DRUG TESTING ADVISORY BOARD

OPEN SESSION

December 13, 2005

Agenda Item: Welcome/Opening Remarks

MR. STEPHENSON (Chair): Good morning. I would like to open this session of the Drug Testing Advisory Board meeting. For anyone here who would like to make a public comment, please let the person at the back table know so we can allocate appropriate time at the end of the open session.

At this time, we will go through the process of addressing the issues that are of public interest and concern before this Board. We will go through some updates on various things, and we have a couple of interesting presentations to make.

Agenda Item: HHS Update

DR. BUSH (DWP): I want to review a laboratory suspension with you. It is not something that we do in haste, unless necessary. We have had situations in the past where testing has taken a turn in a laboratory that was detrimental to both the laboratory and certainly the government and its interests in testing employees.

That has happened in the past, but generally speaking we work with the laboratory to review processes and procedures in the laboratory, identify them for the laboratory, and call those deficiencies to the attention of the laboratory in a most direct manner. Then, only when necessary, after we have exhausted reasonableness and reasonable provisions, do we suspend a laboratory.

I believe in the last 10 years we have suspended about 10 laboratories, or maybe over the course of the program, 10 laboratories and revoked the certification of only one. But we needed to do that. We needed to take action against a laboratory.

On November 14, we issued a suspension letter informing Sciteck Clinical Laboratories, located in western North Carolina, to cease and desist testing. We had gone through a long procedure with them over time, over more than a year, pointing out deficiencies, asking them to correct them. It never really came to pass, hence the basis for issuing the suspension letter.

The suspension letter was issued on November 14, and on November 22 the laboratory went to federal court in the western district of North Carolina asking for a temporary restraining order and declaratory relief based on federal rules of evidence.

Their claims were that there is a genuine controversy in existence between the laboratory and the government -- the laboratory certification program -- concerning the qualifications of the laboratory as a certified laboratory, concerning the inspection process to maintain such certification, and the administrative review process as implemented by the government when a suspension is issued. That was one claim for relief.

The second claim was that the laboratory was being treated differently in the inspection process by the defendant, by the government through RTI from others similarly situated. That such unequal treatment was the result of intentional or purposeful discrimination with no rational basis.

The third claim was that essentially this was going to cost millions of dollars in business lost, and loss of employees, even if the court found that the suspension was not in order, appropriate, and certainly if the suspension was sustained.

This complaint was filed on November 21, after we issued that suspension letter on November 14. On November 22, we received a notification that the judge had granted the laboratory's request for a temporary restraining order, and had set up a hearing to be held in the western district of North Carolina; a hearing to hear both sides of the case concerning laboratory suspension in front of the judge.

The hearing was scheduled for the Tuesday after Thanksgiving, November 29. I have never been at a hearing in Federal court concerning this program. In another life, when I was at the Fort Meade Forensic Toxicology Drug Testing Lab, I certainly appeared in Federal court concerning military drug testing issues

It was very interesting. At ten o'clock, when the hearing was convened, there was a very small showing: an attorney for each of the two sides and a couple of witnesses for each side. I certainly was one and Dr. Michael Baylor from RTI was the second one for the government. Sciteck had their CEO and their representatives present. The two attorneys made presentations to the judge.

The judge then clearly wasn't going to make this hearing intended to be one about a temporary restraining order into a hearing of the facts of the case. This hearing was focused: should the suspension of laboratory certification be imposed, or should it not? He did not want to get into an extended hearing about the detailed science in the suspension letter that was mentioned and described. If the focus of the hearing was changed, then we would have to bring up the laboratory inspection checklist, the number of inspections, outcomes, and possibly bring in inspectors for testimony.

The judge made the decision to just hear the case on the temporary restraining order, to grant or not to grant. That was the question. The judge heard the case for an hour, and then asked both sides to prepare additional affidavits, whatever else they wanted the court to consider in making their decision. And so we did.

Affidavits flowed that day. I saw the intensity of the legal process in trying to do this, and trying to get them electronically filed, which was pretty neat, by close of business that day. Then we waited for the judge to evaluate the submissions by both sides. Patience is a virtue, they tell me.

Late on December 1, I see that it is time and date stamped in Westlaw as December 1, but we found out on December 2 in the afternoon, the judge's decision was issued. He calls it a memorandum and an order of dismissal. I have copies back there at the sign-in desk, and if you did not get a copy, we can make more later.

We are also contemplating what to put up on our website, how to put these affidavits or the final decision on our Website, because at a particular meeting I was at over the weekend, I have gotten questions about its availability already. People are interested in seeing how the process worked, so we will have some form of it up on the Website.

Note: The "Memorandum and Order of Dismissal – Sciteck versus HHS – December 1, 2005" is on our Website at: http://dwp.samhsa.gov/DrugTesting/Files_Drug_Testing/Notices_Docs_Resources/SciteckDismissalOrder011205.pdf

Back to the decision. The judge goes through the facts of the case and the

evaluation standards. There are four prongs that the judge has to consider in granting a temporary restraining order. They cite many legal cases, like we cite peer reviewed scientific literature and all of our work, they cite many legal cases from the past.

The point to this was, granting a preliminary injunction requires that a district court, acting on an incomplete record, order a party to act, or refrain from acting in a certain a way. The danger of the judge making a mistake in this setting is substantial. The judge is in a precarious position. He needs to decide, based on the evidence he has in front of him, to make a decision to impose the laboratory suspension or not impose it. Where is the greater harm? The decision goes through this in-depth.

I understand from our legal counsel and from others who have read the judge's decision, that the judge did a really thorough job in balancing out his reasons for making his decision. One is irreparable harm to the laboratory.

The irreparable harm listed in the lab's affidavit's statement was that clients in western North Carolina will incur additional time and expense in having to use a laboratory outside the area, and the burden to the community or the public at large. The laboratory's affidavit talked about the financial impact of suspension, and that six employees will have to be immediately released. That was harm directly to the laboratory.

In evaluating harm to the government, the judge goes through taking a good look at our job in SAMHSA that is to ensure that the drug testing labs, given the imprimatur as SAMHSA-certified, are operated at or above a minimum threshold level of competence and proficiency as established by the Guidelines. Our interest, therefore, is in accurate testing in order to protect the safety and rights of employers, employees and the government, and the public at large. He went through and discussed that at length.

The likelihood of success on the merits, that means if the laboratory were to bring a full case to the court, could they succeed? The judge, based on affidavits from both me and Dr. Mike Baylor from RTI, and one of the laboratory inspectors, Mr. Ernie Street, who was on the most recent inspection, determined that in fact the government did take the proper action. And he could see from what additional affidavit evidence, sworn to the court, would be a huge problem to the government, and those tested.

He goes through his deliberations here. And the public interest has to be evaluated. The public interest in this case is two-fold. First, issues to the laboratory, then, issues to the government. In his order, it states: it is therefore ordered on December 1 that plaintiff's motion for a preliminary injunction is denied, and further ordered that the temporary restraining order issued by the court on November 21 is vacated, and the matter is dismissed with prejudice. In other words, the case cannot proceed further.

One of the judge's discussion items in here was part of the provisions, and for us who are the technical types, we really pay attention to a lot of science that is detailed in Section A, B, and C in the Guidelines. But Section D, now that is some heavy reading, because that describes the legal and review process when SAMHSA takes action in a suspension and/or proposed revocation of a laboratory.

The judge took all of that into account. Actually, there is a solid provision in Section D for the laboratory to exercise an administrative review process before going on to a Federal court or any other court. The judge stated clearly that the administrative review process should be exercised before you come to court.

That was a big statement about the entire certification and review process that is contained in the Guidelines, and reflects back on how the Guidelines were crafted

in the beginning. The pattern and the model of the existing Guidelines goes all the way back to the first issuance back April 11, 1988. The judge said to the laboratory that it didn't exercise all their administrative remedies, and so this case in Federal court is dismissed.

It was quite a dissertation from the judicial side of government, taking a look at an executive branch program put in place by virtue of Public Law and Executive Order so long ago. It was an extremely informative process, and it is still ongoing because the laboratory still has a window of time, small though it may be, to request an administrative hearing, and we are waiting to see if the laboratory requests that.

This is a process that has not happened.

MR. STEPHENSON: Very briefly, this legal action is important to bring up in a setting like this. One, because it is almost a textbook example. It is a review, almost an audit of the process of what goes on in this kind of program. It speaks to the issue of reasonableness as viewed from a neutral, very keen eye of an outside judge.

Something I have learned in many years is never try to re-interpret something that a judge has already put in writing. It speaks on its own. The 22 page document that is now available speaks volumes about process, reasonableness, and the mechanism by which you go through one of these situations.

Having said that, once one of these documents comes out, we -- I guess it is not sharing a secret -- we tried to find one of our earlier precedent-setting cases from many years ago. It happened so many years ago, they couldn't find the paper copies of it in the office of legal counsel.

This current case [the precedent setting case] certainly puts it down into place and creates a process for [future] administrative review. It sets up a standard for performance that you can look at objectively in terms of what is both reasonable, and a process that is used for government regulation and program oversight. What are the expectations? How is this going to be balanced?

Independent of the fact that it was found in the favor of the government's action, it does speak to an issue that all of us should pay attention to in looking at process. I assure you that in going forward on this case, we had taken every step to be reasonable, balanced, informative, with multiple attempts to be helpful. We do that with every single lab, every applicant lab, and every group that we deal with on any topic.

It is a part of what we have to do. We are not vested in any one tilt of information or process. This case was a return on our long-term investment in process. This is the kind of thing that hopefully only happens once every 10 or 15 years. In this case, it is now part of the record. Even if there were an administrative review that would take place, this is a part of the body of the records that exist.

DR. BUSH: Something else. I think what was of concern, and may be of concern to many people out there, because RTI International is so actively involved because of their contract to assist us to carry out the Guidelines, that they won on a competitive basis, they are front and center. They are the one contacting the laboratories, selecting the inspectors.

We, in the Division of Workplace Programs, participate in many decisions that are made. And certainly, any and all certification, revocation, suspension decisions are made in the Division of Workplace Programs, with advice from our general counsel.

And RTI may make recommendations to us and may discuss in intimate

detail what they know about technical issues that are happening, but certainly the decision process for certification of a laboratory, suspension of a laboratory, and revocation of a laboratory's certification are all made at the SAMHSA level. That was an issue that was discussed a lot in this case.

Clearly, we have enough legal documents and delegation of authority memos from the beginning of time to show that we make the decisions, and RTI is only our action arm that helps us get the nitty-gritty done so that we can carry out the process.

That was interesting too, because we had never been challenged on that process in the past - who makes the decision. They claimed: SAMHSA, you really don't make the decisions. We said: Oh, yes, we do. That is why Bob was saying this is all a key part of what we do. The administrative process would be a key part of what we do.

That does not mean that I would be a finder of fact in a suspension administrative hearing, nor that Bob would. That's not it. It would go to a much higher level in a manner similar to a court, where there are disinterested parties, knowledgeable but disinterested, and not influenced by any previous discussion about the case, no conflict of interest.

MR. STEPHENSON: At this time I would like to have Donna walk through the process for some of our new members of the board, and maybe hear a little bit about each of them.

DR. BUSH: We have new members this time. Lisa, we will start with you over on that side.

MS. TARNAI (Board member): It's still officially Scientific Testing Laboratories. They have not notified us of our new name. I have been with Scientific Testing Laboratories for 11 years, and I'm one of the labs on this list.

DR. COLLINS (Board member): I am from Medtox Laboratories in St. Paul, Minnesota. I have been with Medtox since 1991, so I've been around for a long time also.

DR. NIPPER (Board member): I'm from Creighton University in Omaha, Nebraska. Our laboratory is formerly certified as an HHS laboratory. I gave up the certification many years for internal reasons. We continue to do postmortem toxicology and clinical toxicology. I have been at Creighton for 19 years.

DR. ESTAPE (Board member): Good morning. I am at the University of Puerto Rico. I am a medical technologist, clinical chemistry and pharmacology, toxicologist. I am a dean at the College of Health-Related Professions, and also a consultant for a lab in toxicology.

DR. BUSH: Thank you. We appreciate your volunteering to serve for 4 years. You're certainly not doing it for the money, so we thank you for bringing all your expertise to this board as we continue through challenging issues.

Agenda Item: Department of Transportation (DOT) Update

MR. ELLIS (DOT): My name is George Ellis, and I am here representing the Office of

Drug and Alcohol Policy and Compliance in the Office of the Secretary of Transportation. I want to thank once again, Bob Stephenson and Donna Bush and their staff for their kind invitation to allow us at the DOT to come in and act as observers in the DTAB process.

Our office is among both national and international responsibilities, are the stewards of a regulation known as 49 CFR Part 40, which is the Department of Transportation regulation which governs the collection of specimens, laboratory analysis, medical review officer function and substance abuse professional function for the testing of what we estimate to be up to 12 million regulated transportation workers, and approximately somewhere between 600,000-700,000 regulated transportation employers.

We do that through a number of DOT safety agencies: the Federal Aviation Administration, the Federal Motor Carrier Safety Administration, the Federal Transit Administration, the Federal Railroad Administration, and our relatively new agency, PHMSA, or the Pipeline and Hazardous Materials Safety Administration.

We have, since the initiation of the DOT testing program in 1989, have relied on HHS to assist us with not only the certification of laboratories, but also the establishment of which drugs should we be testing for, and the cutoffs for those drugs. We very much appreciated their scientific and technical expertise, and have relied on them in a number of arenas relating to the interpretation of these results, and the laboratory analysis.

Our concern, and as managed by HHS, is to ensure that test results that are produced for our regulated employers and regulated employees are both scientifically sound and legally defensible. I think the news has been good in terms of the quality of the program that HHS administers through its fine contractor, RTI.

We also work closely with a number of other federal agencies, including friends and colleagues at the US Coast Guard, once part of DOT. They have since moved on to better things perhaps with the Department of Homeland Security. And they continue to use portions of our regulations, certainly large portions of 49 CFR Part 40 for the administration of their testing program for the Merchant Mariners.

We have one big bit of news since our last time together. Certainly, most of you are well aware that we released on October 31, a notice of proposed rulemaking for urine specimen validity testing. It has been a long time in coming, and follows on our friends at HHS in their guidelines for urine specimen validity. In the aggressive movement of federal regulations, it only took us a year after HHS issued its guidelines on urine SVT for us to get our NPRM, notice of proposed rulemaking out.

As many of you are aware, we are required by Congress in cases like this, to establish a separate and distinct rulemaking process in order to give our clientele, both employers and interested parties, the opportunity to comment on issues such as specimen validity, and general issues in terms of our testing program.

Basically, our notice of proposed rulemaking proposes to make urine SVT mandatory. Currently, it is authorized. Employers can choose to have specimens tested for specimen validity. It is up to them. If they do so, of course we require them to do in accordance with HHS requirements, however, it is authorized and not required.

Our new final rule, we are proposing in our final rule that it is made mandatory. All of our employers would be required to perform urine SVT on their samples. In our notice of proposed rulemaking, our NPRM, we propose to continue to rely on HHS for the laboratory issues, not only the establishment of how specimens will tested for specimen validity, but also cutoffs, which adulterants should be identified, et

cetera.

In our NPRM we also try to take care of numerous issues for our medical review officers, because we understand that a large burden of urine SVT will be in the interpretation of these findings, whether it is for adulterated, substituted or invalid specimens. In our NPRM, we try to close as many loops as possible for our MROs, to provide them guidance and for regulation on how we want them to handle these kinds of specimens.

Finally, we ask a lot of questions. We think this is a complex issue, a complex problem, and we are hoping, and in fact begging in some cases for not only individual citizens, but also interested groups, whether it's trade association, employee groups, employer groups, to provide as many comments as possible in terms of issues of concern.

Since we ask a lot of questions, we are required by regulation when you answer, to deal with those, and answer and consider them carefully in terms of the formulation of our final regulation. We really need your input. There are a lot of areas that we ourselves question what is the best approach, what is the best method to proceed. And so we are hoping, hoping, hoping that any here in this audience, and anybody who sees a transcript of this will provide us comment by our deadline.

Unfortunately by the timing of this meeting, our comment period is almost over. It is officially over on December 31 of this year. And then once we receive those comments, we will consider them carefully and issue our final rule as soon as possible.

The only other issue I would like to bring up, or only other comment I would like to make is to remind all of you, if you wish information about the DOT program, to visit our Website, www.dot.gov/ost/dapc. On that Website it will give you access not only to our regulation, 49 CFR Part 40, also our latest interpretations, but it also will give you access to various DOT agencies, both in terms of their program manager, as well as their regulations themselves.

We also included our friends at Coast Guard, because we miss them so much. We don't want them to stray too far from us. So, information on Coast Guard regulations will also be found there.

Finally, on that Website it will give you the opportunity, for those of you who have not yet signed up, we have an automated e-mail notification system, when something new happens, or when we issue our period newsletters, that you will automatically receive them. There is a button for you to sign up. We are hoping, for those of you who have not yet availed yourself of that opportunity, please do so.

MR. STEPHENSON: I guess as part of our HHS updates it would be remiss to continue without using part of the segue here as DOT goes through their NPRM following our process of change in our urine testing validity procedures, incorporating those into theirs, we are still going through I would say the last sharpening of the blade of the new proposed revisions to the mandatory guideline for alternative specimens.

Needless to say, this is a process that has not happened with all of the aggressiveness of the administrative procedures that DOT has used. It has certainly taken us more than a year. But there has been an awful lot of systems development, a lot of second and third level -- and I mean that literally -- rounds of science review, internal alignment among federal agencies that have to deal with various aspects of regulation and so on.

Basically, these issues have been resolved. And it now has to continue on

through a part of the process involving other parts of our government. But this has been quite a process, and I think everything evolved from the start of this process. Is it good to use some other specimens?

Who should help inform us? Well, industry should, and those that have the science expertise and the experience in other areas. What have we done to propose a shell? We put it out for public comment. The comment period has ended, and the comments reviewed internally. We review the process and the next steps. Those are done, all with the issue with the same sense of reasonableness, administrative review, scientifically accurate and legally defensible.

Then the art, as well as the science of writing. Then the process of editing, and then the process of review and clearance and agreement. All of those things have to take place sequentially, and they have. I can't give you a timeline for the next step, but each time we go through this, there is more of a tipping factor that is going to let this start flowing to other places effectively.

It is beyond literally our control to set a time on it, but process is good. It has been happening well. We haven't, nor has anyone else that we have been associated with, been holding this document. Anytime it comes back through our hands, we have usually had it turned around within literally a few days. I mean that quite sincerely, at the low end of few.

Bear with us. There will be more forthcoming on this in the future. I know this sounds awfully old, but it's a part of government. When you talk about aggressiveness of government regulation, as George did, immediately in my mind I think of giant redwoods. It is one of those circumstances.

Agenda Item: National Laboratory Certification Program (NLCP) Website Initiative

DR. MITCHELL (RTI International): I am going to talk about some of the preparations and changes going on within the NLCP. Currently, the contract is at RTI. We presented part of this at the most recent Society of Forensic Toxicology meeting, where we had the workshop for laboratory directors and inspectors dealing with a Website that we have been under development at RTI since October 2003.

This Website is designed to deal with the correspondence that goes on between the laboratories and the NLCP. It is very large. We have found that when we have to go back and produce documents, the storage of these documents has been on film. That meant that you had to go back and take it off there, copy it, and produce it. That's a rather lengthy process, and extremely labor-intensive.

One of the ways with technology, the way it is today, we felt that we could start going to electronic filing of the results. This would also provide us with an opportunity to have these available on a fairly long-term, say for a year or so in an archive which the laboratories could get at any time.

Normally, if a laboratory loses one of the documents, they come to us and ask us for a copy. Now, they will be able to go, when the final phase of this is put into operation, they will be able to go online and obtain a copy themselves in a “PDF” form.

Slide – Website Function

Phase 1 was implemented October 2003. That portion of the Website

really only concerned the PT program. In the PT program we sent samples out to the laboratories. We send forms with those samples, instructions for those samples, all types of paper work. The laboratory tests the samples, then they fill out the forms. They send all the forms back to us. And then we were entering that into a scoring system. This was the first phase in combining an electronic filling out the form with the scoring system that we have developed at RTI.

Unfortunately, currently we will not be able to go completely paperless in this system, because we still have the testing control forms which accompany these samples that the laboratories are required to fill out and send back to us.

This is a secure Website. You need a password to get into it. And you have to be an entity that is approved by the National Laboratory Certification Program.

The phase 2, which will begin in 1 January, will bring in the paperwork and other forms that are filled out for the inspection program.

Slide – Login Screen

Whenever the laboratory comes to the secure Website, they have to provide an identification number, which is their lab number, as well as the user name, which is the name of the responsible person, and a password.

This password has been given to them currently, and prior to this by the National Laboratory Certification Program. With each set of PT samples that went out to the laboratories, a new password was provided. It has allowed us controlled access in and out of this Website the way we have it set up.

Slide – Main Menu shown

When the labs go in, beginning in January, they will find that they go into an area which is primarily for their laboratories. You can see this one is for Lab #1, Toxicology Testing Services, in Miami, Florida. What you see here has nothing to do -- is not necessarily accurate for Lab #1, because we are just presenting it as a dummy case for this presentation.

But when they go in, they will immediately be asked to change their password to one that they would like to have. And from then on, that will be the password that they will use coming into the site. And they will have the option at any time to be able to change that password to another password in case they lose it.

We also have the function in case -- this would never happen -- our RPs forget their password. We will have the option to send it to them by e-mail, as is current practice in many places.

Slide – Upload NNSL

The second function on this list is to upload the current non-negative specimen list (NNSL) before an inspection. Each laboratory is required to identify all specimens that they have tested that were not reported as negative. In other words, we used to call it positive for drugs, and now we have SVT, adulterated, substituted. We have invalids. There are all different types of reporting options other than negative.

And so, any sample that was reported as anything other than negative, they must notify us, and give us a list of those samples, as well as other information. And we

call that the non-negative specimen list. And this is in a format that has been standardized by the National Laboratory Certification Program.

In the past, they either had to send it to us by CD, or in some cases the laboratories decided to e-mail it to us. But this provides a more secure means of providing that information to the National Laboratory Certification Program. They will be able to upload the file directly off of their hard drive onto our Website. And then we, along with that, now have a program which will allow us to process that information, assuming that the laboratories have properly placed the information in the standard form.

This is the point at which they would be able to do that. As you can see, the main thing here is that they are able to click their browser and go onto their hard drive and find the particular file that they want to upload to us, and then upload it. And this is a very secure means of passing that information from one place to another.

Slide – Performance Test Report Form Data Entry

Also with this, they will be able to take the option, which is number three, of the performance test report. And this report actually has a lot of information for the laboratories. It tells the type of lab that they are, that they are a urine drug testing laboratory. Another reason that we have gone to this is we are trying to set up the model and perfect the model that will allow us to easily implement all of the other matrices. In other words, we will clone what we have here for the other matrices, so that they can be handled as a distinct entity.

This will also identify the type of PT set. In this case this is maintenance. This is the normal set that is sent to the laboratories on a quarterly basis. The occasion at which it was sent to the laboratory, we number each occasion or each time we sent it out it's a sequential number. And I believe the last one was 78. There have been 78 occasions of PT since the beginning of this program. This is maintenance.

The date that it was shipped, the status of the occasion, that is once the laboratory has completed their entries and the processing is complete as far as the laboratory, then it will be closed, and they can no longer make edits. You can see down here we have two that are open, just as an example, which means the laboratory is able to go in and edit information that they have provided.

And also, it gives them other information as to the status of the scoring report that will be sent to the laboratory, and as well as any remedial efforts that are being required as a result of that occasion. The advantage here is that a laboratory can come into the site and see what's going on with the most recent occasion, or if they have some questions about something in the past, they can look it up fairly quickly.

Slide – Login to Edit Results

If they decide to edit, then that will take them to a new screen with a new password. And this password will be given by RTI on each occasion, that way we are able to control the access in and out of the data that is there to prevent after we have downloaded that information for scoring, to preclude any changes to the data. And this is very important that we make sure that there have been no changes to the data after we have downloaded it to begin the scoring process.

Slide – NLCP Web

The NLCP Web is the fifth option. This is the area for that laboratory which will provide links to various documents such as the checklist or the guidance documents, the other types links that they would need, that have program documents on it, and as well as your laboratory's documents.

Slide – Your Lab's Documents

Here will be the archiving of all the documents on the inspection process, the PT process, and anything associated with RP issues. There will be a system that is set up for numbering these files so that the laboratory can easily determine the particular document that they are looking for. We will try to keep for at least a year all of the documents pertaining to that laboratory in that archive. They will be archived permanently at RTI on another server.

Slide – Documents Included on the Site

Other documents that we plan -- these are the documents that we plan at this point in time to have, the laboratory result letter, the data from the scoring system, which is performance testing report. It will have the key for interpreting that data. It will have laboratory deficiency letters and remedial letters, that is, letters sent from RTI to a laboratory in case there is an issue with the testing from a particular occasion.

Reporting issues letters, remember I said that the one piece of paper we are not able to get rid of or to do away with is the custody and control form. And so, this we issue reporting issues such as failure to assign CCFs, checking the wrong box, things like this. If it happened to occur, that's in the reporting issues letter. And of course, the invoice for the next PT occasion will be there for the RPs.

In the inspections, currently we will have the inspection report, that is, the report after the inspection, as well as any remedial letters that are sent by RTI to the laboratory. Mike hasn't told me yet whether they plan to put the invoices for the inspection site on there. But we'll have to see about that, because it's a little bit different from the way that the PT cycles are handled as far as billing the laboratories for next inspection.

Slide – Section B: Laboratory Information

One of the big documents on the laboratory side is called Sections B and C of the checklist. And B and C require the laboratory to provide a lot of information about the current status of the laboratory.

Slide – Section B Entry

This particular one is the entry into B, and it allows the laboratories to go to a specific section in there just by clicking on -- so, you click on B-1, and it will take them to that. And this is an example of what they will, whether they just enter their name and address and other information into that particular area.

Slide – Section C: Laboratory Information

The Section C, which is additional information. It has a lot of tables, and it also has a lot of text information which must be entered. You can see here that we have a text box which will allow the laboratories to cut and paste from a Word document or text document into this to cut down on some of the issues that we might have.

It's very difficult when you've got a form up like that, if any of you have applied for the passport, and you have to go in and type it in online. And sometimes you are sitting there trying to figure out, well, where is that piece of information. But if you have it on a document, and you've already got it ready, you can go ahead and put it in. And most of the laboratories currently are maintaining electronic files of B and C, and they just go in and correct that. And this way, if there is a change, they will be able to go in and just paste it.

Slide – Section C Entry

Now, one of the things that we are providing to the laboratories is that they will fill out for the last time, the B and C as either an electronic document that they maintain, or as a paper document. When they send the B and C to us, we will transfer that information for the first time onto the B and C form. Then we will notify the laboratory before they have their inspection, to come online and to check it for accuracy.

From then on then, the laboratories will be able to maintain that form. In other words, at any time they can go in and make changes. They can keep it updated. They can either do it periodically. They have to have it completed before each inspection. But this provides more options for the laboratories to keep things up-to-date.

The advantage to this is it allows us to remove one more requirement that we have had within NLCP on the PT side. We had a PT matrix that the laboratories had to update each time. So, once this is instituted, laboratories -- once we have their B and C in the database, then we will no longer require the PT matrix, because we will have most of that information that we are requiring here off of Section B and C from the lab.

Slide – Certify and Submit

The last thing that the laboratory will do after they have completed filling out the B and C, they will certify that this is true and accurate. This will be certified by either the RP or the alternate RP, and will be using their password that is specific for them in order to be able to do this.

Slide – Print Section B and C

After they have filled out the B and C, then they have an option to print it, if they so desire. That's a lot of paper to print out, as everyone knows. But this way they can have a hard copy. We will maintain a copy of each B and C as it was prior to the inspection. And that particular form will be given to the inspectors who are coming to the laboratory for the inspection. So, we will have a snapshot at the time. We will also be monitoring this for changes, and we'll be able to track changes that are made over time, so we'll have an audit trail on it.

Slide – Future Plans

As we go to alternate matrices, this whole process with the NLCP is going to become very complicated, because we are not dealing just with new matrices. We are going to be dealing with new technologies such as the POCT, the point of collection testing. And there will be a need to be able to pass information back and forth between RTI, some of it general information, some of it information specific to a laboratory.

So, this is going to provide us with an opportunity through a question and answer period on a bulletin board or something of that nature, to provide information on current issues. Many times, things that happen within NLCP, for example, with the urine we would have a report from one lab, well, we are seeing this. Are any of the other labs seeing this type of sample occurring? Meaning that they felt that there was a specific adulterant that was showing up.

This will allow us to post that information on a question and answer bulletin board, and for the laboratories to provide feedback on whether or not they are seeing it. It will allow the program to better monitor what is happening in these types of instances.

We have also been tasked with maintaining a bibliography. We have been tasked by HHS. We thought that we have all these references about all the testing that goes on. And now we are going to hair and oral fluids and sweat and POCT. So, it would be good for the laboratories to have access to this information in case they want to know if a certain thing has been published, or they are writing a paper on what they are doing.

As a service to the laboratory, I think that they should have the availability of the bibliography. They will not have availability through us to the articles, but at least they can get the references that we have.

Again, I talked about the special notices and the news items. I referred to them in general. And Dr. Baylor intends to expand the pre-inspection activities to have additional information there in things that we need from the laboratories in the pre-inspection phases such as the inspector approvals and things of this nature.

So, with the expansion of the National Laboratory Certification Program we feel that this will provide it with a tool that can be used to manage the highly complex system. And it's really going to be highly complex, because we will have new laboratories for different matrices applying for certification, going through the PT process. It's going to take something like this for us to be able to manage it.

DR. VOGL (DWP): I would like to add a few comments to put this presentation in perspective with regard to the entire program. As you know, or may not know, our regulations must be reviewed and cleared by the Office of Management and Budget. And a part of that process requires us to describe in detail what efforts we are making with regard to paperwork reduction and paperwork elimination in our program.

We do this every three years actually, or when a new regulation comes out. We have the federal custody and control form that is approved. We are always trying to explain why we need a paper trail to document the collection and the testing of specimens.

With regard to the information that we gather from the laboratories, they are clients. We are expected to make every effort we can to give them an opportunity to

submit information electronically, just as the government is pushing you to submit your tax return electronically.

As we move forward with the alternative specimens and POCT, allowing labs to do all of this electronically will make it easier. We are going to eliminate a lot of paper. It is going to minimize potential errors that exist when you transfer information from paper to electronic files, et cetera.

We look forward to it being implemented full-time. It will definitely allow us to provide great justification to OMB that we are making strides in reducing paperwork and eliminating paperwork.

MR. STEPHENSON: Again, I can use the word "aggressive" processing. But clearly, there are two forms of this. One of this is it's paperwork reduction, literally. There is an initiative started by OMB a number of years ago which was called the paperless lab. And there was the forensic reality of trying to deal with paperless.

But in the spirit of paperless, there was a federal advisory committee act process that was initiated by DOT that addressed some of the common issues that we deal with, as well as DOT and the laboratory and related paperwork issues.

There is also an issue around what's called e-government, which is a whole spirit of moving things from an electronic environment, as opposed to just pure paper. It's not just a burden. It is not just saving trees and paper, but it is how do you use the data once it is there. How do you make sure that files are available and usable once they are in place? How can you be smarter about what information you have access to in terms of how do you use it? How do you look at trends over time?

There are a lot of things that will come out of this that will be helpful to us in the future. The PDF files that we have today are all totally searchable. The kind of things that exist that are archived will be of benefit to a lot of different folks.

John, your point is well taken. You must have this kind of system in place as the open journal, so to speak, to begin to put entries into it for the alternative specimens for the labs, for the routine processes that we know are going to be coming our way.

DR. BUSH: Well, I haven't gotten any direct message from Tim McCune, so we are going to assume that other duties as assigned took priority to him attending here today. And we are running a bit early then.

MR. STEPHENSON: We have one comment. One individual has requested to speak to the group, so, I will allocate 10 minutes.

Agenda Item: Public Comments

MR. HABER: I am here on behalf of the International Paruresis Association, IPA. I gather there are some new members who may not be familiar with IPA, so I'll briefly explain what IPA is.

Paruresis is a social anxiety disorder in which an individual would be unable to urinate in the presence of others, in close proximity to others, or when under scrutiny. That obviously has significant implications for all the issues of drug testing.

What IPA does is provides a range of services. It is an organization of more than 1,000 members whose mission involves educating the public on the nature of

paruresis or shy bladder syndrome; helping those afflicted with paruresis to overcome the stigma, embarrassment, and isolation associated with it; and serve as an information clearinghouse and a resource center for treatment referrals; sponsor workshops to help paruretics overcome this phobia; facilitate the establishment of support or self-help groups across the world; promote research to help identify the most clinically effective treatment; uncover the etiology of paruresis; and accurately assess the epidemiology and incidence of paruresis.

In July 2004, the IPA sent a formal letter of comment regarding SAMHSA's proposed new regulations regarding testing of federal employees and implementing alternative drug tests such as hair, saliva and sweat testing. IPA members also sent in 130 of the 285 public comments received by SAMHSA on the new proposed regulations.

In our formal letter to SAMHSA, IPA reiterated our position that we are not opposed to drug testing, but we are merely asking that the new regulations be worded in a way that allows those who are unable to provide a voluntary urine sample due to paruresis or other conditions such as u urine void dysfunctions, multiple sclerosis, diabetes, paralysis, or spinal shocks from car accidents to request an alternative drug test such as saliva, hair or patch as proposed by SAMHSA.

The primary difference in our wording from SAMHSA's is that our intent is to allow those unable to provide urine specimen to request one of the new three alternative tests, or even to allow the voluntary use of a urine catheter.

SAMHSA drug testing rules currently rely exclusively on urine testing, and do not permit alternative sample testing for those who suffer from paruresis or other medical conditions which may cause an unexplained inability to produce a urine sample. The IPA has repeatedly contacted SAMHSA officials, commented at DTAB meetings, and spoken with SAMHSA officials concerning the problems that current testing protocols cause those unable to produce a urine sample.

Nevertheless, we have been unable to get assurance from anyone at SAMHSA or at DTAB that there is a real understanding about the problems SAMHSA rules cause many job seekers who are unable to produce a urine sample, including those who apply for non-government positions and positions regulated by DOT.

Now, we are very concerned that SAMHSA will implement the proposed rules promulgated on its Website without properly taking into account either the IPA response or the public comments written by many who suffer from paruresis.

The present reliance on urine-based testing to the exclusion of other viable options is unacceptable to us, as is the insistence by SAMHSA that a failure to produce a urine specimen equates with refusal to be tested. IPA has several comments regarding the regulations and requests for DTABs. That's a little bit complex in the ordering of this. I'm going to try and go a little bit more slowly.

Our requests include: (1) ask SAMHSA to announce an issue date of the new drug testing regulations; (2) ask SAMHSA to officially acknowledge that the problem of paruresis is real, and assure that reasonable accommodations will be built into the testing rules.

Those accommodations would include: (a) specifying that it acceptable for people to provide a urine sample by a self-administered catheterization; (b) de-couple failure to produce a sample due to paruresis or to situational anxiety from the definition of refusal to test; (c) mandating the use of hair, saliva or oral fluid in lieu of urine for anyone unable to produce a urine sample within two hours, or anyone able to document

that he or she has paruresis; (d) implementing alternatives to urine-based testing for new job applications, as well as those already hired.

Item 3, we wish to ask SAMHSA to establish appeal mechanisms for individuals unable to produce urine samples for drug testing. And lastly, item 4, ask SAMHSA to provide and maintain data on the number of people who lose positions due to an inability to produce a urine sample.

We understand that the SAMHSA office only represents those federal employees that are subject to drug testing. We believe that the SAMHSA drug testing standards, when finally published, will be used as the standard, and influence drug testing procedures currently used by DOT and many commercial companies.

We, therefore, ask for SAMHSA's understanding in working with us on drug testing problems for the paruresis community. We hope that meetings will be set up on an ongoing basis with SAMHSA and our organization, as well as other appropriate organizations concerned with this issue.

We are and have always been willing to work with SAMHSA to help it address our legitimate concerns and the need for scientifically valid testing of employees. We are not an adversary of SAMHSA, DOT or drug testing. Some of our members have experienced accidents at work or tragic family situations due to illicit drug use. Our issue is fair treatment of those who have micturition disorders, and reasonable accommodation for those suffering from the social anxiety disorder known as paruresis or shy bladder syndrome.

That concludes our comments, and thank you for the opportunity to say them.

MR. STEPHENSON: As is our established practice, we will not respond to your comments directly here. They stand on their own merit. Again, if you have a paper copy of that, or an electronic file that you wish to submit, we will see that it becomes a part of the record.

I will say that in the publication of public comments that had followed our request for those public comments on the alternative specimens, modifications to the guidelines, all of those are on our Website. They are on public display. All of those have been incorporated and addressed in the documents that are visible and assembled as such. And all public comments are given full consideration in the development of final text and process.

It is just totally inappropriate and unauthorized by legal counsel's interpretation to have any further discussion on any final outcome of the guidelines at this point. It cannot happen from here. And that is the issue which is of concern to a lot of folks. But the process is ongoing, and the reasonableness that we have used in establishing the collection and careful examination of the incoming comments has certainly helped inform us in any way we can.

That's all I can really say.

I would like to conclude this session of the Drug Testing Advisory Board meeting. We will reconvene in closed session in 15 minutes.

The meeting was adjourned at 9:50 am.