later.

There will be more DTAB meetings between now and the time that the revisions of the Mandatory Guidelines become effective next May first. Several items need discussions and decisions in a timely manner, and there will be a public meeting and a process for people to participate using the electronic approach as an option.

We will ask for your feedback on this web-based meeting process, either through RTI, through comments posted on the chat pod, or to members of our staff. Please provide suggestions for improvements so that we can work on them for the next time.

COL. SHIPPEE: Hey Bob, this is Colonel Shippee. I really regret that I couldn't be there.

MR. STEPHENSON: I'm glad to see that you're on line with us. Thank you for participating.

COL. SHIPPEE: Well, I think this is a good way to go. And I agree with you that we should have more meetings using this type of technology.

MR. STEPHENSON: Are at your meeting site yet, or are you calling in beforehand?

COL. SHIPPEE: No, we've started. Once a year, DoD convenes a Joint Service Conference of its drug testing labs, which happens to be this week. I am at Navy Great Lakes facility where we began at 7:00 this morning. I am attending via my Black Berry in a low signal area. If I fade out, I'm sorry.

MR. STEPHENSON: Is Greg Goldstein there from HHS?

COL. SHIPPEE: Yes. He presents in a couple hours.

MR. STEPHENSON: Tell him we say hi to him through you.

**Implementation of Revised Mandatory Guidelines**

MR. STEPHENSON: We need to address the implementation of the Mandatory Guidelines comprehensively. Thus, we must engage in outreach opportunities with those in the private and other sectors who have the information we need. The remaining 11-month timeline is tight considering what must be accomplished, including outreach,

standards development, incorporating protocols and changes in procedures for collection-site reviews, and Medical Review Officer (MRO) certification. Because we couldn't afford to waste any more time before we began this work, we are meeting today.

You will hear two detailed presentations on Guideline implementation from Drs. Bush and Baylor. We are now engaged in beginning of a process of review, change, and update that should become a part of our normal way of doing business. We should expect to learn from what we do. We should expect to have management, procedural, and technical updates that occur as anticipated per the timeline. We were delayed for a few years with the publication of the Mandatory Guidelines because of issues beyond our control. Not everything that we had initially proposed was published, but we have a work plan to proceed with those items at a later time. We will solely focus on those tasks that are essential for the May 1 implementation deadline between now and the end of this calendar year. To the degree that we have successfully reached decision points, attained a consensus, published information, and instituted training protocols, then we will begin to look at moving forward at those other aspects, such as alternative specimens and their technologies.

I suggest that we proceed with the agenda and adjust the timelines as needed.

DR. BUSH: This is Donna Bush. This meeting has information that we wish to convey to the public, and we guesstimated as best we could the time needed to do that. We will next listen to Jim Swart’s presentation.

MR. SWART: Yes, I'm here.

DR. BUSH: Very good. Thank you, Jim.

**Department of Transportation (DOT) Drug Testing Mandate**

MR. SWART: Bob and Donna, I like this methodology because it's more inclusive, allowing those from far away to attend DTAB. And it's been convenient for me today, because I've had to stay at headquarters.

Let me also thank Bob, Donna, and DTAB members for the opportunity to speak about the DOT program and to update everyone on two items of interest. The United States Court of Appeals for the District of Columbia Circuit issued a ruling on the 15 May. I will review that ruling with you today, specifically what they said and what we have said about that ruling.

The appeals court upheld DOT's direct observation drug testing rules applicable to return-to-duty, safety-sensitive transportation industry employees who have already failed or refused to take a prior drug test. The court found that the rules were not arbitrary or capricious and did not violate the Fourth Amendment constitutional prohibition on unreasonable searches and seizures. The direct observation drug testing for such return-to-duty employees was reasonable, the court ruled, because of the compelling governmental interest in transportation safety. Furthermore, the court said that employees that have failed a prior drug test have diminished expectations of privacy. Because of the wide array of available cheating devices and the substantial incentive for these return-to-duty employees to use such devices to cheat on required return-to-duty and follow-up drug tests, the department's steps were necessary, well-grounded, and justified, the court said. When the stay will be lifted? Because there is an opportunity for the parties to seek re-hearing of the court's ruling, the court's stay of direct observation rule continues in effect, and the direct observation collections for

follow-up and return-to-duty testing will remain an employer's option for the duration of the re-hearing process. We cannot give an exact date for the re-hearing process to conclude because it depends on what individuals do in terms of the re-hearing process. That's the most important news that we have for you about DOT.

The second thing I do want to mention is DOT's efforts on harmonizing with the Department of Health and Human Services (HHS) Guidelines. We receive questions about this issue continually. Will DOT indicate to the public that it will or will not seek to harmonize with laboratory testing requirements in the new HHS Guidelines? We are currently drafting a notice of proposed rule making. Our intent is to incorporate the new laboratory requirements and many of the definitions contained in the HHS Mandatory Guidelines that go into effect May 2010. Since this is what we always do when the HHS issues new Guidelines, this is not out of the ordinary for us. And as always, public comment to the Notice of Proposed Rule Making (NPRM) will be welcomed, and all comments will be duly considered.

That's the update from DOT, and I hope that everyone was able to hear me, and fully understand what I had to stay. Thank you very much.

DR. BAXTER: This is Lou Baxter. May I make a couple of comments?

MR. STEPHENSON: Of course, Lou.

DR. BAXTER: Thanks. I am very happy that we now have direct observation for those people who have tested positive. I am a great supporter of direct observation for all testing. I developed that opinion because of the work that I do managing healthcare professionals with impairment. In those situations, when the first test is not observed, there is great opportunity for individuals to substitute urine specimens.

As the Mandatory Guidelines stands, if a person is required to test one time and if that one-time test is negative, there is no recourse to continue to test that individual. We may be missing those folks who actually do have a problem by not having direct observation on the very first screen.

MR. STEPHENSON: Thanks Lou. The comment is understood and appreciated. The issue that emerges from the DOT-related ruling from the Court of Appeals is that it begs for incorporation in other kinds of settings. The ruling will probably be challenged and have to be interpreted. It's one case at a time, creating a diagram as the dots are connected across programs and systems.

The work we will do with collection sites will help frame some of the issues more clearly and create an environment where the use of materials to suborn a Federal drug test can be dealt with more effectively. We need national legislation, and we need changes in the free market ability to manufacture and sell products like this to individuals who then choose to use them in drug testing collections, whether for Federal agency, regulated industry, criminal justice, school, private sector employers, insurance, etc. testing. Without materials to suborn the drug testing process, the procedure would proceed with a lot less burden and be a lot less problematic for many of us. We live in a world of reality, and as such, we recognize that these things are out there. Even if they were illegal, it doesn't mean they wouldn't be available.

So, again, Lou, thank you very much. Are there any other members of the Board who have any questions or comments at this time?

DR. BUSH: Thank you very much, Jim Swart, for that update on DOT activities. I now ask Colonel Ron Shippee to deliver the DoD drug testing update from his remote

location in Great Lakes. Colonel Shippee?

**DoD Drug Testing Update**

COL. SHIPPEE: I really appreciate and support Dr. Bush's and Mr. Stephenson's efforts. I just enjoy the growing, professional relationship that we have, and I hope that they do too. We have fought together through some ITG issues. One of our six DoD labs, the Ft. Meade lab, is National Laboratory Certification Program (NLCP)-certified.

Our website http://tricare.mil/tma/ddrp/ contains much information, including all of our policies, the directives that control military testing and DoD civilian testing, the technical guidance for our laboratories, our metrics, and our annual report.

We have a quarterly report requirement for the Secretary of Defense for personal readiness. This has been spurred by the high suicide rate and post-traumatic stress disorder problems, mostly in the Marines and the Army. This report includes metrics, and the drug testing data are included. Once the report is vetted, it's posted on the website.

DoD tests about 4.5 million military specimens a year. Annual random testing rates are 100 percent of the population for the Air Force, 200 percent for the Army and the Navy, and 300 percent for the Marines. Overall, the positive rate is about one percent to two percent. That's remarkable, given the current stress on the military forces. Being a Vietnam veteran and those of you that know Vietnam experience, the Army that fought in Vietnam could not be performing the mission that's going on now. Again, I think that's remarkable.

We have 145 test-sensitive positions within DoD’s Personnel Reliability Program with about an 80 percent test rate. The goal is to conduct 100 percent random testing of

our civilian population.

Our drug test panel ranges from five to nine analytes, including d-amphetamine, Ecstasy, and oxycodone. We do 100 percent screening for heroin. I applaud the new Guidelines because the cutoffs are more in line with the military's.

We perform prevalence studies in which we test negative urine specimens from the labs a couple times a year for other drugs. Testing is not by donor name but by population. We've just finished a benzodiazepines, hydrocodone, and methadone panel. Based on the findings, we are considering adding hydrocodone, or Vicodin, to our test panel. Prescription drugs are becoming a big challenge to our testing and our MRO systems. We are examining interesting ways that we can increase our lab production to include at prescription drug testing.

Concerning the Guidelines, I applaud SAMHSA and HHS. The new Guidelines are well written and include the cutoffs that are closer to ours and permit field-testing or offsite screening laboratories. DoD dropped field screening years ago, not from the technical point of view because the technology is there but from a forensic point of view. In our 10-10-9, DoD will not be doing field screening of civilians; all specimens will be shipped to the lab.

I also appreciate the stand that's been taken on the non-instrumented testing devices and on the alternative matrices. SAMHSA and HHS are right in line with where they're going with that and consistent with what DoD believes too.

We've reorganized our business structure on civilian testing, which is in line with the Guidelines. We are swinging the pendulum from contractor collectors to government collectors. We're expanding our collector's program, which is again consistent with

SAMHSA. We're striving for more quality assurance in the collection phase.

I am in the middle of my five-year budget planning process for demand reduction in DoD. We have been really significantly impacted by the conversion from a government GS-schedule to NSPS. I knew it would probably cost me more money, but it is an eye-opener when I look at the numbers and see what has happened to our budget.

Bob, thanks for the opportunity. Someone from my office will monitor the rest of the program and take notes for me.

MR. STEPHENSON: Thanks, Ron. That's a great update. Do members of the DTAB board have any comments?

Ron had mentioned his eye-opening experience with the conversion from military personnel to civil service. For the Federal workforce, we historically used the number of about 1.7 million employees. Since 9/11 when other Federal special personnel, including those in law enforcement and the national security, were added, the number is now closer to 2.119 million individuals that are listed as Federal civil service employees. Ron is the beneficiary of a number of those additional personnel.

DR. TURK: This is Bob Turk. I have a question for Ron Shippee. Was the field testing stopped because of a quality issue, that is, keeping track of the quality of the field tests?

COL. SHIPPEE: It was stopped because of the forensic issues. In the late 80s and early 90s, we had some questionable things going on at some field testing sites.

DR. TURK: Thanks, Ron.

MR. STEPHENSON: Ron, one of the issues around field testing that could still be

looked at is Military Entrance Processing (MEP) testing. Do you have any comments about how your experience with that so far?

COL. SHIPPEE: MEP testing for the 65 MEP bases around the country is still lab-based. The use of the non-testing device cup-type testing is for the recruiters. The recruiters will call up the MEP Command and say, "How could you find that guy positive? I cleaned up him before I sent him down there." We tell them, "These cups are an analytical test. You need to quality control them." They literally throw them in their desk drawers and then use them without any quality control. Thus, we shy away from all field screening.

DR. BUSH: Ron?

COL. SHIPPEE: Yes, ma'am?

DR. BUSH: For the purpose of clarifying for the audience and for the record, could you please explain “field testing"? Is that a point of collection testing device? Is it an immunoassay portable instrument? Is it done at base level?

COL. SHIPPEE: Yes, and the last field testing site that we shut down was when I ran the Ft. Meade lab and we were getting specimens from Ft. Rucker, which is the Army aviation school. They were using an immunoassay from Olympus at the flight school on the base. Our lab inspectors inspected the on-site laboratory. We promised them a negative result turn-around time of 24 hours if they sent the urine to the lab. We showed them the expense of maintaining that laboratory and achieving the quality control at the level dictated in your Guidelines. That's why I applaud the demand that you are requiring of those labs. You have to maintain that quality. We just felt that we couldn't afford that quality of field screening. Another reason is the historical issues with

the German field screening labs in the 80s that were managed by enlisted personnel in which some payoffs were involved.

The leadership in the Pentagon is applying pressure to institute screening in Iraq and Afghanistan. I have shown them the financial numbers and what it would take to run that lab properly. Now I can show them your Guidelines and say, "See, we're not just playing a game here. At the SAMHSA level, they require this level of quality control. This is what it's going to cost you." They replied, "Okay, we will pay the FedEx charges to get it to the lab where it can be forensically handled."

DR. BUSH: Thanks, Ron, for that clarification and more detail on the situation. Some of us have been in the business long enough that we remember this. For the record, this is part of the history that we all have to understand.

We've dealt with these issues time and time again, and yes, quality costs money, but jobs are on the line. This is one test, at one moment in time, which is handled once, and it has to be done right. You would expect the same for your own urine specimen.

I applaud you back, Ron, for taking that approach. It is hard when people are looking at money and the expenditures of funds. They ask, "Can't you do it cheaper?" The answer is, "Not really, and here are the reasons why." I applaud you back, Ron. Thank you.

COL. SHIPPEE: Thanks. Everyone is entitled to his/her own opinion, but not everyone is entitled to his/hers own facts. You must provide the metrics when you're arguing these things. Thanks.

DR. BUSH: At this time, I will ask Paul Harris, program manager, Fitness for Duty program at the Nuclear Regulatory Commission (NRC) to provide his updates. Paul is

new to us at this Board.

**10 CFR Part 26 Fitness for Duty Program: Nuclear Regulatory Commission**

MR. HARRIS: (Slide) Thank you very much, Donna.

Good morning. My name is Paul Harris. I'm a senior program manager in the US Nuclear Regulatory Commission, in Rockville, Maryland. I'm in the Office of Nuclear Security and Incident Response. Therefore, my slant is on the security side of the house, but I do come with an operating experience.

Today with me, I have Ms. Autumn Szabo who is representing the Office of Regulatory Research. Her counterpart, Ms. Valerie Barnes, will be here later.

First and foremost, I'd like to parallel all the other speakers who preceded me. I wish to personally thank the Drug Testing Advisory Board for inviting us here today. The work you do significantly contributes to our regulatory effectiveness and to the continued operation, maintenance, and surveillance of our nation's commercial nuclear power industry. I'm very grateful for the work you do. I'm learning a lot, and I'm very grateful for the support you have provided. I'd like to give special thanks to Ron Flegel and Donna Bush. You have some good guys and gals working here. Janine, thanks, I appreciate the help on the slides.

I am relatively new to this job. I started this position in February, taking the place of a senior program manager who was with the NRC for a long time and who was responsible for developing NRC's drug testing and alcohol program for the commercial nuclear industry. He has done a lot of good work. I wish him well.

I'd like to present my background, tell you where I'm coming from, and why the slides are the way they are. I used to be a resident and senior inspector at commercial

nuclear power plants for a number of years. I'm primarily focused on safe operation of these power plants, and I used to do daily safety inspections. A number of activities are safety-significant, and they can result in significant radiological harm to the environment and to people at those power plants. Fitness for Duty is a key program element that we are, as an agency, wanting to ensure is effectively implemented by the industry.

I was a senior resident during the 2003 station blackout that occurred on the East Coast of the United States. The East Coast is on an electrical power grid, of which only nine nuclear reactors dropped off the line. However, those nine nuclear reactors supplied 11,000 MW of electricity to that grid at that time. When that blackout occurred, 80 percent of the East Coast went to blackout. This impacted 10,000 nuclear workers, 55,000 people, and just for example, 80 percent of the households in the Detroit area had to have water supplied to them because sewage systems and potable water systems did not work because of the loss of electricity.

We take this very seriously. Fitness for Duty is a key element of safe operations.

(Slide 2) First of all, I'd like to discuss the recent Part 26 rule making, the commercial power reactor drug and alcohol industry performance, some current issues that we're having at the agency, coordination items that we track, and the next steps.

(Slide 3) Our Part 26 is the NRC's Fitness for Duty requirements that certain NRC licensees are required to follow. Primarily, they're focused on the nuclear life cycle, including in Navy nuclear power plants and the fuel systems and commercial nuclear power plants. Our regulations involve administration program provisions and ramifications should violations occur. We work closely with HHS, and we implement those Guidelines through our requirements, and therefore, that's why we're here today.

(Slide 4) Under the fitness for duty umbrella, we have two key program areas I'd like to point out. One is drug and alcohol, and the other one is fatigue management. We use these within Part 26 to provide assurance that persons who have unescorted access to our commercial power plants are fit for duty.

We've worked tirelessly over the last two decades to get our new Part 26 implemented; it was effective as of March 30, 2009. The second half of the rule, which contains the fatigue portion, will be implemented October 1.

Last year, when my predecessor briefed you, he described a rule-making activity that significantly improved the enforceability of our requirements. Historically over the decades, our rules were not very enforceable for our licensees because of outs caused by union issues and personnel questioning the validity of their tests, their subsequent tests, and confirmatory tests. I'd also like to see that type of detail in your Guidelines. I definitely agree with COL Shippee from the Department of Defense. Clearly, the NRC wants to be aligned on drug testing requirements, techniques, and methodologies with the HHS, but just like other agencies, we have to coordinate with the industry.

Some data on the rule making that became effective on March 30, 2008: the cost to implement the fitness for duty requirement is about $14 million per site. The total cost per site is about $42 million for drug testing at a commercial nuclear power plant or a fuel cycle facility. The total industry cost is about $582 million, which involves 100 nuclear power plants and about 65 major nuclear sites. These costs were passed on to our licensees, and the licensees passed it on to the rate base, which is passed on you when you turn on your light bulbs and pay your electric bills.

Currently, we are monitoring the industry implementation of the Part 26

requirements. Yes, we understand that they are fully prescriptive, giving the industry a double-edged sword. They like the prescriptiveness because they don't have to do much thinking, but clearly, they have to understand the requirements. That's why the Guidelines are so good, because all the industry knows about the Guidelines, including the new ones published on November 25, 2008.

Regarding inspection oversight, we have a very robust inspection program for all our nuclear facilities. We have specific requirements that mandate inspections, and licensees are required to provide us with their documentation and inform us of issues that occur during drug testing, blind performance sampling, and confirmatory sampling. Our representatives go in the field and inspect. We inspect the licensee test facilities maintained by our licensees, and we talk to licensee management to identify areas where we can improve our regulations. When we improve our regulations, we have to ensure they align with HHS.

(Slide 4) On this slide, you can see more on my background, which is security for these commercial nuclear power plants. The lower right picture is what's called a composite adversary force. Every three years we test the security forces at nuclear power plants. Why do we do this? We want to make sure that they're the most highly protective commercial facilities in the United States. We achieve that through a security force. Our fitness for duty requirements are specifically applicable to our security forces, and these individuals have to maintain high vigilance in the conduct of their activities, which is equivalent to the vigilance needed by the control room operators that operate these facilities.

This picture depicts our four-pronged approach, which includes drug and alcohol

testing, fatigue management, and behavior observation. I already discussed drug and alcohol testing and fatigue management, which is ensuring that these persons are wide awake and fit for duty, and that includes prescription drugs. And I was happy to hear COL Shippee mention prescription drugs because I am coordinating with a member of his staff on this. Behavior observation has some interesting insights for me. Drug and alcohol testing is not only for the security officers, but also for the maintenance personnel and the technicians who perform maintenance and surveillance on the industry.

(Slide 5) Regarding industry performance, we have 64 reactor sites. We have 6 corporate entities, including the Institute for Nuclear Plant Operations (INPO), two Category 1 fuel facilities, BWXT, and a place called Nuclear Fuel Systems. We have a number of contractors that also report drug testing data to us.

My predecessor briefed you last year on our initiative for electronic reporting to us. We are very, very close to implementing that. We have affirmation from the commercial nuclear industry that they will use e-reporting, which will hopefully improve, not only data evaluation, but also allow that data to be shared with the industry so that they see how their cohorts are doing in drug performance.

One of the certified labs used by our industry had five reportable events. One was for an inaccurate pre-access test result. This is important for us because part of our design basis for security ensures that everyone has proper access authorization such that they can perform unescorted duties within the site. If someone passes a pre-access screening, that is of significant regulatory concern for us. In addition, we had four false positives on performance sampling. I'm sure you all understand the significance of that,

and the jobs affected. For those false positives, there was no common root cause between the four.

We had one site reporting significant problems with the random selection process, resulting in persons not being within the testing pool. The data from the DoD that indicates testing levels at 100 percent, 200 percent, or 300 percent people per year provides me with some regulatory basis to begin having discussions with my industry counterparts because our testing rate is significantly less than that. We require a 50 percent random testing at our commercial nuclear power plants.

We also have some procedural and policy issues that were of concern.

There are licensees out there, namely the DoD, who are voluntarily lowering their thresholds to or below the HHS Guidelines. We have commercial nuclear power plants that are also lowering their testing cutoffs for alcohol and legal drugs. In fact, one-third of all our licensees have lowered their blood alcohol concentrations (BAC). Almost all licensees have lowered their cutoffs for marijuana, one licensee has lowered its opiate level, and another lowered its amphetamine level. Those are clear examples that the industry wants to do good. Four licensees are also testing for drugs that are not required by our regulation, including barbiturates, methadone, methaqualone, and others.

NRC is a user of your guidance. I am not a drug and alcohol expert. When I hear the number of people being tested in other agencies, the NRC is clearly a small player. We only conducted 142,203 tests in calendar year 2007. Out of those tests, 907 were positive, which represents a 0.65 percent failure rate. This is a slight reduction from the 2002 level of 0.83 percent. The last four or five years has trended downward, with a few

little peaks in there. In conclusion, the testing rates for positives are very low.

This 0.65 percent was composed of four major categories that I'd like to discuss. One is pre-access. These numbers are small, and statistically there's a lot of variability. Pre-access testing positivity was 0.82 percent positive while random testing was 0.23 percent, almost four times less. For-cause testing has two elements: observed behavior at 11.25 percent positivity and post-accident testing positivity at 0.63 percent. Finally, follow-up testing positive rates were 0.62 percent. There was a catchall category at 2.3 percent. We have to provide additional guidance to the industry on that.

Behavior observation definitely was high. We require licensees to perform behavior observation of their employees. With abnormal behavior, personnel are subjected to for-cause testing, which came out over 1 in 10.

Looking at this graph here, overall, contractors at nuclear power plants test positive three times as often as site employees. I don't think that's really surprising for most people. Similarly, testing from behavior observation showed that contractors tested positive three times as often as plant employees. Hence, putting additional money in the behavior observation program might be worthwhile.

There were 50 percent more employees than contractors with refusal to test. I found that interesting. However, contractors tested positive for marijuana and cocaine twice as often than employees. And yet, contractors tested positive for alcohol and amphetamines half as many times as employees. This I found just as interesting.

Currently, we're evaluating our 2008 data, and our contractors have not yet completed that evaluation. That should be published here shortly.

Currently, in 2009, though, we've only had five significant events. We had a

controlled substance in a protected area of a nuclear power plant. We had another individual that had a controlled substance on his body. We had a false positive error on a blind sample, which is currently being evaluated by a Virginia fuel facility. We had a non-licensed employee supervisor test positive for illegal drugs on a follow-up test. Lastly, there was a confirmed positive for alcohol.

(Slide 6) We've already discussed in detail the HHS Guidelines and NRC regulations. We have implemented the Guidelines. One of my biggest concerns is getting accurate cost accounting from the industry. Numbers provided by the industry are verified by me and my staff to determine if they're good, because the industry continually complains about the burden that our regulations place on them.

Because the drug and alcohol Guidelines of Part 26 are relatively new, and because it appears that we will be doing some rule making in the very near term, we will monitor the drug and alcohol and fatigue portion of rule implementation. We will do that through frequently asked questions, site inspections and public meetings.

One of the issues that is near and dear to our hearts is new reactor construction. The industry is trying to build new reactors and get them back on the grid. The NRC has a number of applications that are in various stages of review. Currently, we are in dialogue and negotiations with industry representatives on the testing and sampling populations. We appear to be reaching an agreement whereby the testing population will be 50 percent for new reactor construction.

The big issue there is the transient workforce. During the construction of a power plant, there are 2000-4000 people on-site at any one time. They are coming from union halls in the surrounding areas. It is a huge managerial and administrative effort to track

all those people, to figure out what activities they will be doing, and to figure out what portions of the requirements that they need to test for these individuals. It comes down to the access controls; licensees need to control their individuals and we are in discussions with the industry on how to better achieve that.

(Slide 7) For the next steps, first and foremost, our inspectors in the field are our eyes and ears. Priority number one is responding to inspector calls. We have a very limited number of drug and alcohol experts with the agency, including the one here in audience and the one who is trying to get here. We're doing the best we can.

We want a proactive effort to gain industry perspective through site visits and public meetings. We are looking at the direct final rulemaking like the DOT is doing on the Guidelines. We also have recent enforcement discretion. Our requirements require licensees to do certain testing. But, unfortunately, the wording is wrong. It does not state what we wanted nor does it comply with HHS Guidelines. Our requirements were wrong, so NRC granted the enforcement discretion for the industry such that we will not issue violations if they meet certain testing requirements that we provided to them.

(Slide 8) Listed are the contacts, their phone numbers, and emails for myself; Valerie Barnes, who is a senior level advisor, and Autumn Szabo. Please feel free to email us.

We also have a website that has some good background information and some frequently asked questions by industry.

(Slide 9) Thank you very much.

MR. STEPHENSON: Thank you very much. Do any members of the Drug Testing Advisory Board have questions?

DR. BAXTER: This is Dr. Lou Baxter. I have one. I was wondering what happens to those individuals that refuse to test?

MR. HARRIS: If they refuse to test, our requirements are that the licensees have to identify sanctions for individuals who fail to follow licensees' policies and procedures. A refusal to test would be treated as an illegal activity. I could get back to you with the specifics.

DR. BAXTER: For some agencies, when you refuse to do a test, that's considered a positive test, and then the other Guidelines fall into effect.

MR. HARRIS: I don't fully understand the subtle semantics here. Please email your question to me, and I'll get back to you.

MR. STEPHENSON: I'd like to ask a question, Paul, regarding the issue around alcohol. We in the Federal government have focused for many years on demand reduction, with an emphasis primarily on illicit drugs. Today we are facing an increasing surge of concern around the misuse of prescription drugs. We had a special meeting last August that examined what we could do in the Federal system, based on the experience and knowledge of others. You, in the NRC, have that same experience base for alcohol in the fitness for duty arena. I challenge all of us to think more holistically about the safety and fitness for duty issues and the role that alcohol can play, either by itself or in combination with other drugs. I would like to work with you to see whether we can develop some educational information and perhaps a call to action.

The positive rate for alcohol by employees indicates that we need to strengthen education and recognition that this is a serious problem for themselves and others. Many believe that alcohol doesn't have an effect on safety or performance, either

because of inexperience with alcohol or cultural acceptance. This is an issue that we face across this country in many different arenas. We could look to the experience of DOT and DoD, to the degree that they're willing to identify or participate with us, with these alcohol issues.

The highest positive testing rate for marijuana was among contractors. This fact might serve as ammunition to use in your negotiations with the industry for hiring during the construction phase of testing, before you have a fuelled facility and Part 26 is effective. Industry must be made aware of the impairing effects of marijuana on the ability to quickly respond during emergencies and accidents. It may be of some importance to the industry to reconsider a higher testing percentage.

Thanks again for sharing your insights. We look forward to working with you more in the future on a sustained basis.

MR. HARRIS: I thank you for that. Those are very keen insights, and I definitely will consider them.

These new reactors are being constructed with this transient workforce. Throughout the industry, the core numbers of individuals who have nuclear experience has not grown as fast as the nuclear industry can grow. This will cause stress at the new employee level, because the people are needed. However, it will also cause stress on the aging population as well. The industry is hiring many retirees, who have left the nuclear industry, to come back to help them design and construct these nuclear power plants. On the SAMHSA website, there are links to prescription drug use by elderly individuals and illegal use of those prescription drugs for the elderly.

MR. STEPHENSON: This goes right back to the impact of prescription drug

misuse. There are two aspects that you need to face that we don't do in our demand reduction area. You may have an individual who has a prescription for a particular drug, and is in fact taking that drug in accordance with the medical instructions. That drug itself may have an effect that is impairing to that person's ability to perform particular job.

As we age, we have more chronic pain that we must deal with every day. The degree that someone then brings that condition and perhaps that medication into your workforce proposes a special challenge to you, especially if you first recognize it when you have a positive drug test.

This is one of the topics that we discussed during our special prescription drug meeting last year. There is the quandary between chronic pain management and access to these drugs as well as the misuse of a prescribed drug by someone who has a habit but not necessarily the pain to go with it.

Your insights and what you're able to do with this issue could prove very instructive for us because we don’t have the same challenges that you do. We utilize a demand reduction strategy, not a fitness for duty. Alcohol is a fitness for duty issue because you're doing impairment detection.

I look forward to working with you on that, too. It is an area where your insights and your industry observations will be helpful to us.

Thank you.

DR. BUSH: That was a wonderful discussion. I really thank you, Paul, for sharing that information. I appreciate the statistics and numbers that you presented.

There are currently 75 people attending online, including our Advisory Board. It is

11:15 am and time for a short break. We will reconvene at 11:30.

(Break)

**Review of Significant Changes in the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs**

DR. BUSH: (Slide 1) It is 11:30 and time to resume the open session of the Drug Testing Advisory Board. I'd like to introduce myself because I'm giving this presentation on the review of significant changes in the revised Mandatory Guidelines for Federal workplace drug testing programs with an effective date of May 1, 2010.

(Slide 2) This program dates back to September 15, 1986 when then-President Ronald Reagan issued Executive Order 12564 to began this entire program. One statement from that Executive Order is: “The Federal government, as the largest employer in the nation, can and should show the way toward achieving drug-free workplaces through a program designed to offer drug users a helping hand.” (Slide 3) This Federal employee workplace drug testing program was established as a deterrent program, focused on demand reduction of illicit/illegal drugs, to include marijuana, cocaine, opiates with a focus on heroin, amphetamines with a focus on methamphetamines, and phencyclidine. Alcohol is not included; prescription drugs are not included.

(Slide 4) Federal initiatives began in 1986 with the Executive Order through to an establishing, empowering public law, 100-71, which allowed Federal agencies to spend appropriated Federal funds to establish this drug testing program, as well as a much more comprehensive drug-free workplace program.

On April 11, 1988, the Mandatory Guidelines for Federal workplace drug testing

programs were issued. They set scientific and technical standards for drug testing of Federal employees and for certification of the drug testing laboratories. This program was established by technical experts who created a very sound program.

DOT, with separate authorizing legislation, published their regulations in the Code of Federal Regulations (CFR) in 1989. These regulations, which require similar programs to ours, impacted private sector employers in the DOT-regulated industries. Effective May 1, 2010, a fifth revision to the Mandatory Guidelines will be implemented.

(Slide 5) SAMHSA has oversight responsibility of Federal agency drug-free workplace programs. We have about 120 Federal agencies with drug-free workplace plans and annual reporting requirements. Using the data submitted from these agencies, we prepare a report to Congress.

We have about 2.119 million Federal employees and job applicants that are covered under this program. Not everyone in the Federal government is tested. There are about 400,000 testing-designated positions, with about 210,000 forensic workplace urine drug tests conducted per year.

(Slide 6) Components of that comprehensive drug-free workplace program can be found on our website. I will display the website URL at the end of my presentation. There is much more to a drug-free workplace program than just drug testing. There's formal written policy, employee assistance programs, supervisor training, employee education, and methods for detecting illicit drug users. Might we add a new goal in the future under health reform umbrella? Might there be health and wellness added to this?

(Slide 7) The first Guidelines were published in the Federal Register on April 11, 1988, with the fifth revision effective May 1, 2010. There have been sporadic

publications of new policy changes, cutoffs, etc., in-between. The National Laboratory Certification Program was established to ensure that the certified laboratories meet the minimum requirements of these Mandatory Guidelines as far as the drug testing portions of it are concerned. A list of certified laboratories is published monthly in the Federal Register.

(Slide 8) The testing-designated positions are safety- and security-sensitive positions that include, but are not limited to, national, chemical, or nuclear security and such agencies as DoD, NRC, and the Department of Justice which includes law enforcement, customs agents, and Federal Bureau of Investigation (FBI).

To protect employees or property from harm, certain health care positions involved with client contact and positions covered under the DOT regulations, such as those motor vehicle drivers who transport passengers, airline pilots, airline mechanics, airline flight crews, air traffic controllers, railway workers, and marine personnel. A large number and type of people are in safety and health-sensitive positions.

(Slide 9) Now, I'd like to review for you the proposed revisions that were published in plain language format on April 13, 2004 for public comment. Proposed were additional new requirements and capabilities for urine drug testing laboratories. Proposed were the use of alternative specimens, such as hair, oral fluid, and sweat patch, for Federal employee drug testing. Also proposed was the use of point of collection testing (POCT) for urine and oral fluid for Federal employee drug testing programs. As published on November 25, 2008, the revisions to the Guidelines are restricted to urine drug testing only.

(Slide 10) For the November 25, 2008 publication, we were actively tracking the

progress of the final document on its way through the Department, through the Office of Management and Budget (OMB), through the Department again, and out to the Federal Register, where it was posted in the reading room as a preview of what's soon to be published in the Federal Register. Up to the day before publication, all was well with the document. When the document was published in the typical, easy to read, three-column Federal Register format on November 25, the effective date was wrong. An immediate request was made to publish the correct effective date of May 1, 2010. This was published in a different Federal Register Notice on December 10, 2008. For the Guidelines, I always provide both Federal Register Notices, the December 10 and the November 25 documents.

(Slide 11) Unchanged from the previous requirements of our Guidelines is that urine is the only specimen that can be collected for Federal and agency workplace drug testing programs. Reiterated are the circumstances under which a Federal agency may collect a specimen, which are applicant pre-employment testing, random testing, reasonable suspicion and for cause testing, post-accident testing, return to duty testing, and follow-up testing. If you're not covered by one of these testing-designated positions or applicant process, you voluntarily sign up for that drug-testing program, as I have done.

(Slides 12-13) Six major changes were published in those revisions to the Guidelines: revised requirements for specimen collections; standards for collections and collection-sites; revised laboratory testing requirements; new technologies allowed for confirmatory drug testing; new type of testing facility, called the instrumented initial test facility; and revised standards for Medical Review Officers.

Every presentation that will follow today and tomorrow in this Drug Testing Advisory Board session will expand upon each one of these and describe where we are now, what our approach is, and the timeline on which we are embarking to complete everything necessary by May 1, 2010.

(Slide 14) There were questions from OMB that we had to explain and justify. Why was there an 18-month implementation date? It was to allow time for the manufacturers of immunoassay test kits to modify or manufacture new kits and ensure compliance with any applicable statutory and regulatory requirements before commercialization of those kits. HHS-certified laboratories will need to validate and implement the new immunoassay testing kits before May 1, 2010. The NLCP must challenge the HHS-certified labs with performance testing (PT) samples to ensure that the test kits and the test results satisfy the required performance criteria as published in those Guidelines. HHS, other Federal agencies, and the various industries will need to implement new and revised procedures to ensure compliance with the Guidelines. Currently, we're at 11 months and counting until implementation.

(Slide 15) Regarding collectors and collection-site issues, the collection of specimens is much akin to collecting forensic evidence in this program. (Slide 16) The collection of a biological specimen has been discussed in several Supreme Court decisions concerning pre-employment, random drug testing, and other types of drug testing for Federal employees. The uniformed and military services in their drug testing program perform their uniformed service collections under direct observation. However, this civilian-based program is footed in and cornerstoned in the right to donor privacy. Thus, we don't have direct observation except under very specific conditions.

The specimen is collected with a chain of custody form that attests to the integrity, security, and identification of that specimen. The very first evidence collected is the specimen temperature that is recorded on that form. A tamper-evident bottle seal is used. This entire process, when performed according to the provisions of the Guidelines and our collection-site handbook, minimizes specimen tampering by the donor. There are collector standards, collection-site standards, and inspection of collection-sites that are coming to a collection-site near you.

(Slide 17) The collection handbook can be found on our website at http://workplace.SAMHSA.gov, along with many other documents. The last version of the collection handbook is dated 2004 when the last revisions were implemented. An update will be made for 2010.

(Slide 18) Revised collection procedures include a requirement that each specimen be collected as a split specimen; there will no longer be single specimen collections. To the greatest extent possible, we have tried to harmonize procedures and processes with those of DOT. I want to thank Jim Swart, his staff, and the Division of Workplace Programs (DWP) staff for making this happen. We did it the best way we know how, and we'll continue to do so in the future.

(Slide 19) There is additional clarification of collection procedures, for instance, when a donor does not provide a sufficient volume of urine, when and how a direct observed collection is performed, when and how a monitored collection is performed, and when the collector reports a refusal to test.

(Slide 20) Collector requirements include knowledge of the Guidelines collection procedures and documentation of that knowledge. A collector must complete training

with a qualified trainer on the following subjects: all steps necessary to complete a collection correctly; proper completion and transmission of the Federal custody and control form; problem collections, including fatal flaws and correctable flaws; and how to correct problems in collections.

(Slide 21) The collector's responsibility is to maintain the integrity of the collection process, to ensure the privacy of the individual being tested, to ensure the security of the specimen, and to avoid misconduct or misstatements that could be viewed as offensive or inappropriate. They must demonstrate proficiency by performing five error-free mock collections. Refresher training is required every five years. All training records must be maintained and provided to the agency upon request. There are specific training requirements for an observer of a direct observed collection.

(Slide 22) There are specific requirements for a trainer of collectors. There are requirements for Federal agency oversight of this entire collector and collection process to ensure that collectors meet the Guidelines requirements to be a specimen collector. The collector must maintain a copy of his/her training records and provide a phone number of a contact person in the event that problems or issues arise during any collection procedure.

(Slide 23) A collection-site is defined as a permanent or temporary facility. Requirements for that facility include: provisions for donor privacy, clean surface area for handling the specimens and paperwork that are not accessible to the donor, a secure temporary storage capability, the ability to restrict access during the collection and restrict access to collection supplies, and requirements to secure collection-site records. (Slide 24) There are required procedures to ensure the security and integrity of

specimens, including no unauthorized personnel in that collection-site area; collection of only one specimen at a time; restricted access to collection supplies; maintenance of the Federal chain of custody (CCF) and all the attributes about it, and training concerning completion of that Federal CCF.

(Slide 25) The agency must ensure that the collection-sites meet those Guidelines and annually inspect at least 5 percent, or up to 50, of the collection-sites randomly selected. Since many agencies share collection sites through contractual arrangements, they will communicate amongst themselves to ensure that the same collection site is not inspected twice by two different agencies. Agencies must ensure that evidence is collected on collector errors, whether they're in-house collections collected by Federal employees on Federal facility property or whether they're contracted services at facilities outside, and accept responsibility for their programs.

(Slides 26-27) For the laboratories that we certify, there are semi-annual on-site laboratory inspections and quarterly performance testing. That hasn't changed.

(Slide 28) This is a schematic of a day in the life of a urine specimen to show how many integrated portions, parts, procedures, and processes are all tied together in this drug testing process. Time is always of the essence, from the time a specimen is collected, to the time a result is reported to the MRO, and until the MRO performs whatever review is necessary on that result. Though it looks very complicated, we have many very competent laboratories that have implemented this drug testing ballet very well. (Slide 29) The laboratories will implement the new acts to the ballet because of the two new initial drug test analytes: 6-acetylmorphine (6-AM), which is a heroin marker metabolite, and methylenedioxymethamphetamine (MDMA), which has the

street name of Ecstasy. The revised Guidelines will require initial testing of all specimens for 6-acetylmorphine, regardless of the morphine concentration. Current Guidelines only require confirmatory 6-AM testing of all morphine-positive specimens with results greater than or equal to 2000 ng/mL. (Slide 30) Under the current Guidelines, MDMA is not routinely tested in Federal workplace programs, but it will be come May 1, 2010.

(Slide 31) We have lowered some drug test cutoffs, particularly for amphetamines. The initial test cutoff has been decreased to 500 ng/mL. Confirmatory test cutoffs for both methamphetamine and amphetamine are lowered to 250 ng/mL. Thus, it is important for manufacturers making new immunoassays or retooling existing ones to meet new cutoff requirements. The amphetamine presence reporting requirement for methamphetamine in the confirmatory testing process has been lowered to 100 ng/mL. For cocaine, the initial test cutoff has been lowered to 150 ng/mL, while the confirmatory test for the cocaine metabolite benzoylecgonine was lowered to 100 ng/mL.

(Slide 32) New confirmatory test analytes include MDMA, 3,4-Methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA).

(Slide 33) For new confirmatory test technologies, the current Guidelines allow for gas chromatography/mass spectrometry (GC/MS) only. The Revised Guidelines will allow additional analytical methods that combine chromatographic separation with mass spectrometric identification. Many people say, "If GC/MS is the gold standard, why are you changing away from it?" When these Guidelines were first established and implemented in 1988, there was no such thing as GC/MS/MS and liquid

chromatography (LC)/MS was just being developed. Truly, GC/MS was the state of the art and the gold standard at the time. It still is, and yet we're expanding on those technologies with mature technologies that weren't even invented yet or considered for implementation in a drug testing lab way back when. We are expanding our gold standard capabilities because Federal law requires HHS to establish comprehensive standards, which include the use of the best available technology to ensure the full reliability and accuracy of drug tests.

(Slide 34) An instrumented initial test facility (IITF) is now allowed to perform the front-end, receiving, accessioning, and screening portion of the initial test which is currently conducted in an existing, complete forensic laboratory facility. This new type of facility will perform the initial drug test and the first tests conducted to determine specimen validity. This facility must be certified under the National Labs Certification Program to perform Federal employee drug testing.

There will be an application inspection PT process analogous to the existing NLCP processes for labs. Key personnel must meet Guidelines requirements. The same procedures that are in effect in a full-service, comprehensive NLCP lab are similarly required in the IITF.

(Slide 35) The IITF can report specimen results as negative, negative dilute with creatinine levels between 5 and 20 mg/dL, or rejected. That's a very limited repertoire of results that that IITF can report. IITF specimens with results indicating drug-positive, adulterated, substituted, invalid, or dilute with a creatinine less than or equal to 5 mg/dL must be sent to a certified laboratory for testing.

(Slides 36-37) The Medical Review Officer must be either a Medical Doctor or a

Doctor of Osteopathy. That is an existing requirement. Other existing requirements include knowledge regarding the pharmacology and toxicology of illicit drugs. New MRO requirements include training that includes a thorough review of collection procedures; interpretation of test results reported by laboratories; chain of custody reporting and record keeping requirements for Federal agency specimens; knowledge of the HHS Mandatory Guidelines and procedures for interpretation, review, and reporting results specified by any agency for which the individual may service as the MRO; and successful completion of an exam administered by a nationally-recognized entity that certifies MROs or subspecialty boards for physicians performing review of Federal employee drug test results which has been approved by the Secretary of Health and Human Services.

(Slide 38) There are additional details and clarification of MRO responsibilities, and additional details and clarification of MRO actions when donors do not provide sufficient volume for a drug test. These requirements are harmonized with DOT's 49 CFR Part 40. (Slide 39) On the same website I mentioned earlier is posted a Medical Review Officer manual. The currently posted version was revised in 2004, consistent with the requirements implemented in 2004. Updates will be made, though, for 2010.

(Slides 40-41) There are additional Guidelines revisions under Section 3. The tests to be performed for Federal employee drug testing specimens were clarified. It was clarified about how a Federal agency can routinely test for additional drugs or on a case by case basis. The Guidelines address situations in which there is no initial test kit available for a drug for which a Federal agency wants to test.

(Slide 42) There is a revised number of blind samples that must be submitted by

an agency: three percent of the total specimens, regardless of the age of the drug testing program. There are requirements for supplier validations of blind samples, including sample content and concentration ranges. Lastly, investigation is required for inconsistent blind sample results.

(Slide 43) Criteria for rejecting specimens include fatal flaws, correctable discrepancies, and uncorrectable discrepancies that are clearly spelled out in Section 15.

(Slides 44-45) Current and future activities include revised requirements for specimen collection and revision of the Federal CCF through OMB clearance procedures.

Performance standards and recommended procedures and practices for Federal agency oversight activities of collectors and collection sites are mandated. (Slide 46) PT sets will be designed and implemented to challenge the labs with new analytes and new cutoffs and to verify each lab's ability to perform the requirements prior to May 1. The NLCP documents, such as our checklists and our manuals, will be revised.

Because new technologies are now allowed for confirmatory drug testing, method validation and minimally acceptable acceptance criteria requirements for these new technologies will be established. (Slide 47) NLCP processes and documents for the IITF will be developed. Qualification standards for MRO oversight groups and standards for the content for the certifying exams will be set. Procedures for HHS annual review and approval of those MRO oversight groups will be implemented.

(Slide 48) This is all required for the implementation of the Guidelines in May 1, 2010. We will be issuing additional notices in the Federal Register requesting

information and assistance from the public in providing or identifying data and research findings that address specific areas of interest concerning point of collection testing devices and the use of alternative specimens, such as oral fluid, sweat patches, and hair.

(Slide 49) The DWP website has many resources available on many different subjects and not just on drug testing. These include general drug-free workplace programs, young adults going into the workplace, and workplace health, wellness, and safety.

I thank you for your attention. Do any members of the Board have questions?

DR. BAXTER: Dr. Bush, this is Lou Baxter. I don't have a question, but I do have a comment. I am so happy to see how much this has progressed since 1988. Some of the things that we suggested have been implemented, and it's pretty exciting to see that change can occur although it takes time. I think that these changes are for the better.

DR. BUSH: Thank you for that comment, sir.

MR. HARRIS: Donna, I have a question. Regarding the instrumented initial test facility, do you had any insights on what kind of licensees or entities will use such a facility and how much that would cost them?

DR. BUSH: There are indications that several existing certified laboratories would choose to become an IITF and forward those specimens that need additional testing to another certified laboratory. Thus, the business model will change amongst the existing certified laboratories. As for new applicants to the program, I have received only two phone calls shortly after the Guidelines were published asking me pointed questions about the IITF. Interest may increase as we present this information in open session

and continue to do so in the future. As for costs, I really don't have any idea, but it would depend on the size of the IITF.

MR. STEPHENSON: Because of the current economic conditions, a rearrangement of the total business volume across testing resources in the laboratories within a chain might occur. This laboratory rearrangement could involve a partial constriction or a total consolidation. For instance, if a laboratory has a large market share in a given geographic area, there may be an advantage in performing screening only. Since most of the laboratory work is at the screening level, then only a few specimens would be forwarded to another member of the same laboratory chain. The confounders are the economy, the volume of testing, and the laboratories' business models.

MR. STEPHENSON: There is a comment from another member of the NRC Technical Group.

MS. SZABO: I just have a clarifying question for Donna. I wanted a clarification of when immunoassay is utilized in the initial, validity, and confirmatory tests.

DR. BUSH: Immunoassay is the testing technology that we implemented 20 years ago to test for the drugs of abuse in a specimen. There are no immunoassay tests for any of the attributes for specimen validity. If a specimen tests positive in the initial immunoassay drug test, then an aliquot is removed under intra-laboratory chain of custody from the original specimen bottle, which is maintained in a secured, controlled environment, temporary storage area, and taken into the confirmatory testing process. Immunoassays are not used in the confirmatory drug test process; they are employed only as an initial test for drugs at the very beginning of the laboratory process.

The next presentation, the “NLCP Planned Implementation of the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, May 1, 2010”, will be given by Dr. Michael Baylor from RTI.

**NLCP Planned Implementation of the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, May 1, 2010**

DR. BAYLOR: (Slide 1) Thank you, Donna. For the next 15 minutes, I will discuss the National Laboratory Certification Program's planned implementation of the Revised Mandatory Guidelines for workplace drug testing.

(Slide 2) The National Laboratory Certification Program provides oversight for the drug testing facilities that are certified to perform Federal drug testing. This involves both an inspection program in which on-site inspections are conducted at least twice annually, as well as performance testing challenges. The expectations of performance by the laboratories, or drug testing facilities, are defined in the National Laboratory Certification Program's checklist, the inspection manuals, and the quarterly performance testing cycles. These quarterly performance testing cycles have both routine drug specimen validity testing and retest challenges. This will be explained in much more detail by my colleague John Mitchell later today.

For a smooth implementation of the Revisions to the Mandatory Guidelines on May 1, 2010, which is approximately 11 months from now, much preparation, revisions, and inspector training, as well as the distribution of new and revised documents, must be accomplished. This must be accomplished over the next 11 months.

(Slide 3) The NLCP has a number of inspection oversight tools that it uses to ascertain the laboratory's fulfillment of the expectation of performance for the drug

testing. These tools are primarily documents that are used in the process of evaluating the laboratories' capabilities, instrumentation, training, staffing, as well as their methods. The application is a document that's used to assess the laboratories' capabilities as far as the staffing, the instrumentation and the methods that they have available, as well as the procedures they envision utilizing for workplace drug testing. The program uses checklists to provide uniformity in the conduct of on-site inspections at the drug testing facilities. There is a laboratory as well as the instrumented initial testing facility information checklist which is confined to sections A, B, and C of the checklist. This describes the laboratory's general layout and the laboratory's staffing. It defines the key staff, the hours of the laboratory's operation, as well as a synopsis of the procedures, methodologies, instrumentation, and some of the key criteria utilized within the methods and instrumentation for conducting workplace drug testing as well as specimen validity testing. Sections B through Q describe laboratory and IITF inspections, specifically the areas that are examined while inspectors and auditors are on-site at the laboratories. The program also looks at the laboratory and IITF computer systems, which is Section P of the checklist. The final area is the laboratory and IITF records audit, which are found in Sections R through U of the checklist.

The NLCP manual essentially takes the checklist questions and provides a comment, expectation, or explanation concerning the specific criteria or parameter addressed in that question, and more or less, defines acceptable technical parameters of performance.

To ensure that laboratories are being equitably inspected and evaluated, inspector auditor training is conducted on an annual basis, and there are inspector

requirements that individuals performing as consultants to the National Laboratory Certification Program remain active in workplace drug testing and forensic toxicology. Inspector auditor training is generally held in conjunction with the Society of Forensic Toxicologists meeting, which is usually held in the fall of each year.

(Slide 4) The National Laboratory Certification Program has oversight of performance testing (PT), which are called PT cycles. PT samples are drug testing and specimen validity testing samples that are shipped out to the laboratories. The laboratories treat these as blind specimens and conduct specimen validity testing screening, initial testing, and confirmatory testing, if required. Included in PT are samples that mimic Bottle B retesting, in which the drug or analyte is tested to the laboratory's limit of detection limit of quantitation, irrespective of the decision point cutoffs. This retesting generally focuses on the methodologies utilized by the laboratory, including immunoassay, spectrophotometry, colorimetry, mass spectroscopy, pH meter, as well as refractometry.

(Slide 5) This slide depicts the documents and PT challenges for urine laboratories. It is organized into columns of two-month intervals except for October 2009, which is an individual month, and looks at the implementation planning process from December 2008 through May 1, 2010 and on a five-month interval from June through October, 2010. The first row shows that the final rule was published in the Federal Register on November 25, 2008. Implementation of the Revised Mandatory Guidelines is anticipated to be May 1, 2010.

(Slide 6) This particular slide indicates the four documents that would be used in the implementation of the urine laboratory oversight, and the legend lists most of the

draft documents whose preparation was begun in December 2008/January 2009. The “D” indicates when the documents were resubmitted for DWP review. Documents that do require solicitation of information from the laboratory do require OMB submission for OMB clearance and OMB numbering. The table also indicates the planned/envisioned PT production and PT shipping cycles. Included in the PT cycles are practice PT (PPT) cycles, special PT (SPT) cycles, and maintenance PT (MPT) cycles sent to the laboratory.

(Slide 7) Looking at some of these documents in more detail, the first document I'd like to discuss is the revised lab application. The draft was initiated in the latter part of December, 2008, and we'll be submitting it in the latter part of June 2009 for DWP review. Upon conclusion of that review, it is submitted to OMB by DWP for review. Its anticipated release is in January/February in 2010 to allow interested laboratories access to the expectations defined in the revised lab application.

Sections A, B, and C of the lab checklist, which solicits information from the laboratory to be returned to the program, was initially drafted in the latter part of December 2008. The draft is almost finished, and it will be submitted to DWP for review. Following OMB clearance, its release is expected sometime in the first quarter in 2010, hopefully in January or February.

Sections B through U is the revised laboratory initial checklist, which is for those laboratories in the first initial inspection of the certification process. This draft was begun in December, with an expected completion by the end of July and submission to DWP in August. A release date of October is anticipated, to be in concert with inspector training at the Society of Forensic Toxicologists meeting.

Sections D through U, the lab maintenance checklist, are used in maintenance inspections and audits of the laboratories. This also follows the same chronological timeline projection, with a draft hopefully being submitted to DWP by the middle of July.

(Slide 8) For the PT challenges, we envision that we will be manufacturing and fortifying certified negatives samples in the months of August and September. Reference-testing of these samples will be completed by October 2009, which will allow practice, non-scored PT cycles to be shipped during November and December, special PT cycles shipped January through April, and a special PT set shipped just after the implementation date. The normal maintenance PT cycle, encompassing the new Revised Guidelines, would be issued in July 2010.

(Slide 9) This slide brings all the documents back together. It is essentially the same slide we first looked at for those documents for urine laboratories. It summarizes the plan for the implementation of the Revised Guidelines for the urine laboratory facilities.

(Slide 10) This slide looks at the analogous documents that would be necessary for certifying the IITFs. The table configuration is the same, using two-month intervals except for October 2009. Checklist sections A through C are the IITF application, which essentially solicits information on the laboratory's procedures, instrumentation, staffing, and training of key staff. The laboratory initial checklist would be used for those candidate laboratories seeking certification as initial testing facilities. The initial testing facility maintenance checklist is found in sections D through U.

The IITF urine PT cycles would be manufactured in the months of August and September, with reference-testing occurring in October and availability upon

implementation on 1 May 2010.

(Slide 11) The ITF urine application draft was initiated in late December and early January 2009. Our draft is nearing completion and will be submitted within the next six weeks to DWP for review. Following that, it will be reviewed by OMB. We're envisioning and hoping for availability in the January/February 2010 timeframe.

(Slide 12) The IITF checklist sections A, B, and C, as well as the sections D through U, were drafted in late December to early January. Drafts are nearing completion, and sections A, B, and C will require OMB review. The IITF checklist will hopefully be released in October 2009, with sections A, B and C released in the January/February 2010 timeframe.

(Slide 13) The PT cycle samples will be manufactured and available for release; you will learn more about that in John Mitchell's presentation this afternoon.

(Slide 14) This slide summarizes the planned chronology, timeline, and implementation for the instrumented initial testing facilities over the next 11 months.

(Slide 15) Revision of the NLCP manual was begun in April/May. A final draft should be submitted to DWP for review in late August. Hopefully, the document should be released in October, commensurate with inspector training. Inspector training materials are in development, with an anticipated release in November or December 2009. Inspector web-based training will be available by the end of December 2009 and will be conducted during the first four months of 2010.

Charles LoDico will be discussing the new Federal CCF, which will hopefully be released in early 2010. Work on the inspection handbook, especially the collection handbook, has just begun. It should be to DWP for review by October 2009 for a

November/December 2009 release.

(Slide 16) In summary, the NLCP is on track with the established timeline goals. It appears that our documents will be in place and training will be completed prior to implementation, which is anticipated to be May 1, 2010. Completed applications from non-certificated urine laboratories using new confirmatory technologies will not be accepted prior to implementation. Completed applications from urine IITFs will not be accepted prior to implementation.

Thank you.

**DTAB Panel Discussion**

DR. BUSH: Mike, thanks for that summary presentation. Does everyone appreciate how much work goes into an implementation? There's much thought, timing, review of documents, OMB clearance, et cetera. It's a worthy effort, and we want you to know that we're on top of things. Hopefully, you now have a better understanding of the amount of lead time necessary to implement changes of this magnitude to the Guidelines.

It is now time to engage in a half-hour Drug Testing Advisory Board panel discussion. I invite any members of the Drug Testing Advisory Board who would like to discuss or ask questions to please do so at the time.

DR. COLLINS: I have a question for Mike. It sounds like you would anticipate that the first group of IITFs would be certified in the first quarter of 2011. Is that right?

DR. BAYLOR: With the applications received in May 2010, it would be at least a three month process due to the two initial PT cycles and then the one PT cycle with the initial inspection. The first certifications would occur in the August/September/October

2010 timeframe.

DR. COLLINS: Will the certification process be different for currently certified laboratories that want to transition to the IITF status versus new applicants?

DR. BAYLOR: It would be an easier process, but it would be the same process. They would submit an application and transition over. That certainly would have the potential to be an expedited process because of their experience with the NLCP procedures and having been previously inspected and certified as a laboratory.

DR. TURK: Mike, it's Bob Turk. Is all this predicated on the OMB's timely approval of documents?

DR. BAYLOR: Yes.

DR. TURK: So it could be delayed if they delay things?

DR. BAYLOR: That is always a possibility.

DR. BUSH: Bob Turk, this is Donna Bush. We are not anticipating a delay on these documents. We have a process and staff in our division, with Charlie LoDico taking the lead, to move these documents along. We have contacted our OMB representative, and because she is engaged, we're on a reasonable timeline. After you hear Charlie LoDico's presentation tomorrow, you'll appreciate where we are with the custody and control form. The other documents are also moving ahead. We don't want delays, but we recognize that we have many major projects underway. That's why we have the timelines and Gantt charts to make the deliverables and reviews happen to avoid those delays. But delays are possible; you're right.

DR. BAYLOR: This is Mike Baylor speaking. For every document undergoing review and clearance, there is a current document that has already been cleared. There

is an application that has OMB clearance and an OMB number; there is section A, B, and C of the laboratory checklist that has current clearance. The revised documents will not be that much different than the current documents, including the CCF as you'll see in Charles LoDico's presentation.

DR. BUSH: Any other discussion items at the time from our Drug Testing Advisory Board members?

DR. BAXTER: Yes, this is Dr. Lou Baxter. I have a question for Dr. Bush. In your presentation, you made mention that there are some situations where physicians will be qualified or certified to act as MROs if approved, or recognized, by the Secretary. Do you know whether the physicians that are currently certified by the American Society of Addiction Medicine, the American Board of Addiction Medicine, or the American Osteopathic Association as medical physicians will be recognized by the Secretary?

DR. BUSH: Dr. Baxter, on the agenda tomorrow at 11:15 is a presentation entitled: Gathering Information for Presentation for Open Session Meetings for Implementing the Revisions to the Mandatory Guidelines.

DR. BAXTER: Okay.

DR. BUSH: The Medical Review Officer and collection site certifications will be the topic of that discussion. We'll talk about the process we will implement, which will answer your question on how we're moving ahead with the MRO certification. Okay, Dr. Baxter?

DR. BAXTER: Okay, thank you.

DR. BOURLAND: This is Jim Bourland. I had a question for Donna Bush. Donna, what's the timeline for the implementation of the validation and acceptance criteria for

MS/MS? Also, for those that aren't involved in that working group, will there be a public comment period before those criteria are finalized?

DR. BUSH: There will be a presentation tomorrow at 11:25, which will provide an update on the expanded confirmatory test technologies. Let us show you tomorrow what we have done so far, and then we will entertain your question and comment. During this open session, we're presenting what we are doing, including you. Jim, as a valued member of the DTAB, we absolutely want your comment and your input. Quite frankly, that's one of the reasons you're on the Drug Testing Advisory Board. Your technical expertise is what we need. I appreciate your question, but may we defer it until tomorrow?

DR. BOURLAND: Absolutely, no problem.

DR. BUSH: Thank you, Jim.

DR. COLLINS: This is Jennifer Collins again. I have a question for Donna related to a topic your will cover today. Have you received comments or feedback from the Federal agencies regarding the new requirement for inspecting the collection site?

DR. BUSH: This is Donna Bush. Some Federal agencies really embraced the new requirements for inspecting collection sites when we incorporated it in the 2004 proposal. Some are concerned about how we are going to do this. Some expect us to provide them and their staff with more information. We have experience with inspecting, outlining requirements, and preparing checklists with appropriate answers and expectations of what we want to see. We will create a manual, which will include a series of questions, for the agencies can use to inspect their collections sites. The manual will provide inspection expectations to guide them on good procedures.

Tomorrow, Jim Swart will review collection issues. DOT has taken the lead on collection site training because of the issues raised to them by Congressmen from their constituents and others. Usually, an error omission mistake, something performed in a manner less than perfect, will gain attention at the highest levels of government.

Not everybody is thrilled with the concept of inspecting all their collection sites. But over time, and with our helping hand, they will do fine. In the end, they will appreciate this process. The Department of Justice has already embraced this process. Hopefully, we'll see more of that in the future. Some agencies really ran with it, some didn't want it at all, and then in the middle of the bell curve is everybody else saying "Okay, we have to do this. Please help us."

DR. COLLINS: Thank you. This is Jennifer again, one more question in that regard. I'm assuming that the Federal agencies will be sharing the inspection results between themselves. Has there been any discussion about possibly sharing the results of collection site evaluations in a broader sense?

DR. BUSH: We can discuss that in the future. We didn't have that on our list of things to do, but we can put it on the issue board and discuss it in the future.

DR. COLLINS: Thank you.

DR. BUSH: You're welcome. Is there any other discussion at this time?

MS. HARBISON: As a reminder, you can *6 to unmute yourself and then *6 to re-mute again.

DR. BUSH: Since there is no further discussion, at this time I will close this part of the open session of the Drug Testing Advisory Board. We were planning to adjourn for lunch at 1:00. We will adjourn for lunch now at about 12:50 pm EDT. We will resume

the afternoon session at 2:30 pm EDT. Thank you very much for your attention.

Erica, do you want to advise on how to proceed?

MS. HARBISON: Yes. We will leave the room open as well as the call you are currently on. If you wish to mute your phone and leave it open, you're more than welcome to do that. You can also stay in the room. However, if you want to exit the room and hang up your phone, you can do that as well and re-enter the same way you did this morning. I will post on the note pod the 800 number with the pass code for those of you who want to stay in the room but wish to hang up and you dial back in later.

DR. BUSH: Okay, see you back at 2:30.

(Whereupon, a luncheon recess was taken at 12:50 p.m.)

**Afternoon Session: Urine Laboratory Technical Issues** (2:30 p.m.)

**Call to Order**

DR. BUSH: This is Donna Bush speaking. It's 2:30, and I'd like to convene this afternoon session of the Drug Testing Advisory Board.

I've received some good comments about this morning's session. We're pleased with the technical aspects of this meeting so far. This morning about 83 people logged in, which includes our Drug Testing Advisory Board members.

At this time, John Mitchell will give his presentation on: "Initial Testing for New Analytes and New Cutoffs".

DR. MITCHELL: Thank you, Donna.

DR. BUSH: You're welcome.

**Initial Testing for New Analytes and New Cutoffs**

DR. MITCHELL: (Slide 1) In the next few minutes, I will present the efforts that

have been, and will be, undertaken in support of the implementation of the Revised Mandatory Guidelines. Drs. Bush and Baylor have given you overviews of the work to be completed and the timelines. It is my task to fill in some of the details.

(Slide 2) The Revised Guidelines added new drug analytes and lowered the positive cutoff designations for others. As Dr. Bush also pointed out, this is not the first time we've been through this routing. The processes for implementing these changes to the Guidelines are those that we developed previously, including previous efforts when we changed the cutoffs for $\Delta^1$-tetrahydrocannabinolic acid (THCA), the marijuana metabolite, and opiates.

In this presentation, I will discuss issues associated with the changes that affect initial testing for cocaine, 6-acetylmorphine, and the amphetamines.

(Slide 3) In the revised program requirements, a new initial test analyte is MDMA, a designer drug that is a structural analyte of methamphetamine. Its cutoff will be 500 ng/mL. Another new analyte for initial testing is the opiate 6-acetylmorphine, which will have a cutoff of 10 ng/mL. Since both of these are new initial tests, they will require development of initial test methods.

The revised initial test cutoffs were published for methamphetamine and amphetamine. The cutoff for the initial test for these analytes was decreased from 1000 to 500 ng/mL. Likewise for cocaine metabolites, the cutoff was dropped from 300 to 150 ng/mL. This cocaine cutoff change will probably not require development of a new initial test assay; it may just require modification of those in existence at the current cutoffs.

(Slide 4) We have several concerns about implementation, the first of which is the timeline for the implementation. We will cover the timeline in some detail, even

though Dr. Baylor gave you the overall timeline. The other concerns include the awareness of required changes by the laboratories' supporting industries, such as the immunoassay manufacturers; availability of the material for implementing the changes, primarily, the immunoassay tests; and the readiness of the laboratories.

(Slide 5) First, let's begin with the implementation timeline from May through November of 2009. The NLCP/HHS-certified laboratories are expected to begin validating the new immunoassay kits and to have them validated prior to November 2009 because at that time the NLCP will be shipping to the laboratories PT samples to verify their validation. From January through May of 2010, the laboratories will be receiving qualifying PT samples.

(Slide 6) In an effort to make sure that the laboratories were aware, in January of this year we sent out a questionnaire, which consisted of two questions -- one asking them to determine who their immunoassay supplier was and to contact their immunoassay kit manufacturers to determine when those kits would be available. (Slide 7) From the survey, we identified 31 immunoassay supplier contacts. We subsequently sent a questionnaire to each of them, asking them when their new immunoassay kits would be available for the laboratories to validate and to test. (Slide 8) The current certified laboratories employed immunoassays from three manufacturers: Roche, Siemens, and Thermo Fisher.

(Slide 9) The manufacturers, in their reply to us, gave us information about their kits. Roche plans on providing a single kit which would detect amphetamine, methamphetamine, and MDMA at the 500 ng/mL cutoff. They had already submitted it to the FDA for review, and they anticipate a response from the FDA in the third quarter

of 2009. They do not anticipate offering a 6-acetylmorphine immunoassay at the 10 ng/mL cutoff. The cocaine immunoassay at the 150 ng/mL cutoff was already available.

(Slide 10) Siemens currently offers an Ecstasy (MDMA) kit and an amphetamine/methamphetamine kit at the 500 ng/mL cutoffs. They are developing a 6-acetylmorphine kit at the 10 ng/mL cutoff, but as late as this week, that kit had not been submitted to the Food and Drug Administration (FDA) for approval. They currently offer a cocaine kit at the 100 ng/mL cutoff.

(Slide 11) Thermo Fisher has kits currently available for all of the new analytes as well as the analytes with the revised cutoffs.

(Slide 12) We are concerned with is the performance of an immunoassay. Since there are new ones to review, what performance is desired in an immunoassay? (Slide 13) In a desirable immunoassay, a positive result should reflect the presence of drug analytes that are metabolically-related to the target analyte used to calibrate the assay. The immunoassay should also be formulated to maximize the response to the target analyte used for the calibration and the metabolically-related analyte. Many amphetamine assays have cross-reactivities with amphetamine, methamphetamine, and its metabolites, as well as the designer drugs which are synthesized chemically, even though they are not metabolites or derivatives of amphetamine or methamphetamine.

(Slide 14) An example of one immunoassay with desirable performance is that for opiates. In that particular assay, morphine is used to calibrate the assay. Morphine is produced through the metabolism of heroin, 6-acetylmorphine, and codeine. From the manufacturers' immunoassay package inserts for opiates, their assay responses for

minor metabolites and structurally-related compounds such as hydrocodone, hydromorphone, oxycodone, and so forth, do not exceed that obtained with morphine, with one exception. That exception was for dihydrocodeine for one manufacturer. While this is not ideal, it is acceptable at this time.

(Slide 16) The Guidelines require the amphetamine immunoassay kit to be calibrated with d-methamphetamine at 500 ng/mL. Of course, the cross-reactivity for that analyte is 100 percent. From the literature provided by the manufacturers as to the specificity of their amphetamine immunoassay kit, t the cross-reactivities for the three structural analyte derivatives, MDMA, MDA, and MDEA, are less than 30 percent. Missing is the cross-reactivity with d-amphetamine, which was not provided in any of the literature obtained from the manufacturer.

(Slide 17) For the Thermo Fisher cloned enzyme donor immunoassay (CEDIA) kit for amphetamines, there is equal reactivity with d-methamphetamine and d-amphetamine. The cross-reactivity with MDMA/MDA is 69 percent or less. The literature did not provide the cross-reactivity with MDEA for this particular kit. The concentration required for response is equivalent to 1000 ng/mL of methamphetamine. For this kit, there is no listed cross-reactivity at the 500 ng/mL level. It is not expect to be much different from what it found at the 1000 ng/mL.

(Slide 18) Thermo Fisher offers another immunoassay for amphetamines called the DRI kit. It has similar cross-reactivities for amphetamine and methamphetamine, whereas MDA and MDEA both are 77 percent are less, which is less than the activity with methamphetamine and amphetamine. The reactivity with MDEA is not given.

(Slide 19) There is only one kit for the new analyte, MDMA or Ecstasy, which is

offered by Roche and is currently under reviewed by FDA. The Siemens kit has a cross-reactivity of 100 percent at 500 ng/mL for MDMA. MDA and MDEA are just a little bit below 100 percent; this is good, meaning similar compounds exhibit similar activities. The cross-reactivities of this assay with d-amphetamine and d-methamphetamine are good. It required 430,000 ng/mL of d-amphetamine to give a reaction equivalent to 500 ng/mL of MDMA. It required 130,000 ng/mL of d-methamphetamine for equivalency to 500 ng/mL of MDMA.

(Slide 19) In the Thermo Fisher DRI MDMA assay, MDMA has 100 percent, MDA has 56 percent, and MDEA has 83 percent cross-reactivity. The two amphetamines, amphetamine and methamphetamine, exhibited no cross-reactivity even at 600,000 ng/mL. At that concentration, they gave negative results with about 0.1 percent cross-reactivity.

(Slide 20) In summary, the certified laboratories are aware of the revised Guidelines, and they are planning for the implementations. The immunoassay manufacturers are aware, and they are preparing to support the needs of the laboratories.

There are several issues, though, that we need to be mindful of. Only one manufacturer has a FDA-cleared immunoassay for 6-acetylmorphine. There is another that has not been submitted to FDA yet.

(Slide 21) All identified manufacturers have FDA-cleared immunoassays for cocaine. Two manufacturers have FDA-cleared immunoassays for methamphetamine, amphetamine, and MDMA. One manufacturer has submitted for FDA clearance a single immunoassay that detects d-methamphetamine, amphetamine, and MDMA.

This concludes that part of the Initial Test presentation. Are there any questions at this time?

DR. NIPPER: This is Henry Nipper. Could other manufacturers exist that would be potentially interested in this market, that haven't been contacted yet, and that might have assays for 6-AM? Have you considered casting a wider net?

DR. MITCHELL: Yes we have, Henry. That's one of the things that we're involved in now. We are contacting the manufacturers of immunoassay kits, outside of the three already identified, to determine whether anyone is planning to do that. Another concern is will the manufacturer of the only one kit available be able to supply the needs of the program? Neither concern has been answered at this point in time.

DR. NIPPER: Thanks, John.

DR. MITCHELL: You're welcome, Henry.

DR. BUSH: John, which was a great presentation. Henry, thanks for that great question. John, your next presentation is next on the special PT program.

**Special PT Program**

DR. MITCHELL: (Slide 1) In the past, we learned that the laboratories needed to demonstrate their ability to conduct the testing and meet the requirements of the Guidelines. In this talk, I will discuss what is effective in accomplishing that aim.

(Slide 2) This slide depicts the special PT program and the timeline for the special PT program activities. Between May to October 2009, we expect the laboratories to validate their new immunoassay tests for the revised cutoffs and new analytes. Also, we expect them to develop and validate confirmatory methods for the revised cutoffs and also for the new analytes. In November of this year, we will send practice sets to the laboratory to allow them to verify their validations.

(Slide 3) From January through March 2010, three rounds of qualifying special PT samples will be shipped to the laboratories. The results from these samples will be scored. Laboratories with unsatisfactory scores will be remediated as required. Remediation is a process employed within NLCP for those laboratories who do not meet the expected level of proficiency and accuracy. There are certain steps that they have to perform to achieve proficiency and accuracy. (Slide 4) That process, which includes additional SPT testing, must be complete by April 2010 so that all certified laboratories will be ready as of 1 May to implement the new Guidelines.

Three weeks after implementation, all laboratories will receive a limited set of SPT samples, which are focused on the new analytes and the revised cutoffs. We will be able to demonstrate that laboratories not only were able to do it before implementation but were continuing their performance after implementation.

(Slide 5) The new cutoffs for benzoylecgonine, the cocaine metabolite, will be 50 ng/mL for the initial test and 100 ng/mL for the confirmatory test. For 6-acetylmorphine, the initial test cutoff will be 10 ng/mL, while the confirmatory cutoff will remain at 10 ng/mL; that's unchanged from the current confirmatory cutoff for 6-acetylmorphine. For methamphetamine, the initial cutoff will be 500 ng/mL, while the confirmatory cutoff will be half that at 250 ng/mL and requires that 100 ng/mL or greater of amphetamine be present for all methamphetamine positives. The cutoff for amphetamine is 250 ng/mL for the confirmatory test. For the designer drugs, the cutoff for the initial test will be 500 ng/mL for Ecstasy or MDMA, with a confirmatory cutoff of 250 ng/mL; 250 ng/mL is also the confirmatory cutoff for MDA and MDEA.

(Slide 6) The objective of the practice PT set is to provide samples to check the

performance of the laboratory's initial and confirmatory test methods. The focus will only be on the new analytes and the analytes with revised cutoffs. (Slide 7) The composition of this practice PT set will be 10 to 12 samples, which will contain drug analytes at 0.5 to 1.5 times the immunoassay cutoff as well as 1 times and 2 times the confirmatory cutoff concentrations. These samples will have been pre-tested, and the laboratories may use them in any way verify their validations. Laboratories are not required to report these practice PT results back to the National Laboratory Certification Program.

(Slide 8) Now we come to the heart of the program, which is the special PT sets. The objectives of this PT are to verify the ability of the laboratories' test methods to meet new and revised requirements and to verify the ability of laboratories to correctly report results in accordance with the new and revised requirements. The focus of these sets will only be on the new analytes at the specified cutoffs and current analytes at the revised cutoffs. This process will give laboratories an idea of what to expect upon implementation. (Slide 9) In January 2010, about two weeks after they have completed their normal maintenance PT set under the current Guidelines, laboratories will be sent a set of 15 to 20 special PT samples for analysis. These samples, which will contain methamphetamine, amphetamine, MDMA, MDA, MDEA and 6-acetylmorphine and benzoylecgonine at and around the cutoffs prescribed in the Guidelines, will be tested by immunoassay using the laboratory's validated procedures as directed by the NLCP. After immunoassay testing, we will direct the laboratories as to which samples are to be tested by confirmatory methods and the analytes for which they are to be tested. (Slide 10) The laboratories will be given five days to test the samples and report the results back to the NLCP. After we have received all the test results, the results are scored,

with those scores reported back to the laboratories in about two weeks after we receive them.

(Slide 11) Additional PT sets will be shipped in February and March 2010. These will not be the same samples, but it will contain the same analytes.

If a laboratory is having troubles with one particular analyte, we will send then focused SPT sets for them to demonstrate their ability to test only that one analyte. Hopefully, this will not be necessary for any of our laboratories.

(Slide 12) The laboratories must demonstrate acceptable performance on each PT set as delineated in the Revised Guidelines. Failure to meet standards will require remediation of errors and demonstration of acceptable performance through testing of additional samples. Laboratories must meet acceptable criteria in order to test upon implementation. If they do not meet acceptable criteria, they will not be allowed to implement the testing for the new analytes and the analytes at the revised cutoffs.

(Slide 13) Post-implementation we will ship to each of the laboratories a set of PT samples that would challenge the new analytes and revised cutoffs. Those will be sent within three weeks of implementation to demonstrate continued acceptable performance.

(Slide 14) The objectives of the immunoassay special PT samples are this:

1) to determine the specificity of the immunoassay, and

2) to determine assay performance at high analyte concentrations because sometimes problems arise with immunoassays at high analyte concentrations where there is apparent reduced activity of the immunoassay.

3) The specificity of these immunoassays will be assessed in the presence of

over-the-counter medications and other potential interfering and cross-reacting compounds.

(Slide 15) We will also verify adherence to the revised new cutoffs and will determine performance of each immunoassay at plus or minus 25 percent of the cutoff.

(Slide 16) The confirmatory samples have these objectives:

1) to verify the ability of the laboratories to identify and quantify the required analytes at the revised and new cutoffs, and

2) to determine the quantitative accuracy at analyte concentrations from 40 percent of the cutoff up to 20 times the cutoff.

(Slide 17) 3) to verify the performance of the confirmatory procedure in the presence of over-the-counter medications and potentially interfering compounds.

(Slide 18) The initial PT sets for IITFs will be available upon implementation of the Revised Guidelines, which is anticipated to be May 1, 2010. The NLCP's MPT program will resume in July 2010 and incorporate challenges for all drugs and all SPT testing as specified in the Revised Guidelines.

Are there any questions?

DR. BOWERS: John, this is Larry Bowers. Why are you challenging the range from 40 percent to 20 times? You should encourage the labs to optimize their precision near the cutoff, which suggests that their calibration curve should be focused in that area and not focused at 20 times.

DR. MITCHELL: Larry, we are dealing with limited analytes and the requirement to have accuracy of the cutoffs. We have determined that on some analytes, laboratories can easily quantify up to 20 times the cutoff. Later on, we will try to define

certain criteria for the program, including linearity of the analyses that are conducted by the laboratories. This is what we have used historically with GC/MS for the other analytes, and the laboratories have been able to meet this criterion. Thus, I don't see any need to not do it at this point in time.

DR. BOWERS: Thank you.

DR. MITCHELL: There's one other issue. We also look for carryover, and highly concentrated samples are one way to assess carryover. Regarding sample dilution, we really don't asses dilution in these samples. We'll use higher concentrations entirely and that normally assesses dilution errors. Because MROs will ask for the concentration of an analyte in the urine, which may be above the upper limit of linearity, there's the possibility of getting carryover into another specimen. Thus, we use these higher concentrations to look for those various parameters. Are there any other questions?

DR. BUSH: The next presentation is “Instrumented Initial Test Facilities (IITFs)”, presented by Susan Crumpton from RTI.

**Instrumented Initial Test Facilities (IITFs)**

MS. CRUMPTON: (Slide 1) Thank you, Donna. I'll be talking to you today about instrumented initial test facilities. This new type of testing facility will be allowed for Federally-regulated workplace drug testing under the HHS Guidelines to be implemented in 2010. In my presentation, I will discuss the Guidelines' requirements for IITFs and overview of the application process for an IITF to become certified by HHS under the NLCP.

(Slide 2) Per the 2010 Guidelines, an IITF is defined in the as the permanent location where initial testing, reporting of results, and record keeping are performed under the supervision of a responsible technician. Basically, an IITF is the front or initial

testing part of a laboratory. An HHS-certified laboratory must perform initial and confirmatory testing for drugs and determine specimen validity. An IITF does not perform confirmatory testing; it only performs initial tests for drugs and performs screening or initial tests to determine specimen validity.

(Slide 3) The draft Guidelines, which introduced IITFs, were published in the Federal Register on April 13, 2004. The reason given for allowing this type of test facility was that IITFs could be established in locations to more quickly and economically meet special local testing needs. These new test facilities enable the quick turnaround times needed by some Federal and some Federally-regulated employers for negative and negative-dilute results. One example was the Nuclear Regulatory Commission's use of licensee testing facilities to perform initial testing to support the increased drug testing needs of nuclear power plants during facility maintenance or fuel-rod replacement. During those events, nuclear plants needed to quickly screen hundreds of additional maintenance workers. (Slide 4) In allowing these test facilities, HHS maintains that they must be subject to the same forensic requirements as a certified laboratory. In addition, they must be held to the same analytical requirements as a certified lab for the initial drug test, the specimen validity screening test, and the specimen validity initial test. HHS requires that IITFs should be at a permanent location, meet program forensic standards, participate in open and blind proficiency testing, have a rigorous quality assurance program, be subject to site inspections, use instrumented immunoassay tests for drugs which meet FDA requirements for commercial distribution, conduct required specimen validity tests, use the HHS cutoffs, and submit all non-negative specimens to a full-service HHS-certified laboratory for testing. The 2010 Guidelines

address all of these requirements. Section 12 of the 2010 Guidelines provides requirements specific to IITFs. The requirements are the same as, or are analogous to, the requirements for laboratories. I'll cover the IITF requirements in detail; however, I'm not going to go over the details of each requirement. I have included references to the relevant Guidelines section.

(Slide 5) First, section 12.1 requires the IITF to maintain a complete standard operating procedures (SOP) manual describing all operations. This section lists some required elements of the SOP and requires archiving of retired procedures for at least two years to allow reconstruction of the procedures used for regulated specimens that may still be in storage at an HHS-certified laboratory.

(Slide 6) The Guidelines specify personnel requirements in sections 12.2 to 12.4. An IITF must have a responsible technician (RT) and must have an alternate RT (Alt-RT) in order to maintain certification and continue testing regulated specimens in the extended absence of the RT. The RT is defined in the Guidelines as the person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF. The Alt-RT definition in the Guidelines is the same, with the qualifier that the Alt-RT assumes responsibilities when the RT is unable to fulfill the obligation.

Section 12.2 describes RT responsibilities, while section 12.3 describes the qualifications that an individual must have to be approved as an RT. In addition to the educational training and experience requirement, the individual must be found acceptable upon interview by trained NLCP inspectors. The RT is interviewed and must demonstrate acceptable performance of RT responsibilities at each NLCP inspection.

Section 12.4 addresses what happens if the RT is absent or leaves an HHS-certified IITF. If the RT is gone for two weeks or less, a certifying technician may oversee the operation. If the RT is absent for more than two weeks, an NLCP-approved Alt-RT may assume the RT's duties in order for the IITF to continue testing regulated specimens. An Alt-RT may serve as the acting RT for 180 days. HHS will suspend an IIT certification if the IITF is without an approved RT or alt-RT for a period of more than 2 weeks or if the IITF has not hired a permanent replacement RT after the Alt-RT's 180 days are up.

(Slide 7) The 2010 Guidelines definition of a certifying technician (CT) is the individual responsible for verifying the chain of custody and scientific reliability of negative, negative-dilute, and rejected for testing specimens reported by a laboratory or IITF. The qualifications in section 12.5 for IITF and in section 11.5 for laboratories are the same. A CT must have training and experience in the analytical methods and forensic procedures relevant to the results that the individual certifies, and training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action and response to problems that might arise. The term "certifying scientist" replaces that the current term “negative-certifying scientist". The same term is used for this position in both IITFs and laboratories.

Requirements for other IITF personnel are addressed in section 12.6. All staff must have appropriate training and skills for their assigned tasks. Additionally, each individual must be trained in forensic procedures related to their job duties before he or she can work with regulated specimens. This section also specifies that the training

must be documented.

(Slide 8) Section 12.7 addresses security. An IITF must control access to the facility and ensure that no unauthorized individual can gain access to regulated specimens, their aliquots, and records. This section requires the IITF to provide an escort for authorized visitors at all times, with the exception of emergency services personnel, such as firefighters and emergency medical services teams, and accrediting agency personnel, such as NLCP inspectors. The requirements are the same as for HHS-certified laboratories.

(Slide 9) Section 12.8 addresses internal chain of custody requirements for an IITF. The purpose of the IITF internal chain of custody procedures is to maintain control and accountability from the time of specimen receipt until final disposition of the specimen, that is, when a specimen is discarded after reporting or when a specimen is forwarded to an HHS-certified laboratory for testing. Either paper or electronic chain of custody documents may be used. The requirements are the same as the 2010 Guidelines requirements for laboratories. The use of electronic internal chain of custody documentation is new. This is not currently used for regulated specimens in HHS-certified laboratories.

(Slide 10) The initial drug testing requirements for an IITF are the same as those for a laboratory. Section 12.9 addresses the requirements for the initial drug test to be immunoassays test that have been approved, cleared, or otherwise recognized by FDA as accurate and reliable for drugs of abuse testing. The IITF may also use a different immunoassay test as a second initial drug test to rule out common cross-reacting compounds. That second test is subject to the same quality control (QC) requirements

as the first test.

Section 12.10 specifies the required method validation and the requirement to verify new reagent lots prior to use. Section 12.11 described quality control requirements. (Slide 11) The Guidelines address specimen validity testing and IITF in sections 12.12 through section 12.14. The analytical and batch QC requirements are in sections 12.12 and 12.14, and the method validation requirements are in 12.13. These requirements are the same for those for screening or initial specimen validity tests in laboratories.

Section 12.14 allows an IITF to use a pH screening test and a specific gravity screening test to determine if a specimen must be subjected to the initial pH and specific gravity test. If initial testing is needed, the specimen is then sent to an HHS-certified laboratory. The IITF will send specimens with screening test results outside the acceptable range to an HHS-certified lab. The lab will conduct the screening pH test, followed by the initial and confirmatory test, if needed, using a pH meter. This policy allows the IITF to determine pH in the acceptable range without a requirement to have a pH meter.

For specific gravity, the IITF will screen specimens using the refractometer that measures to three decimal places and will send all specimens with creatinine results less than or equal to 5 mg/dL and specimens with specific gravity less than 1.002 to an HHS-certified lab. The laboratory will perform specific gravity testing using the four decimal space refractometer, if needed. Thus, the IITF is not required to have that additional refractometer.

(Slide 12) Section 12.15 addresses reporting requirements for an IITF. A CT may

report a specimen as negative, negative-dilute with a creatinine between 5 and 20 mg/dL, or rejected. The reason that a CT may not report a specimen as dilute with creatinine less than or equal to 5 mg/dL is because the DOT requires recollection under direct observation for specimens meeting those criteria. Since this additional action is taking for such specimens, testing must be performed at an HHS-certified laboratory that has initial and confirmatory creatinine and specific gravity tests to support the reported results. The IITF may report specimen results using the standardized Federal custody and control form, an electronic report, or both. However, rejected specimens must be reported using the Federal CCF which is signed and dated by the CT who certified that the specimen met the criteria for rejection.

(Slide 13) The Guidelines requirements for final specimen disposition by an IITF are covered in sections 12.16 and 12.17. Section 12.16 requires the IITF to send any possibly positive, adulterated, substituted, or invalid specimens to an HHS-certified lab for testing. The specimen must be sent within one day after the IITF has completed the drug and validity testing. Section 12.17 requires the IITF to discard the negative, negative-dilute, or rejected specimens for which it has reported results.

(Slide 14) This next slide will show the steps from collection through result reporting and how an IITF is involved. The collector receives the specimen from the donor and sends it from either an IITF or a laboratory. The IITF tests the specimen. If it's negative, rejected, or negative-dilute with creatinine greater than 5 and less than 20 mg/dL, results are reported to the Medical Review Officer. Or, if it's possibly adulterated, substituted, invalid, or positive, it is sent to the lab.

The laboratory tests all primary specimens received as if they'd never been

tested before, regardless of whether they came from a collector or from an IITF, and reports the results to the Medical Review Officer. This ensures that the final analytical results for the initial and confirmatory drug tests and for the screening, initial, and confirmatory specimen validity tests and their associated internal chain of custody documents are generated by one HHS-certified laboratory and can be properly reviewed and certified before the results are released to the MRO.

(Slide 15) The Guidelines provide specifics on how a specimen is from sent from an IITF to a laboratory. The IITF staff person reseals the primary specimen bottle, Bottle A. The individual completes the appropriate entry on the Federal CCF to document the handling. Both specimen bottles, A and B, along with the Federal CCF are sent to the HHS-certified laboratory.

(Slide 16) Section 12.18 addresses records retention. Routinely, records must be kept for two years. For specimens under legal challenges, records must be maintained for a longer period, if requested in writing by a Federal agency. Section 12.19 requires the IITF to submit a statistical summary report to each Federal agency for which testing is performed. Specific items are listed, as well as the required schedule for submission. Section 12.20 addresses donor access to his or her drug testing records.

(Slide 17) Section 12.21 prohibits relationships between an IITF and an MRO. In section 12.22, there are no restrictions on the relationships between an IITF and an HHS-certified lab. In fact, the IITF must have a relationship with an HHS-certified laboratory. Arrangements must be made in advance for the IITF to send specimens to the laboratory for testing and for the laboratory to test and report the specimens from the IITF.

(Slide 18) Section 10 addresses Federal agency blind samples that must be sent to an IITF. Federal agencies must send blinds to the IITF and to the laboratory for which their workplace specimens are sent.

(Slide 19) Section 9 addresses the HHS certification of laboratories and IITFs, which will both be under the NLCP. This section describes the application process, the PT processes, PT scoring criteria for both applicant and certified IITFs, the inspection processes for both applicant and certified IITFs, the requirements for an individual to be an NLCP inspector assigned to inspect IITFs, and the program actions when an applicant or certified IITF fails to meet either the PT or the inspection requirements. HHS will publish a list of certified IITFs each month in the Federal Register. Section 16 details the conditions and procedures for suspension or revocation of certification for both IITFs and laboratories.

(Slide 20) This next slide steps through the NLCP application process for an IITF. First, the HHS Guidelines provide the scientific and forensic standards. These are covered in the NLCP checklist and the NLCP manual. The first step in the application process is for an IITF to contact the NLCP for an application package. The package sent will include a copy of the Guidelines, the IITF application form, and relevant NLCP checklists and documents explaining the program.

The IITF uses this information to perform a self-assessment and revise its procedures, if necessary, for compliance. Then it submits the completed application to the NLCP, where it's reviewed versus the program requirements. The NLCP will send a report either notifying the applicant of the acceptable application or listing identified deficiencies. If the deficiencies noted are minor or easily corrected, that applicant IITF

will be allowed to correct the deficiencies and submit additional information for review.

Once an application has been accepted, the next steps include two cycles of initial PT and a third initial PT cycle in conjunction with an on-site inspection. That applicant must perform acceptably on the three initial PT cycles and inspection to be certified by HHS.

(Slide 21) This slide has the NLCP contact information for requesting the IITF application package. At this time, the NLCP expects to have the application packages available in January 2010. Completed applications will not be accepted until the new Guidelines have been implemented in May 2010.

(Slide 22) Once certified, the NLCP will maintain oversight of the IITFs through the PT and inspection processes, as is currently done for certified labs. HHS will establish and publish a fee schedule for IITF PT and inspection processes, including remedial fees.

(Slide 23) Finally, I'd like to summarize what might be considered challenges in starting an IITF for Federally-regulated workplace drug testing. Regarding the client base, remember that the reason for an IITF is to serve particular clients by providing initial drug testing services and locating the facilities to expedite specimen transport and to enable rapid turnaround time for negative and negative-dilute results. Those results constitute more than 97 percent of the results reported in Federally-regulated workplace programs overall. Thus, there must be a client base that would choose this type of testing as a feasible alternative to laboratory testing. The IITF must have the secure facility, the equipment and instrumentation for initial drug testing and specimen validity testing to meet Guidelines requirements. Another challenge is to hire and train qualified

staff, including an RT and Alt-RT. Reporting mechanisms, including those for electronic reporting, must be developed to ensure that results are accurately reported and transmitted and to ensure the confidentiality of the results and donor information. Finally, an IITF must establish a relationship with an HHS-certified laboratory and have arrangements in place for specimen transport to the laboratory and for the laboratory to test and report specimens received from the IITF.

Thank you for your attention.

DR. BUSH: Thank you very much, Susan. That was comprehensive coverage of IITFs. Do any of the board members have any questions for Susan Crumpton?

DR. TURK: Bob Turk for Susan. Susan, how will the quality control be monitored for these labs? What is the requirement for the IITF?

MS. CRUMPTON: Through the PT and the inspection process.

DR. TURK: I am concerned about the situation Ron Shippee described in his field laboratories. I am asking about quality assurance.

MS. CRUMPTON: We will evaluate them in the same way as we do the laboratories, through the PT and the inspection processes of the NLCP.

DR. TURK: What's the requirement at the lab site? What quality control process are they expected to have at the IITFs to ensure they aren't screwing up?

MS. CRUMPTON: The batch quality control?

DR. TURK: Correct.

MS. CRUMPTON: It's the same as they are for the laboratories for the initial, the screening specimen validity, and the initial specimen validity tests.

DR. TURK: Since the IITF will re-seal bottle A to send it off to a laboratory,

doesn't that arouse concerns with possible tampering if the case goes to court?

MS. CRUMPTON: The process is documented on the chain of custody. The IITF will re-seal everything. The donor does have the opportunity to test the B bottle.

DR. TURK: Wouldn't the B bottle be the better bottle to send to the full-service laboratory?

MS. CRUMPTON: The B bottle belongs to the donor and is there for the retesting purposes, so that remains inviolate.

DR. TURK: Thank you. Appreciate it.

MS. CRUMPTON: Okay, thanks.

**DTAB Panel Discussion**

DR. BUSH: This is Donna Bush. Before the afternoon DTAB panel discussion of today's presentations, I want to review for you the public comments for today. I received an email notice from Mr. Steven Soifer, who would like to make public comment at 4:00 pm. Since N.B. Varlotta and Eric Quilter wish to make public comments concerning the custody and control form, their public comments are best presented tomorrow afternoon after the presentation by Charles LoDico. Three other people indicated they might want to make public comment - Taretha King, Timothy Nelson, Dr. Crumper, and Robert J. Bard. They are currently not in the room, but maybe someone is attending on their behalf. If you wish to make a public comment, email me at donna.bush@SAMHSA.HHS.gov. With my BlackBerry, I can check for requests from any last-minute commenters. There are no public commenters registered here on the sign-in sheet.

MR. STEPHENSON: May I raise one other issue? Are there any questions input by participants that are not visible on the chat pod?

DR. BUSH: Jared Cooper reported that there were no questions coming in from the listening public. There was one from a Drug Testing Advisory Board member, Jim Bourland. His question will be reserved for tomorrow after the relevant presentation and discussion.

MR. STEPHENSON: Are there questions from members of the public present in the SAMHSA meeting room that should be considered prior to the public comment period?

DR. BUSH: Are there any further questions from the DTAB panel?

MR. STEPHENSON: Individual comments are not to exceed 10 minutes, as has been our tradition.

DR. COLLINS: It's Jennifer Collins. I do have one more question concerning the relationship between the IITF and the certified laboratories. Because the certified laboratories will be treating the samples that they receive from IITF as if they hadn't been tested, the samples will go through the screening process again. What discussion, if any, has there been about discrepancies that might arise between the results from the two laboratories? Obviously, there will be samples that screen just above the cutoff at the IITF that may screen below the cutoff at the certified lab. Are there any thoughts as to whether or not there's any usefulness to monitoring the discrepancies?

DR. BUSH: This is Donna Bush. I will defer this question to RTI because of how we collect information from laboratories to prepare for our inspections. The laboratories provide reports of the specimens tested, analytes found in those specimens, and specimens reported as substituted, adulterated, etc. From this report, very interesting specimens have been found, and then the program asks to see all the data concerning

those specimens. At the inspection, these data are reviewed and questions are asked to understand what we're seeing and how the laboratories are reporting. I mention this because we are discussing the creation of a reporting system. How will IITFs be inspected, and what data will be reviewed? Thus, RTI has been assembling their thoughts about that. RTI?

DR. BAYLOR: This is Mike Baylor speaking from RTI. We have looked at a variety of different approaches to monitoring the forwarded specimens from an IITF that go through a certified laboratory that are reported as positive or negative.

IITFs, as part of their inspection process, will be generating a forwarded specimen list which would identify those specimens which are forwarded by that IITF to a certified lab for additional testing. By the CCF numbers and identifiers, the program can track those specimens as they feed into certified laboratories. Those specimens could be evaluated during that certified laboratory's on-site inspection process. The specimens that are forwarded by an IITF can be tracked by reviewing the certified lab's non-negative list, which contains specimens reported as a positive adulterated, substituted, or invalid specimen, and also looking for those specimens forwarded to a laboratory that aren't reported out in the categories of drug-positive, substituted, adulterated, invalid, or rejected. We are investigating a variety of ways, especially the most efficient way to monitor and track those forwarded specimens from an IITF to the certified laboratory for reporting by the MROs.

MR. STEPHENSON: There's an interesting parallel between linking for inspections of real, submitted, non-negative IITF specimens with the PT process to compare the initial screening and confirmation components. The same thing will occur

for POCT testing, as it evolves, and the non-negative specimen submissions to the laboratory for screening and confirmation testing. This is similar to our experience of almost 20 years and that of NRC in which we looked at the relationship between authorized on-site testing and the concordance with the laboratory results. There are several areas that we can look at and perhaps put on the agenda for the next DTAB.

DR. COLLINS: This is Jennifer again. Is the representative from the NRC still there?

MR. STEPHENSON: We have at least one here.

DR. COLLINS: I wondered how many licensees are currently operating on-site laboratories. Do you have a number?

MR. STEPHENSON: We'll ask that question, and then we'll provide that as a feedback to you.

DR. COLLINS: Thank you.

DR. BUSH: There are two questions in the Q&A chat, both of them from Paul Bellis of Quest Diagnostics. “Assuming an IITF begins the application process in January 2010, what type of timeline might we expect for approval before an IITF becomes operational?”

RTI, can you go back to that presentation that had the timelines in it? Mike, since it was your presentation, would you cover that same topic again?

DR. BAYLOR: Mike Baylor of RTI speaking. We envision that the IITF application would be available to ship to interested parties sometime after the first of January 2010. Applications would not be accepted at the NLCP until after implementation of the revised urine Guidelines on 1 May 2010. Assuming an application would be submitted

on 1 May 2010, that application would be reviewed, any deficiencies would be corrected, and that application, once acceptable, would allow the laboratory to request initial PTs. Upon satisfactory completion of two initial PT cycles, the laboratory could request an on-site initial inspection in concert with the laboratory testing initial PT cycle three during that initial on-site inspection. Now, assuming an initial PT cycle, laboratory testing, results reporting, and PT scoring by RTI take about two weeks, the first two PT cycles would encompass at least the month of May. Scheduling the initial inspection and identifying inspectors is generally a four- to six-week process. Now we are in the middle of July. Assuming that the inspection and initial PT cycle three have successfully occurred sometime on or about the middle of July and that the laboratory would be notified that they have acceptability sometime in the beginning or middle of August, theoretically, a new IITF would be initially certified sometime around the middle of August as an extremely optimistic timeline.

The second part of the question is would the fee schedule include the appropriate resources? For initial inspections, the appropriate resources are at least two people for at least 1.5 days. It's not unreasonable that a Category 3 certified lab in a good geographical location could transition to an IITF. In that case, with a significant number of specimens received on a daily basis, that initial inspection might require more than two people for approximately two days. Thus, we would take into consideration the lab facilities. As in the past, with a laboratory starting up from scratch with no specimen load, the initial inspection has generally required two inspectors. Those transitioning with an established specimen load could, theoretically at least, require more resources, which would necessitate a larger fee to be associated with

those resources utilized in an initial inspection or in the maintenance phase subsequent to the initial inspection.

DR. BUSH: I hope that answers Mr. Bellis's question. He could submit an email if he needs anything else clarified.

MR. BELLIS: Donna, this is Paul Bellis. You've answered the question. Thank you.

DR. BUSH: Thank you, Paul.

MR. BELLIS: Thank you for taking the question.

**Public Comments**

DR. BUSH: If there is no further discussion of the Drug Testing Advisory Board, we will proceed with the public comment period. Mr. Steven Soifer, you have the floor.

DR. SOIFER: Thank you. This is Dr. Steven Soifer. I am the CEO of the International Paruresis Association and an associate professor of Social Work at the University of Maryland, Baltimore. The organization, which I co-founded, helps people who suffer from the social anxiety disorder and chronic pubic floor dysfunction, better known as Shy Bladder Syndrome.

Three hundred members of the public commented on the HHS-proposed Mandatory Guidelines for Federal workplace drug testing programs. Well over half of the total comments asked for reasonable accommodations regarding their disorder in terms of drug testing in the workplace and were simply ignored.

Well, no more. On September 26, 2008, Congress passed Senate Bill 3406 or the American with Disabilities Act (ADA) Amendments Act. Most importantly, from our point of view, the amendment, which took effect January 1, 2009, defined disabilities and clarified them to include major bodily functions, including those of the bladder. It is

now illegal to discriminate against people with bladder problems, which clearly includes shy bladder.

Consequently, reasonable accommodation now must be provided to people with paruresis. If the new HHS regulations do not address shy bladder, we may be forced to seek an injunction against them. Moreover, any Federal agency or department not making reasonable accommodations could be sued for violation of the new ADA amendment.

We ask that DTAB immediately take this under advisement and take the necessary steps to provide reasonable accommodations in the drug testing arena by making alternative testing like saliva and hair available to shy bladder sufferers.

Thank you very much.

**Closing Comments/Adjourn**

DR. BUSH: Thank you for your public comment.

At this time, I see no further emails to me or questions in the chat room. As Designated Federal Official for the Drug Testing Advisory Board, I will close this meeting. We will resume session tomorrow at 10 am EDT.

I will turn the meeting over to Erica who has some instructional notes for the participants.

MS. HARBISON: Yes, for those of you who attended this meeting by telephone only or called the system number as opposed to entering the telephone number and having the system call you, we appreciated it if you could call us and let us know your name so that it can be captured for the record. If you did have any problems today, please let me know via email, and we will try to resolve them before tomorrow. Also, you will log in tomorrow morning the same way that you logged in this morning.

DR. BUSH: Any more announcements, Erica?

MS. HARBISON: No, unless there's something else you would like me to cover.

DR. BUSH: No, just you're interested in capturing the name and affiliation of those people who just called in by phone.

MS. HARBISON: If they would state their name before they hang up, then the reporting will capture it with the rest of the meeting.

DR. BUSH: Very good. Thank you. See you in the morning, so to speak.

(Whereupon, the meeting adjourned at 3:51 p.m.)