SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

DRUG TESTING ADVISORY BOARD

June 3, 2009 Transcript

One Choke Cherry Road
Rockville, MD 20857

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Proceedings

DR. BUSH: Good morning. I am Donna Bush, Designated Federal Official of the Drug Testing Advisory Board. It is my pleasure to call this meeting to order this morning and open the session. Bob Stephenson will provide discussion about yesterday's meeting and how we are going to proceed today.

Welcome and Opening Remarks

DR. STEPHENSON: This is the second day of the Drug Testing Advisory Board meeting. First, I suggest that RTI provide instructions for those of you who are participating remotely.

MS. HARBISON: Thank you, Bob. Hello. My name is Erica Harbison. I will point out a few things, as I did yesterday, about the web page you are viewing. Your screen is broken into several different sections, called section pods. Each pod serves a different function during the meeting. Most of the presentations will be shown through the share pod, which is the largest pod and normally takes up the most of your viewing screen.

The attendees list section pod on the left-hand side of your screen displays everyone attending remotely, including those who are calling but not viewing the presentations. At the top of the attendees list, there is a "My Status" drop-down arrow. Please go up to the "My Status" drop-down arrow and select the green "Agree" checkmark, so that I know that you have audio and not are having technical problems thus far. On the "My Status" drop-down arrow, you will also notice that there is a "Raise My Hand" icon, which a great way for you to communicate with us. If any DTAB member has a comment or question on a presentation, select the "Raise My Hand" icon. If you cannot unmute yourself in time, then we will call on you when we answer questions.

On the right-hand side of your screen, there is a chat pod, which allows you to submit questions to us at any time concerning either technical problems or pertaining to the meeting materials. To enter your question, click on the white bar at the bottom of

your chat pod using your cursor and then hit “Enter” to send your message. All submitted questions by attendees will be held until the allotted discussion time. At that time, the meeting host will inform you when it is your turn to address the group.

Notice the timer pod, located in either the right- or left-hand corner of your screen, which will help us stay on track with the agenda.

If you have any technical problems or any questions pertaining to the meeting material, please feel free to submit those into the chat pod.

Donna and Bob, I’ll turn it back over to you.

DR. STEPHENSON: Thank you. Do any of the members of the Board have any procedural questions this morning for RTI?

DR. BAXTER: This is Lou Baxter. I’m having trouble removing the “Call My Number” icon from my screen.

MS. HARBISON: There should be a “Call My Phone” and a “Cancel” button. If you click on the “Cancel” button, does it go away?

DR. BAXTER: I just have “Call My Number” there.

MR. COOPER: Lou, it appears that pod is hung up. Please close out and reenter the room. The pod will stay there until you do that.

DR. BAXTER: Okay.

MS. HARBISON: Lou, you do not need to disconnect your phone. You can stay connected with us, so you can listen as you log back in.

DR. BAXTER: Thank you.

DR. STEPHENSON: Yesterday we learned that we had sufficient time allocated on the agenda for each topic. Although it was a good intention to adhere to the time schedule, we will progress through the agenda, regardless of the listed times. We promise to dismiss on time for the breaks and the closing. Since this is going to be a busy day, let’s proceed because we have a lot of information to present to you.

Donna, I’ll turn it over to you.

DR. BUSH: Thank you, Bob. Charles LoDico, of our drug-testing team, will give his presentation on the 2010 Federal Custody and Control Form (CCF) update. Charles?

Revised Federal Custody and Control Form Update

MR. LODICO: (Slide 1) Good morning. I have been tasked to take the lead in the revision of the Federal Custody and Control Form. Normally, this task would have been assigned to my coworker, Dr. Walt Vogl, who has since retired. Dr. Vogel was instrumental in how the current Federal CCF looks and is used today. I hope he will look favorably on the new 2010 Federal Custody and Control Form when it is released.

I will present today the proposed 2010 Federal Custody and Control Form and detail the many necessary changes that were made to the current Federal Custody and Control Form. I will begin with a review of the history of the Federal Custody and Control Form, then look at the individual sections of the new 2010 Federal Custody and Control Form, and finally highlight the changes made in each section. I will also briefly discuss the status for the renewal of the OMB expiration date for the current Federal Custody and Control Form.

With the publication of the Mandatory Guidelines in November 2008 with an implementation date of May 2010, there was a need to revise the Federal Custody and Control Form. A major reason for the revision is to accommodate the inclusion of the Instrumented Initial Test Facility (IITF) on the Federal Custody and Control Form.

(Slide 2) The Mandatory Guidelines require the use of the Federal Custody and Control Form. The original Custody and Control Form was a seven-part form. In 2000, a joint effort, initiated by SAMHSA and the Department of Transportation (DOT), developed a new Custody and Control Form that was easier to use. (Slide 3) Here is an example of the original 1988 Custody and Control Form. As you can see, this was a busy form.

(Slide 4) Some of the major changes to the original form were:

- It was reduced to a five-part form from the original seven-part form.
- The bottle seals were moved from the right-side of the form to the bottom.
- The chain-of-custody step was simplified by requiring the collector to only sign the form once.
- We also provided a wider choice of terms that a laboratory can select from to report specimen test results. The original form used the term “Test not performed” to report any result other than a negative or a positive result. The current CCF has checkboxes for “Invalid result,” “Adulterated,” “Substituted,” or “Rejected for testing.”
- The Medical Review Officer (MRO) steps for both the primary and split specimens were relocated on the MRO copy. This change permits the MRO to record the determination for both the primary specimen and the split specimen on the same copy and to use this copy to report results to the employer.

(Slide 5) The CCF must be approved by the Office of Management and Budget (OMB) and contain an OMB number. The OMB number will be the same number as the current Federal CCF.

The Federal CCF has a three-year expiration date on the use of the form, and this is to reassess the burden hours that it takes to use this form. The current form expires in September 2009. I will briefly discuss the OMB renewal process for the current Federal CCF.

On April 22, 2009, a notice was published in the Federal Register for public comment on the estimated burden hours needed to complete the Federal Custody and Control Form; the comment period is 60 days. If no comments are received, the Federal Custody and Control Form package, with supporting reference material, will be submitted to OMB. SAMHSA anticipates that the approval for the continuation of the

current Federal Custody and Control Form will be in place prior to the CCF expiration date. We are working both to renew the current form and, at the same time, propose to change the form to be consistent with the Mandatory Guidelines when they are implemented in May 2010. SAMHSA is on two parallel tracks to complete both tasks on schedule.

As before, SAMHSA and DOT have entered into a joint effort to make changes to the Federal Custody and Control Form that reflect the new Mandatory Guidelines that will be implemented on May 1, 2010.

(Slide 6) This slide depicts an example of the current Custody and Control Form. The current CCF was a collaborative effort involving the staff at the Division of Workplace Programs, the Department of Transportation, and the National Laboratory Certification Program at RTI.

(Slide 7) Change for the sake of change is generally not successful. It is not the intention of the Department of Transportation and SAMHSA to change the Federal Custody and Control Form radically. We ultimately want to keep as much of the new form in appearance to the current form.

In the next two slides, I will list some of the facts and assumptions concerning the Federal Custody and Control Form.

(Slide 8) The 2010 Federal Custody and Control Form will be for urine specimen collections only. This form will be used by the Federal agencies, most notably, the Nuclear Regulatory Commission (NRC) and the Department of Transportation, and employers in the regulated industries. The 2010 Custody and Control Form will also be used by both the National Laboratory Certification Program HHS-certified Instrumented Initial Test Facilities and Laboratories.

(Slide 9) The primary purposes of the CCF are:

- For the collector and the test facility to document the chain of custody of the primary and split specimens.

- For the test facility to report primary specimen test results to the MRO.
- For the MRO to report drug test results to the Federal agency or employer.

The CCF also must document the transfer of specimen from an IITF to a laboratory for further testing.

(Slide 10) It is also desirable to use checkboxes, the same as on the current CCF, for reporting test results by the IITF or the Laboratory. We also will add the new drugs, MDMA (3,4 methylenedioxymethamphetamine), MDA (3,4-methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine), and add check boxes in front of those analytes.

(Slide 11) In the real estate business, the mantra is: location, location, location. When looking at the Federal Custody and Control From, one must look at the form as a parcel of land. Therefore, wherever the information or instructions is located on the form, this will increase the value of that parcel of real estate.

(Slide 12) Having said that, it may be difficult to report split specimen results by the second split laboratory on Copy 1 of the CCF as it is currently configured. It may be more reasonable to move split specimen test/retest results to the MRO copy. Data from 2008 show that the split specimen retest represented 0.07 percent of specimens tested or 3.7 percent of the reported positives. Also, with special validity testing and/or multiple drug results, the remarks line comment often led to “See attached for second laboratory results”.

(Slide 13) Overall, it is desirable to retain as much as possible the format and function of the current Custody and Control Form. The 2010 CCF will have five copies, the same as the current Custody and Control Form. There is a significant advantage to maintaining the current 8.5-by-11-inch Custody and Control Form size over the 8.5-by-14-inch size, which was the size of the original form. Also, we will keep the bottle seal labels on the bottom of Copy 1 - Test Facility.

(Slide 14) This is a proof of the 2010 Federal Custody and Control Copy 1 - Test

Facility. I will highlight the changes that were made from the current Federal Custody and Control Form.

As you can see, the layout of the 2010 Federal Custody and Control Form looks very much like the current Federal CCF, but there are some major changes in the different sections or steps. In the next few slides, I will focus on the individual sections or steps of the 2010 Federal Custody and Control Form and identify the changes made from the current Federal Custody and Control Form.

Because this presentation is broadcast both to a remote audience and a live audience, I will use the green arrow on the computer to the point to the section of the slide that I am commenting on, unlike the use of the laser pointer in a live presentation. I will also beg for your forgiveness and indulgence in my being slow and deliberate in these next few slides because I want to be accurate in my commenting on the section to which I will be referring. I also have one other apology. The resolution on my monitor is not optimal, so I will have to go back and forth between my monitor and the projected image to verify the area that I am pointing to.

(Slide 15) This slide represents the top form of the Copy 1 - Test Facility. On the top of the form, we have changed the “Lab Accession Number” to the “Accession Number.” Also at the top of the form, is an area for the name and address of the IITF or Laboratory to be affixed.

Concerning the changes in Step 1, in item B we added “No.” after “Phone.” A major change is occurring in line D, where the collector will specify the testing authority, whether it be HHS (Department of Health and Human Services), NRC, or DOT. We will also request that the collector specify the particular DOT agency, such as FMCSA, FAA, FRA, FTA, PHMSA, or USCG. This change request was made by the Department of Transportation because it would be easier for results to be reported to the Department of Transportation agency when their rules require it. Currently, pilots and mariners need to have their results reported to FAA and Coast Guard, respectively. Also it is expected

in the near future that the Department of Transportation will require the reporting of positive and refusal to test results into a database for employers. This addition will make documentation simpler for the result reporter, usually the MRO, to have that information already stipulated by the employer on the form. Also, the labs will capture the data elements in step 1D for reporting to DOT.

DR. STEPHENSON: For clarification purposes, on this form under line D "Specify Testing Authority," the first checkbox is HHS, which refers to all executive-branch Federal agencies, including DOT, Homeland Security, etc. The checkbox options behind NRC refer to all the regulated industry testing for which they are responsible. The checkbox options behind DOT's checkbox specify all the different regulated industry testing components.

MR. LODICO: That is correct. Thanks, Bob, for clarifying that.

To continue, in line E, we placed on a single line the reasons for test. Lines F and G remain the same as the current form.

(Slide 16) This image is of Step 2 of the Custody and Control form. The changes in this section are:

- After "Completed by the Collector," we added the instructions, "Collector reads specimen temperature within four minutes."
- In the temperature section, we deleted the sentence, "Reads specimen temperature within four minutes," and we changed the phrase, "Is the temperature between 90 degrees and 100 degrees Fahrenheit" to "Temperature between 90 degrees and 100 degrees Fahrenheit."
- The three sections, "Temperature", "Collection", and "Observed", were placed on a single line.
- More space was inserted for the collector's remarks.

Step 3 did not change from the current Custody and Control Form.

(Slide 17) This slide highlights Step 4 of the Custody and Control Form. This is

the area of the CCF where real estate was maximized because the space on the form was critical, and a decision was made on what to add and what to subtract. The changes that were made are:

- First of all, we changed the “Completed by Laboratory” to “Completed by Test Facility.”
- Secondly, a space was added for the Collector’s Chain of Custody Section “Signature of Collector” block.
- The size of the “Specimen bottle(s) released to” area was reduced.
- The line between the “Chain of Custody” of the collector block and the “Received an IITF” block was bolded.
- An IITF Chain of Custody section was added, which is major real estate. This was not present in the current Guidelines, but it is in the 2010 proposed Mandatory Guidelines.
- An “IITF name and address, if not above” block was inserted.
- The “Primary specimen Bottle Seal Intact” block was reworded and resized.
- The “Transfer from the IITF to Lab” block was added in the event of further testing.
- The line between the “Received at IITF” block and the “Received at Lab” block was bolded.
- A space for “Signature of Accessioner” within the “Received at Lab” Chain of Custody section was added.

(Slide 18) This slide depicts the section of the Custody and Control Form that highlights Steps 5A and 5B. The changes that were made in Step 5A are:

- In Step 5A, we changed the “Primary Specimen Test Results” to the “Primary Specimen Report” and changed the “Primary Laboratory” to “Test Facility.”

- The new drugs and analytes, MDMA, MDA, and MDEA, were included.
- The results checkboxes were staggered for clarity and to facilitate form completion.
- We also added in parentheses "△9-THCA" after the marijuana metabolite and "BZE" after the cocaine metabolite.
- "Rejected for Testing" was changed to "Rejected".
- We changed "Test Lab, if different from above" to "Test Facility, if different from above."
- "Certifying Scientist" was changed to "Certifying Technician/Scientist," on both the signature and the printed-name lines.

In Step 5B, the changes are:

- The split specimen test result section was deleted and a section was included for "Completed by Split Testing Laboratory", to indicate whether the split specimen was tested.
- We also added a checkbox to indicate "Split Specimen Tested, See Laboratory Report" and included a section for the split testing laboratory name, city, and state.
- Also the labs will be using an internal split specimen report form, which is now part of the 2010 Federal Custody and Control Form.

At the bottom of the form, the changes made are:

- The width of the label seals was reduced from 0.75 inch to 0.5 inch.
- We changed the footer to read "Copy 1 - Laboratory" to read "Copy 1 - Test Facility."

(Slide 19) This slide is a proof of the 2010 Federal Custody and Control Copy 2 – Medical Review Officer Copy. The changes that I describe in the next slides will be the same for Copy 2 through Copy 5. These include the copies for the MRO, the collector, the employer, and the donor. The front-page copies are identical. Also, Steps 1 through

4, Copy 1, are the same and will appear on Copies 2 through 5. We make Steps 1 through 4, through the collector's custody and control section, identical to the revised Copy 1.

(Slide 20) This slide depicts Copy 2 and Steps 1 through 4, which is similar to Copy 1.

(Slide 21) In Step 5, the donor section, there really were no major changes but only a few word changes. We changed the first sentence in the instructions after Step 5, "Donor Entries," from "Should the results of the laboratory test for the specimen identified by this form be confirmed positive, the medical review office will contact you to ask about prescriptions and over-the-counter medications you may have taken." We changed this to, "After the medical review officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken." What was removed from this statement was the term "confirmed positive".

The line before Step 6 was bolded to separate the donor section from the MRO section.

(Slide 22) Here are the highlights to changes to step 6:

- The "Determination/Verification" has been changed to "Verification" only, and this is to be consistent with both HHS and DOT terminology.
- The "Results" box was repositioned for clarity and to facilitate form completion. After the "Positive," the checkbox for the MRO to specify drug analytes was added. After the "Adulterated," a line was also inserted for the MRO to specify the adulterant and the reason.
- We also added the "Other" to "Refusal to Test" to allow additional reasons for this result. As an example, the MRO reports a refusal to test because the collector reports insufficient urine provided and the MRO determined there is no medical condition that prohibits provision of sufficient urine.

- Also, the additional line for the MRO's remarks was included.

Because of additional available real estate, in Step 7 we were able to add new information that is not in the current CCF. The highlights to the changes of Step 7 are:

- We changed "Determination/Verification" to "Verification" only.
- After the "Reconfirmed," we added a line for the MRO to specify reconfirmed drug analyte or substituted or adulterated.
- The "Test Canceled" box was added.
- After "Failed to Reconfirm," a line was included for the MRO to specify drug analytes, substitution, or adulteration that was not confirmed and added the "Remarks" line for the MRO to add reasons for "Failed to Reconfirm Results" or for directed actions.

(Slide 23) This slide shows a proof of the back of Copy 5 - Donor Copy of the 2010 Federal Custody and Control Form. The order of the information on the back of this form is:

- First, the instructions for completing the Federal Drug Testing Custody and Control Form.
- Second, the Privacy Act, for Federal employees only.
- Third, the Public Burden Statement.

This order is consistent with the current Federal Custody and Control Form.

On the back of the Federal Custody and Control Form, we changed the instructions for completing the Federal Drug Testing Custody and Control Form from the current Federal Custody and Control Form which was a list of instructions in an alphabetical order, letters A through J, to the 2010 Federal Custody and Control Form which lists the instructions in step order, 1 through 4, to be consistent with the collection steps. Steps 1, 2, 3, and 4 will mimic whatever was in the sections of Copy 1 for the collector to perform. This gives the opportunity for the donor to also review the

instructions and follow the instructions of the collector.

(Slide 24) I will read the next slide to highlight the changes made to the back of the 2010 Federal Custody and Control Form. These are the instructions as written: “When making entries, use a black or blue ink pen and press firmly.”

Other instructions include “The collector ensures that the name and address of the HHS-certified Instrumented Initial Test Facility, IITF, or HHS-certified Laboratory are on the top of the CCF and the specimen ID number on the top of the CCF matches the specimen ID number on the labels/seals.” We made it a point that rather than having “and/or,” we chose to have it one or the other. That is a decision that was agreed upon by the collaborative group that produced this product. There will be an opportunity for the public to make a comment on it.

(Slide 25) The instructions for Step 1 are: “The collector ensures that the required information is in Step 1. The collector enters a remark in Step 2. If donor refuses to provide his/her SSN or employee ID number, the collector gives the collection container to the donor and instructs donor to provide a specimen. Collector notes any unusual behavior or appearance of donor in the remarks line in Step 2. If the donor, at any time during the collection process, clearly indicates an attempt to tamper with the specimen, the collector notes the conduct in the remarks line in Step 2 and takes action as required.”

(Slide 26) The instructions for Step 2 are: “The collector checks specimen temperature within four minutes after receiving the specimen from the donor and marks the appropriate temperature box in Step 2. If the temperature is outside the acceptable range, the collector enters the remarks in Step 2 and takes action as required. The collector collects the specimen and notes any unusual finding in the remarks line in Step 2 and takes action as required. Any specimen with unusual physical characteristics, for example, unusual color, presence of foreign objects or material, unusual odor, cannot be sent to an IITF. It must be sent to an HHS-certified Laboratory for testing as required.

The collector determines the volume of specimen in the collection container. If the volume is acceptable, the collector proceeds with the collection. If the volume is less than required by the Federal agency, the collector takes action as required and enters remarks in Step 2. If no specimen is collected by the end of the collection process, the collector checks the “Non-provided” box, enters a remark in Step 2, and discards copy 1 and distributes remaining copies as required. Lastly, the collector checks the split or single specimen collection box. If the collection is observed, the collector checks the “Observed” box and enters a remark in Step 2.”

(Slide 27) The instructions for Step 3 are: “The donor watches the collector pour the specimen from the collection container into the collection bottle or bottles, place the caps on the specimen bottle or bottles, and affix the label seal on the specimen bottle or bottles. The collector dates the specimen bottles after placement of the specimen bottles. The donor initials the specimen bottles after placement of the specimen bottles. The collector turns to Copy 2, medical review officer copy, and instructs the donor to read and complete the certification statement in Step 5. This is where the signature, printed name, date, phone number, and date of birth is included. If the donor refuses to sign the certification statement, the collector enters a remark in Step 2 on Copy 1.”

(Slide 28) Finally, the instructions to Step 4 are: “The collector completes Step 4 on Copy 1, signature, printed name, date, time of collection, and name of delivery service, places the sealed specimen bottles and Copy 1 in a leak-proof plastic bag, seals the bag, prepares the specimen package for shipment, and distributes the remaining Custody and Control Form copies as required.”

(Slide 29) This slide represents the Privacy Act statement. No changes were made from the current Federal Custody and Control Form. This is intact and will be placed on the back of the Custody and Control Form.

(Slide 30) This is the Public Burden Statement. This is the statement that will appear on the back of all five copies. The statement was reviewed and cleared by the

SAMHSA OMB clearance officers. The SAMHSA OMB officer has assured me that the OMB number will remain the same on the 2010 Federal Custody and Control Form.

(Slide 31) Where do we go next? The 2010 Federal Custody and Control Form is currently in the proof stage. These are the steps to proceed.

- SAMHSA will begin to craft a Federal Register notice announcing the proposal to revise the current Federal Custody and Control Form. This proposal will include a background, summary, a discussion of the proposed changes, and a proof of the new proposed Federal Custody and Control Form, all pages included.
- This is followed by a 60-day public comment period. At this time, the public will be encouraged to contact SAMHSA with their comments or recommendations. When the comment period is over, SAMHSA will evaluate the public comments and respond to the individual comments. After this process, we will produce a final form format.
- The next step is to publish in the Federal Register a notice of final form and then a submission to OMB for clearance, with an anticipated implementation date of May 1, 2010.

Thank you. That completes my presentation on the 2010 Federal Custody and Control Form. At this time, I would be happy to entertain any questions.

DR. STEPHENSON: Do members of the Drug Testing Advisory Board have any questions at this time?

MS. ROWLAND: Charlie, this is Barbara Rowland. I have a concern. I like the form, but the order of the opiates and the amphetamines is different from on the current form. This seems likely to create potential signing errors for the certifying scientists (CS) because of the different order.

MR. LODICO: Let me go to that particular slide, Barbara. Are you saying that the order should be morphine, codeine…

MS. ROWLAND: It should be codeine, morphine, and 6-MAM, like it currently is.

MR. LODICO: All right. That's wonderful, Barbara. If you can make that as a comment, I think that's a wonderful suggestion.

One of the things that we didn't do is catch everything. That is why it is so important that the public engage in this discussion, commenting on the form once it is published. Those are the kinds of comments that we really appreciate and will be happy to fulfill.

MS. ROWLAND: Thank you. And amphetamines are the same.

MR. LODICO: Right. Can I expect a comment from you, Barbara?

MS. ROWLAND: Sure.

MR. LODICO: Great. When this is published, I want you to submit this comment for the record.

MS. ROWLAND: Okay, I'll be glad to.

DR. STEPHENSON: Are there any other questions from members of the Board?

(No response)

At this time, I want to engage Paul Harris from NRC in dialogue. Have you or any representatives of your agency been participating in this process with us? You are a user of the form as it is. I remember from your presentation yesterday that you don't count yourself as a major player in terms of the number of specimens per year, which is about 150,000 or so per year. You have to consider two different testing groups, one as it relates to those who fall under your Part 26 testing and who work inside the secure footprint area in a fueled facility and two as it relates to those working for construction companies erecting new reactors. As with the DOT-regulated industries, this may become an important exercise that could make your data collection and analysis of testing results much simpler for your tested populations. You may see different patterns of drug use in the contractor-based donors from the construction phase as opposed to those individuals that are employees inside the nuclear facilities. Please consider

engaging in this process with us. We would be glad to talk to you about this.

MR. HARRIS: I appreciate that. There was some discussion that I previously had with Donna regarding this form and the implementation by the licensees. I think our regulations give the licensees an option to either use this form or not use this form. We are researching that also to make it more consistent.

DR. STEPHENSON: Thank you.

DR. BUSH: DOT requires collection of split specimens, and HHS procedures for the Federal agencies are also going to require split specimens. On the 2010 CCF are checkboxes for split or single specimen collections. NRC allows the collection of a single specimen, so that is why this option is still on the form for NRC's recording purposes.

DR. STEPHENSON: Charlie, thank you for a well-constructed and enlightening presentation. Redoing the CCF is a tedious, difficult process. Your analogy to real estate is extremely appropriate, given the limitations on the physical space of the form.

The basic underlying premise here is to coordinate and consolidate standard requirements for the Federal Custody and Control Form. This has led to better training of collection-site personnel, medical review officers, accessioning personnel, and the lab personnel. This will continue. Although the Office of Management and Budget has an oversight responsibility for burden hours and that OMB number is the legitimizer for using that form for directed test collections, OMB also had an interest in that we were consolidating our processes to use a form. They had encouraged us to examine electronic protocols and other formats. This has never come to fruition, even though we had a Federal advisory committee process in the past. The courts and other forensic applications will remain paper-based. Until that changes and there is successful Federal litigation to sustain that, we will be using a paper form, without exception, as an input process for these kinds of specimen collections.

This is a complicated process right now, just with the addition of the IITF and

additional metabolites. This process will become even more complicated as we add point-of-collection testing and alternative specimens because we have to revisit current technologies and opportunities. These modifications to the Custody and Control Form that will be used in 2010 are occurring as a gradual transition. As we look at these other additions occurring over the next two or three years, we must think out of the box or off the paper to the degree that we can.

Charlie, thanks for what you have done. Paul, you are formally invited to participate more proactively.

Jim Swart, are you online?

MR. SWART: Yes, I am here.

DR. STEPHENSON: Okay. These changes to the CCF are still meeting your needs, too. Is that correct?

MR. SWART: Certainly.

DR. STEPHENSON: Thanks.

DR. BUSH: Jim, you are next.

DR. BUSH: Very good. I have asked Jim Swart to provide a presentation on regulated industry urine collection and collection-site procedures. Jim has several great tools prepared by he and his staffers concerning collection-site issues. I really want to give him some time to demonstrate and talk about them.

Regulated Industry Urine Collector/Collection Site Procedures

MR. SWART: Thank you, Donna.

Those of you who are familiar with the HHS program and the content of its Guidelines will note that the Federal agencies are responsible for inspecting the collection sites that they use. The DOT agencies have been concerned with collection-site issues and have the responsibility for inspecting those collection sites used by Federal transportation employers. There are approximately 23,000 collection sites

throughout the United States, which poses a huge obstacle for inspecting all these locations. What we have done in this past year is to increase our emphasis on collection-site creditability. The Government Accounting Office, as well as our DOT agency clandestine inspections of collection sites, has highlighted the need for increased collection-site security and integrity. The most prevalent egregious failures have been:

- Allowing donors to have easy access to a collection site's own adulterant and dilution materials.
- Failing to supervise donors throughout the process.
- Failing to secure water sources.
- Failing to have donors empty their pockets.
- Allowing unauthorized personnel into the collection area, including friends of the donors and coworkers of the donors.
- In some cases, failing to set time limits for urination. In some case, they have allowed 20 to 30 minutes in the toilet area for a person to produce a specimen.

These are egregious mistakes that occur most prevalently at collection site.

This is a real issue for DOT and it is a real issue for HHS. To address these and other collection-site issues, we have created DOT's poster "10 Steps to Collection Site Security and Integrity". This poster has been ordered by and sent to over 24,000 collection sites across the U.S. and Canada. These collection sites collect 6 to 7 million DOT specimens per year and a good number of Federal employee specimens per year.

We have also increased opportunities for DOT inspector training regarding collection sites, including how to review collection sites and how to inspect collection sites. More importantly, the DOT agencies have increased their collection-site inspections. Some DOT agencies have begun and have subsequently increased their clandestine inspections of collection sites. We also have support in Congress for and

are working on civil penalty authority against service agents, including collection sites. DOT agencies now have access to one another's collection-site inspection findings.

Finally, we created a collection-site video that shows collectors and collection-site managers how to make their collection site suitable for DOT collections. The 10 steps poster and this video will be suitable for HHS Federal programs as well.

Could you please start the video?

http://www.dot.gov/ost/dapc/10_Steps_Video_Final/Start.html

(A video was shown.)

MR. SWART: Based on the number of downloads of the video from our web site and what collection trainers, collection-site managers, and even transportation employers have told us, the video has become and should become a main element of collector training efforts and also collection-site inspections and reviews.

I wish to give my appreciation to the two people on my staff who made the video happen. That's Mark Snider and Bohdan Baczara. They did a great job with this.

If you wish to go to our web site, and I urge you to do so, you will see that the 10 steps and the video can be easily downloaded. In addition, you will see the collection-site security and integrity poster, just to the left below the video. The poster can be ordered, in both English and Spanish. There are other things on our web site that allow you to become more familiar with collection-site issues, as well as laboratory issues and issues for drug program managers, employers, and employees.

Thank you for allowing me to show this video to you and talk about the steps for collection-site security and integrity. That concludes my presentation. Are there any questions?

DR. STEPHENSON: Do members of the Drug Testing Advisory Board have any questions of Jim?

DR. NIPPER: This is Henry Nipper. I want to thank you for the video. I'm sure I'll be able to see it again later. It will help us tremendously in other areas than Federal

testing, to ensure people understand how to collect a good urine specimen. Thank you so much for showing that.

MR. SWART: Thank you, Henry, for the compliment.

DR. STEPHENSON: Jim, this was a wonderful presentation. Please consider a split specimen-type clone of this video for Federal agency work.

DOT's 10 steps and the video should be of value to those individuals subject to testing. An individual who is identified for pre-employment or periodic testing could be invited to view that video before they have their drug test, so that they know what to expect.

MR. SWART: In actuality, employers are using this video as part of their employee education program, but also they are determining whether their collection sites comply with Part 40 requirements. Employers are, in many cases, accompanying employees to collection sites and asking for a review of the procedures, whether they have the poster, and whether those collection-site personnel have seen this video. It is paying dividends in many different respects.

DR. STEPHENSON: That's exactly the point. In the Federal agency program, we have received complaints from individuals subject to testing who reported collection sites that were not in compliance. It took a rather circuitous process to get action taken or awareness developed at a level where we could respond.

We need to establish an error-trapping process where an employee or individual being tested provide instantaneous feedback if there is a problem that they encountered at a collection site. A peer-to-peer, as well as a supervisory-down process, would work well to improve quality control issues at collection sites.

Thanks, Jim. We appreciate it very much.

MR. SWART: Thank you.

DR. BOWERS: This is Larry Bowers. I have one other comment. We have done this with the U.S. Anti-Doping Agency for some time. We posted a video on the web

site that is directed to the rights and responsibilities of the person participating in the collection process. If you are thinking about doing an additional video, I would suggest that you take the rights-and-responsibilities approach.

DR. STEPHENSON: It's a good point.

MR. SWART: All right. We will certainly be in contact with you related to that.

DR. STEPHENSON: Your insights would be helpful, especially regarding direct-observation issues. DOT, with your new direct-observe protocols, is mirroring what has happened in the sports testing arena. Perhaps collectively we can have that discussion. Thanks.

MR. SWART: Exactly. I would draw your attention to the direct-observation instruction sheets that we have on our web site, which is located just to the right, below the 10 steps video.

DR. STEPHENSON: Good.

DR. BUSH: Jim, I really want to thank you. You have taken the lead on getting the message out. We wanted to present the video here at our Drug Testing Advisory Board. We wanted to learn from it and move forward with our Federal agency collection site and collector requirements. We will definitely use this as the backbone. Thank you.

If we are finished with that topic, we'll proceed with the agenda.

Gathering Information for Presentation in Open-Session Meetings for Implementing the Revisions to the Mandatory Guidelines

DR. BUSH: When there are Federal processes involved, they take longer to review, evaluate, dissect, and discuss than expected. This Advisory Board is convened under the authority of the Federal Advisory Committee Act, which became law in 1972. It is the legal foundation for defining how Federal committees operate. The law has special emphasis on open meetings, chartering, public involvement, and reporting.

One major change in the revisions to the Mandatory Guidelines addresses

medical review officer training, examination, and certification requirements. Implementing this change to the Guidelines will require that the Division of Workplace Programs in CSAP and the SAMHSA Drug Testing Advisory Board establish an ad hoc working group composed of subject-matter experts from outside of the DTAB membership to supplement the scientific expertise of the Division of Workplace Programs' technical staff and the technical competencies of the DTAB members. The mission of this ad hoc and time-limited medical review officer certification working group will be to discuss this change in the Mandatory Guidelines, to query MRO training and certifying bodies, to obtain information on their programmatic approaches, and inform the DTAB membership and SAMHSA, who are charged with developing the process whereby the Secretary of Health and Human Services will approve the nationally recognized entities who train and credential licensed MDs or DOs (doctors of osteopathy) wishing to serve as medical review officers.

For these initial approvals, these certifying entities must initially submit to the Secretary their application, applicant qualifications, a sample examination, and annually thereafter. The Secretary will perform an objective review of the entity's applicant qualification and examination content and publish the list of approved entities in the Federal Register.

Working with and through our Office of General Counsel and SAMHSA's committee management officer, Bob, as the DTAB chair, and I, as the Designated Federal Official, as well as my team members, have developed the concept of a medical review officer certification-working group. We obtained the signature of our acting agency administrator, Dr. Broderick, who agrees with our approach and concurs that we should convene such a group. We need that additional information and technical expertise in a timely manner so that when DTAB reconvenes, we will have additional information to present to you. The 11 months left to us do not allow us the luxury of convening a meeting, with the Federal Register notice, to discuss the dynamics of

gathering this information. We will promise to you, by the terms and conditions of establishing this working group, that this group will work in an efficient manner. Some members of the Drug Testing Advisory Board, Bob, I, my team members, and some knowledgeable members of the public sector who have expertise in this area will work offline, with the full intention of gathering information to provide to you transparently, in open session, the next time we meet. This working group concept will be utilized for both the medical review officer certification and collector and collection-site issues. In addition to the wisdom and knowledge of DOT, there are others from whom we wish to gather more information. This full complement of information is required to make policy and develop processes that will be effective for us and for the users.

DR. STEPHENSON: This is a complicated process that is time-urgent. These working groups will provide not just the expertise, but also the experience, the data, the protocols, the testing standards, and the training issues. This is the process by which information will be assembled to establish a standard level of consistency and quality that will be part of that certification process provided by the Secretary of HHS.

A side benefit to both of these working groups will be that we may garner some additional insights about revisions to manuals, to guidance documents that would go out.

This working group process will proceed rapidly because of our electronic environment. The MRO and collector certification process must be developed, considered by the full Board in open session, and then presented to OMB, go out for publication, or made available through clearance processes, as an additional set of documentation.

Our work cut out for us. The MRO working group process has been approved. Individuals have been identified and have accepted participation. We will do a similar process for the collection-site issues, too. Soon we should have information to share with you.

Thanks, Donna.

DR. BUSH: Indeed. A presentation is promised for the next Drug Testing Advisory Board meeting.

We will move on to the next item in our agenda, entitled “Update on Expanded Confirmatory Test Technologies,” a presentation by Dr. Jeri Ropero-Miller, of the NLCP staff at Research Triangle International. Jeri?

Update on Expanded Confirmatory Test Technologies

(Slide 1) DR. ROPERO-MILLER: Good morning. This presentation will share with you efforts of the HHS and NLCP to address changes to the Mandatory Guidelines that will expand confirmatory testing technologies (ECTT), as well as assist in an update to the minimally accepted criteria or ECTTs which will be published in the NLCP Manual for Urine Laboratories.

(Slide 2) In the preamble of the revised Mandatory Guidelines, published in the Federal Register in November 2008, there are revisions to allow expanded confirmatory test technologies to include liquid chromatography/mass spectrometry (LC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), and liquid chromatography/tandem mass spectrometry (LC/MS/MS).

Two evaluation projects are currently under way for implementation of expanded confirmatory testing technologies by NLCP for Federally-regulated workplace drug testing. These projects are the focus of this presentation. Project 1 consists of multiple ECTT forums and Project 2 is a comparison study of GC/MS to LC/MS/MS, which includes validation of the LC/MS/MS procedures used in this study.

(Slide 3) The next two slides are the pertinent sections of the November revised Mandatory Guidelines that address the use of expanded confirmatory test technologies. Section 1113 asks what are the requirements for a confirmatory drug test? Requirement A states that the analytical method used must combine chromatographic separation and

mass spectrometric identification and can include the currently accepted use of GC/MS, as well as LC/MS, GC/MS/MS, and LC/MS/MS. Requirement B states that a confirmatory drug test must be validated before the laboratory can use it to test specimens.

(Slide 4) Section 1114 states the requirements for what an HHS-certified laboratory must do to validate a confirmatory drug test. Part A states that an HHS-certified laboratory must demonstrate and document for each confirmatory drug test the linear range of the analysis, the limit of detection, the limit of quantitation, accuracy and precision at cutoff and 40 percent of cutoff, the potential for interfering substances, and the effect of carryover that may occur between aliquots. Part B states that an HHS-certified laboratory must reverify its confirmatory drug test methods periodically or at least annually.

These are the two sections that these projects were dealing with in the revised Mandatory Guidelines. (Slide 5) With these sections, we will move on to Project 1, which involves the expanded confirmatory test technology forums. (Slide 6) The objective of the ECTT forums is to convene stakeholders with MS-MS experience from the field of forensic toxicology to provide comments on issues and minimally accepted criteria for the ECTT. Information gathered in these forums will assist in updating the NLCP manual, which provides information and guidance based on HHS Mandatory Guidelines for Federal workplace drug-testing programs.

There are four planned forums scheduled to be three hours in length. Each will include presentations by the instrument manufacturers, followed by open discussion by all participants. The first forum was convened April 30 with its focus on chromatography. The second forum was held May 7 and covered the MS-MS detector. The third forum was held May 14 and discussed maintenance and validation issues. The fourth forum has yet to be scheduled, but it will be a follow-up to the three previous ones and include a summary of the previous topics to summarize the minimally accepted criteria for

ECTT.

(Slide 7) These forums have over 20 participants and representatives from 5 instrument manufacturers. There are seven NLCP staff members from RTI, including Mike Baylor, John Mitchell, Peter Stout, myself, Susan Crumpton, Jerad Cooper, and Erica Harbison. Federal agency participants include Dr. Donna Bush, Jason Schaff of FBI Laboratories, and Frances Scott of the National Institute of Justice. (Slide 8) In addition, there are 11 experts in the field of forensic toxicology and ECTTs participating in the forums. They include Larry Bowers of the U.S. Anti-Doping Agency, Jennifer Collins of MEDTOX, Tony Costantino of Drug Scan, Denny Crouch of Aegis, Richard Hildebrandt of Toxicology Consulting, Marilyn Huestis of the Intramural Research Program of NIDA, Bram Jones of Alberta Medical Examiner's Office, Rod McCutcheon of the Bexar County Office of the Medical Examiner, Christine Moore of Immunanalysis, Timothy Roberts also of Aegis, and Matthew Slawson of the Center for Human Toxicology. (Slide 9) The MS-MS manufacturers agreeing to provide information and who participated in the forums include Agilent Technologies, Applied Biosystems, Thermo Fisher Scientific, Varion, and Waters Corporation.

(Slide 10) As part of the NLCP Manual for Urine Laboratories published January 1, 2009, GC/MS minimal acceptance criteria for confirmatory testing are described and are currently used by the laboratories. The ECTT forums will assist in determining similar acceptance criteria for the ECTTs. These GC/MS minimal acceptance criteria will serve as a model. I will briefly review them here. The quality of the chromatography is one of the best indicators that a laboratory's procedures are acceptable. Section L8 states that all analytes and internal standard ion peaks should be narrow, Gaussian-shaped, all separated from other ion peaks, and have an acceptable signal-to-noise ratio. However, some peak broadening and tailing will inevitably develop with use of chromatographic columns, and objective criteria must be established to assess whether chromatographic performance continues to be acceptable. For example, percent

skewed allowed symmetry criteria for peak width at half height and tailing/fronting calculated at 10 percent of the peak height are all that can be considered as minimal acceptance criteria. Chromatograms should be evaluated to determine if analyte and internal standard peaks have been adequately resolved from co-eluting peaks. Minimal resolution between adjacent peaks must be at least 90 percent of all ions monitored, that is, 10 percent of the valley-to-peak ratio.

(Slide 11) In Section L-12 of the Manual, the NLCP has adopted the following policies concerning GC/MS minimal acceptance criteria for all quality-control samples and drug-positive specimens:

- First, the chromatography of the ion peaks for analyte and internal standard must meet the laboratory's chromatographic acceptance criteria.
- Second, the retention time of the ion peaks for the analyte and internal standard must meet the laboratory's acceptance criteria. Analyte retention times must be within a time range established from the retention time of a calibrator used for the batch. It is also a common practice to establish the relative retention time criteria.
- Finally, the ion ratios of qualifying ions for analytes and internal standards contained in specimens and quality control (QC) samples must agree within plus or minus 20 percent of the corresponding ion ratios established by the calibration. The ion ratio acceptance range may be based on a single calibrator or an average or weighted average of those calibrators in a multipoint calibration set. The ion ratios of the internal standard are evaluated to ensure that contamination does not interfere with these ions and alter the quantitative results for the compound of interest.

The Manual states that the determination of the ion ratio ranges should be outlined in the Laboratory's standard operating procedures (SOP) and predetermined for each batch. Ion ratios should be uniformly applied to all specimens in the batch, and

a change in the ion ratio requires recalibration and reinjection of all samples in that batch.

(Slide 12) Section L-12 of the Manual states that the relative internal standard of each specimen must be greater than or equal to 50 percent and less than 200 percent of the internal standard area of one or more QC samples. It goes on to say that when a specimen's internal standard is outside the established range, the laboratory should reextract the specimen for the affected analytes. If the internal standard area for the reextracted aliquot is still outside the range, that is, consistent with the first extraction, the Laboratory has demonstrated that the internal standard recovery probably was affected by a factor other than an internal standard addition error, and the Laboratory can report, based on the test result, as it deems forensically defensible.

Finally, Section L-12 describes that the HHS Guidelines do not require blind controls in confirmatory drug test batches. However, if a Laboratory chooses to include blind controls, the Laboratory must apply the same acceptance criteria as it does for open controls.

(Slide 13) Sections L-13 and L-14 address corrective actions. Section L-13 states that if a QC sample or donor specimen fails to satisfy the acceptance criteria, the Laboratory may elect to reinject or reextract the entire batch of specimens or repeat only certain specimens. The SOPs should clearly outline corrective actions to be taken, and the analyst must comply with the procedures to ensure consistent treatment of specimens.

Section L-14 states acceptance criteria for when a specimen quantitates above the carryover limit or exhibits overloaded peaks and how the laboratory should have corrective actions to address potential carryover in the subsequent specimens. The laboratory's SOPs should contain procedures that address the potential for carryover and ensure that carryover does not affect the result reported for a specimen. Unless the Laboratory has demonstrated that carryover did occur, the specimen immediately

following a specimen with a concentration higher than the carryover limit must be reextracted.

These four sections of the Manual complete discussion of the current GC/MS minimal acceptance criteria that the forum and the NLCP will use as a model for determining similar acceptance criteria for LC/MS, GC/MS/MS, and LC/MS/MS.

(Slide 14) Project 2 compares results of urine workplace drug-testing samples with traditional GC/MS analysis to LC/MS/MS. (Slide 15) The primary objective of the project is to explicitly demonstrate that LC/MS/MS as a technology can produce results at least as valid as GC/MS.

First, linearity, precision, and accuracy studies were conducted in urine samples. As part of the evaluation, retention time reproducibility, product ion ratios, and target analyte and internal standard responses were investigated by both technologies.

Second, interference and matrix-effects studies were modeled after the NLCP Manual for Urine. The matrix effects were evaluated both between and within urine lots by LC/MS/MS.

Third, archived, previously confirmed samples were analyzed by both GC/MS and LC/MS/MS. Similar to the LPA studies, retention time reproducibility, product ion ratios, and responses were compared between the two technologies.

(Slide 16) This is the project timeline so far. This project began in August of 2008, with the delivery of a new LC/MS/MS to RTI. In the next six months, method development and sample analysis were performed. In March of this year, RTI submitted a manuscript to the October special issue of the Journal of Analytical Toxicology, which was subsequently accepted for publication. Analytes included in this manuscript included benzoyleconine, morphine, codeine, and 6-acetylmorphine. We are currently working on analyzing the remaining target analytes, including PCP; amphetamine; methamphetamine; and the amphetamine analogues, MDA, MDMA, and MDEA; and also THCA.

(Slide 17) For the validation studies involving linearity, precision, and accuracy, all of these samples were manufactured in human urine. RTI performed 10 replicate analyses by LC/MS/MS and 5 NLCP HHS-certified Laboratories performed 5 replicate analyses by GC/MS. All runs included past proficiency testing (PT) samples as controls. For each target analyte, there were 10 samples, ranging in concentration from 10 percent of the cutoff to 2,000 percent of the cutoff. Morphine, codeine, 6-acetylmorphine, and benzoyleconine were included in these studies. The cutoff concentrations for these four analytes are 2,000, 2,000, 10, and 150 ng/mL, respectively.

(Slide 18) For the interference studies that were performed, the validation samples included the opioids' structural analogues: hydrocodone, hydromorphone, oxycodone, oxymorphone, and norcodeine. The target analytes were added to these validation samples at 40 percent of cutoff, as outlined in the NLCP Manual. Again, RTI performed the LC/MS/MS and the NLCP HHS-certified Laboratories did the GC/MS. Samples 1 and 2 both contained norcodeine at 5,000 ng/mL, and sample 1 also had the target opiate analytes at 40 percent of the cutoff concentration. Samples 3 and 4 had hydrocodone and hydromorphone at 5,000 ng/mL. Again, sample 3 had the target opiate analytes. Finally, samples 5 and 6 had oxycodone and oxymorphone at 5,000 ng/mL, sample 5 also having the opiate target analytes.

(Slide 19) For evaluating the matrix effects of the LC/MS/MS method, RTI chose to follow the Matuszewski methods to validate its LC/MS/MS procedures and investigate the presence of matrix effects. Matrix effects were only a part of the RTI validation of the LC/MS/MS. For matrix-effects studies, 10 different lots of urine were used so that we could look at the relative matrix effects from urine to urine sample and from different standard lots.

There are three types of matrix-effects samples. First, pre-extraction spikes, labeled as type C samples by Matuszewski et al., were made by fortifying negative urine

matrix with target analytes and internal standards prior to solid-phase extraction. Target analytes were spiked at cutoff concentrations. Next, post-extraction spikes, labeled as type B samples by Matuszewski, were made by fortifying the eluent from the solid-phase extraction of negative urine matrix with target analytes and internal standards. Lastly, a neat and mobile phase, labeled as type A samples by Matuszewski et al., was made by comparing an equivalent amount of target analyte and internal standard into the mobile phase and then added to the auto-sampler vials. All three of these samples were analyzed by LC/MS/MS to look at matrix effects. For this validation, the matrix effect measures the absolute matrix effects of the LC/MS/MS response, the detector performance in chromatography. A ratio of sample B to A multiplied by 100 evaluates the matrix effect. A value greater than 100 percent would indicate possible ionization enhancement, while a value less than 100 percent indicates ion suppression. The extraction efficiency is calculated by the ratio of sample C to sample B and then converted to percentage. This is a true recovery, that is, free of matrix-effects contributions. It should approach 100 percent, but not exceed it, to demonstrate good recovery of the analyte. The overall process efficiency can be obtained by multiplying the absolute matrix effect and the recovery, that is, the ratio of sample C to sample A, which is then converted to a percentage. The higher the number, the greater the presence of a matrix effect.

(Slide 20) This slide depicts the LC/MS/MS ions that we chose for our method, including the precursor and the product ions, and codeine and its trideuterated internal standard, morphine and its trideuterated internal standard, 6-acetylmorphine, and benzoyleconine. Benzoyleconine and all internal standards did not have a third-product ion monitors.

(Slide 21) This slide depicts representative chromatography and the ions that were used using calibrators at cutoff concentrations. Since 6-acetylmorphine is the one of lowest concentration, the chromatogram was enlarged to show the response and

prove that it is acceptable by the current GC/MS minimally accepted criteria.

(Slide 22) Other criteria RTI is investigating as part of the validation process include qualifier ions and retention times for the manufactured linearity, precision, and analysis samples. Each target analyte had100 analyses performed. In the next two columns are listed the average target qualifying ratio and their respective percent CVs, which range from approximately 1 percent to 11.6 percent. 6-acetylmorphine had the highest percent CV. Similarly, in the next two columns, the average internal standard qualifier ratios and their respective CVs are shown. Again, the range for the percent CVs is 1 to 7.5%, with 6-acetylmorphine having the highest percent CV. From the average target retention times and percent CVs, the percent CVs for the target retention times do not go above the 1.78% for codeine. Finally, from the average internal standard retention times and percent CVs, codeine had the highest percent CV at 1.99%.

(Slide 23) The accuracy and precision of GC/MS and LC/MS/MS results were similar. The linear range of LC/MS/MS using a five-point calibration was broader than for GC/MS. Finally, no significant interferences were determined by investigated opioids' structural analogues, including norcodeine, hydrocodone, hydromorphone, oxycodone, and oxymorphone.

(Slide 24) For the final LC/MS/MS validation study, RTI and one selected NLCP HHS-certified Laboratory analyzed archived, previously confirmed positive urine samples by LC/MS/MS and GC/MS, respectively. The number of samples analyzed for each target ranged from 5 for the 6-acetylmorphine to 60 for the benzoyleconine. The r^2 value gives the correlation of GC/MS to LC/MS/MS using linear regression analysis. The next column gives the regression slope. Unity slope means both technologies gave the same quantitative results. All are at unity except codeine. This is probably due to the hydrolysis step used for the LC/MS/MS here at RTI, which may be more efficient because pressurization or the autoclave is employed to achieve the desired

temperature. We also had a longer hydrolysis time. However, we could not verify this because, while all of our runs included a morphine hydrolysis control,none of the runs included a codeine hydrolysis control. T-test values greater than 0.05 indicate no significant difference between the regression analysis of GC/MS and LC/MS/MS.

For codeine and morphine, there are significant differences in the regression of the two technologies, again most likely due to the hydrolysis technique employed by RTI. Also, there was more of a spread in the codeine results. This may be because some individuals are good glucuronidators and others not so much.

The LC/MS/MS ion ratios and retention times, shown in the last four columns, were similar to the manufactured samples previously shown in this presentation.

(Slide 25) Where do we go from here? In summary, in preparation for inclusion of expanded confirmatory test technologies in the revised Mandatory Guidelines, effective May 1, 2010, we will complete GC/MS and LC/MS/MS validation comparisons for PCP, amphetamine, and THCA, as well as convene the final ECTT forum. We will prepare an update to the NLCP Manual for Federally-regulated workplace drug testing Laboratories and inspectors, with the inclusion of ECTT minimally acceptable criteria, review comments, and finalize the revised NLCP Manual in preparation for May 1, 2010 and beyond.

Thank you for your time.

DR. STEPHENSON: Any questions from members of the Board?

MR. COOPER: There are several in the chat pod from Dr. James Bourland which I will read aloud. Dr. Bourland, thank you for your questions.

The first question from Dr. Bourland is: Was GC/GC/MS ever considered or would it be considered GC/MS?

DR. BUSH: And he is looking at the term “GC/GC/MS.”

DR. BOURLAND: Is that going to be an acceptable technology for a regulated laboratory? I’m just curious.

DR. ROPERO-MILLER: It will be considered, and it is being used now. It was not specifically mentioned in the revised Mandatory Guidelines. Therefore, I did not put it in the slides.

DR. BOURLAND: That's great, Jeri. I just wasn't aware that it was because I hadn't inspected a lab that was using it.

I have another question for Jeri. Jeri, I see the CVs that were established. Has the forum come to any kind of consensus on specific ion acceptance criteria based on the data that you have generated experimentally?

DR. ROPERO-MILLER: No. The members have seen the data, but since we have not yet held the fourth forum, we have not made any final decisions.

DR. BOURLAND: Thanks.

DR. BUSH: Jim, this is Donna Bush. There was much discussion about those acceptance criteria. Since we had so many different people different experiences with different applications of those varying technologies, everybody saw a different possible need, depending on their background. Thus, the discussion goes on.

DR. STEPHENSON: This is one aspect of the process that makes this a living program. It is not only important to do this now because of the availability of the new technologies, but this also helps set the stage for some of the standards issues we must address with alternative specimens. Different kinds of technologies will be necessary to get the required precision for future work. Though that could be a year or two from now, if we don't set the standards now and begin to look at this proactively, we will have some serious limitations to what we really, in fact, can do.

We ought to be amazed at the level of technology and the amount of precision we are able to achieve at this point in our scientific ventures. I'm glad that we are having these kinds of discussions and assessments; it is absolutely essential. All of the screening technologies aside, it is the confirmation issues and how to interpret the results that are the heart of what we all do.

MR. COOPER: There was one more question from Dr. Bourland. He asked, was it necessary to have two forum participants from the same private company? Dr. Miller, I think I know the answer, but I'll defer that to you.

DR. BAYLOR: This is Mike Baylor at RTI. The direct answer to that question is, no, there wasn't a necessity. As other committees were approached, such as the SOFT committee, and as individuals were appointed to succeed John Cody in the SOFT technical committee, the affiliation of such members took a different direction. The SOFT committee was represented and participated, as well as the American Academy of Forensic Sciences, Toxicology Section and members from the NLCP.

DR. BOURLAND: I understand the history behind that. I appreciate that, Mike. Thanks.

DR. STEPHENSON: Are there any other questions from the Board?

MR. CROUCH: Bob, this is Denny Crouch. Can I respond to the last question? I assembled the SOFT committee. Those were people that, one, volunteered and, two, had the time and were committed to be a part of the committee and fulfill the requirements and responsibilities. Then, we were invited to participate with the NLCP committee. I don't know if we are formally members of the NLCP committee, unless RTI deems us so. We functioned more as observers, but we could comment, et cetera. Anybody who is a member of the SOFT committee is my responsibility and not RTI's or SAMHSA's or NLCP's.

DR. BAYLOR: Right. The SOFT (Society of Forensic Toxicologists) committee was involved as a separate entity.

DR. BUSH: Dr. Marilyn Huestis is at the National Institute on Drug Abuse (NIDA) Addiction Research Center. She is researcher on many and varied projects using these technologies. Larry Bowers of the World Anti-Doping Association is using these technologies for sports drug testing. At SAMHSA, we are looking at workplace drug testing. The Society of Forensic Toxicology is also examining the application of these

technologies to the analysis of solid evidentiary materials, such as drug bust material, as well as looking at analysis of tissues for various drugs. These are just a few of possible applications for these technologies.

We are trying to keep an open mind. Different applications may not be able to accept the same standards. With the NLCP, we are fortunate to have nice, clean, yellow urine as a matrix. For many people in the Society of Forensic Toxicology, their applications may involve tissue extracts that are quite so clean because of co-extractants.

Though this is an open session, you need to hear the technological aspects required to set these standards. Many heads must come together for hours of discussion to make some hard decisions.

Thank you.

DR. STEPHENSON: Do we have any other questions in the chat pod?

DR. BOURLAND: This is Jim Bourland. For the record, I did withdraw that question. It was just an observation that I did not expect to be read.

DR. STEPHENSON: That's okay. These are the kinds of issues that would happen in a real room anyway.

Let's proceed with DTAB panel discussion. Are there any issues that members of the DTAB want to discuss, either related to the issues raised this morning or any other issues that they believe are necessary for this meeting?

DTAB Panel Discussion

DR. COLLINS: This is Jennifer Collins. I have a comment and then a question, which are both related to the additional technologies.

My comment is that I had an opportunity to sit in on the forum, and I have to applaud the approach. By bringing that many people from many different areas together, I think we all benefited from the excellent information that was presented. I

found that the different perspectives were very valuable. Because I work in a urine drug-testing laboratory, you sometimes don't think about the many different ways that other people apply the same technologies. Given the fact that we had representatives from different manufacturers, I think it was remarkably free of bias. People were really focusing on the science and trying to provide information. For me, it was really an excellent experience.

My question is concerning the data that Jeri presented from the perspective of proficiency testing and as laboratories incorporate different technologies. In terms of evaluating those results, might you expect that the coefficients of variation (CVs) to be different because you are evaluating not just GC/MS data, but different technologies as well? For those of us who participate in the College of American Pathologists (CAP) proficiency testing program, they will often present the results in a number of different ways. They might give an overall mean and then look at the mean results by specific methodologies. Are you thinking at all about that issue?

DR. MITCHELL: This is John Mitchell. Yes, we have thought about that. We are well aware of the process that has been used in CAP in the past. That's why we are doing this preliminary work with the LC/MS/MS, to determine what the difference is between the two testing methods. Currently, there doesn't appear to be much difference. I was expecting more variance in the LC/MS/MS than I was in GC/MS, but I haven't really seen that much more. We will just have to wait and see.

One of the problems with separating them out is associated with some of the requirements of grading that are currently in the Guidelines. We will have to play that by ear as we proceed with the implementation of these particular technologies.

DR. STEPHENSON: Thank you very much. Are there any other questions or comments that members of the Board have at this time?

DR. TURK: This is Bob Turk. I have a question about the IITF. If the IITF has a presumptive positive for cocaine on its initial screen and they send it to the Laboratory,

which determines a negative for cocaine but a positive for THC, how is that going to be reported? How are we going to handle that?

DR. BAYLOR: This is Mike Baylor of RTI. I think we briefly covered that yesterday in the IITF presentation. We will be examining the correlation between the forwarded specimens from an IITF and what is reported from a certified Laboratory. We will be studying the forwarded specimen lists from the IITFs, and we will have identifiers that will allow us to look for those results from the certified Laboratories that these forwarded specimens are sent to.

That specimen would be reported as negative. It was a presumptive positive at an IITF that was forwarded on for testing at a certified Laboratory.

DR. TURK: Mike, it was a presumptive positive for cocaine, but the certified Laboratory found a positive for THC and a negative for cocaine. It still would go out as a negative?

DR. BAYLOR: That would go out as a negative for cocaine, but it would go out as positive for THC.

DR. TURK: Although the initial screen was negative for THC?

DR. BAYLOR: If the certified Laboratory indicates the confirmed presence of a drug or metabolite, with initial testing and confirmation testing, it would be correctly reported as a positive result from the certified Laboratory. The Laboratory won't know what it was positive for at the IITF.

DR. TURK: Okay, thank you.

DR. STEPHENSON: Are there any other questions?

DR. BOWERS: This is Larry Bowers. I just want to ask if we would have access to the slides from the presentations today. I noticed they weren't on mine download bar. At least on mine, I was still looking at the presentations from yesterday.

DR. STEPHENSON: For members of the Board, I have no problem with this being made available at this time. Hopefully, you won't have problems with animation

lag and so on. For public release, documents must be made 508 compliant, which is a different process.

DR. BUSH: Larry, we'll check again. I believe those presentations went out in an email yesterday. We'll double-check to make sure you get them.

DR. BAYLOR: Larry, they were sent out last night. Please let us know if you didn't get it. It was sent as an email, with an email attachment, at about 1:35 p.m. yesterday afternoon.

DR. BOWERS: It does not appear that I got that one. Sorry.

MS. HARBISON: I'll go ahead and send it to you now, just to be sure.

DR. BOWERS: Thank you.

DR. STEPHENSON: Thanks for asking the question. We'll send it back out again. Are there any other questions?

MR. COOPER: Barbara, do we have you on the phone?

MS. ROWLAND: Yes. I just want to make a comment about what Bob Turk said. He is raising the issue about what if the IITF had a valid negative result on one drug, maybe just right below the cutoff, and then the confirmatory lab had a positive result right above the cutoff. Do we send that second drug on for confirmation, even though the valid negative was in the IITF? I see his concern on that.

DR. STEPHENSON: We'll log your question and consider that as part of our process for evaluation. This is going to have to be dealt with, both in the theoretical world and in the real world, as we go forward.

MS. ROWLAND: Thanks, Bob.

DR. TURK: Thanks, Barbara, for clarifying that.

MR. COOPER: William Linn has raised his hand. William, do you have a question? You can unmute yourself by pressing *6, and we'll be able to hear you.

DR. LINN: Thank you. I just have a quick question for Jeri. Do you anticipate that there is going to be any problem with finding three product ions for the native drug in all

the instances?

DR. ROPERO-MILLER: The requirement for three ions has not been established. Since we entered into this before the forums had met, based on our method development, we went with the ions that were best to use, to see if it was possible.

DR. LINN: Just a question at this point. Thanks.

DR. BOURLAND: Jeri, when you say three ions, do you mean one precursor and two product ions or are you talking about one precursor and three product ions?

DR. ROPERO-MILLER: All of them had at least one product and two precursors. There was a third precursor that we looked at for all of the opiates. We did not look at a third precursor for benzoyleconine or any of the internal standards.

DR. BOURLAND: I just wanted you to clarify what you meant by three ions. Thanks.

DR. STEPHENSON: We have, if not exhausted, then completed the questions of interest from the Board. We have not received any questions from on site members.

(Pause)

At this time, Donna will give the instructions regarding the timing and the order of public comments.

Public Comment

DR. BUSH: We have received three requests for public comments. Our first request for public comment was received from Mr. Robert Bard, the second request was received from N.B. Varlotta, and the third from Eric Quilter. Mr. Bard is availble on the telephone, but he is not logged in. N.B. Varlotta is online. Eric Quilter is here on site. I would like to extend no more than 10 minutes to each of those individuals to make their public comments.

MR. COOPER: Mr. Bard, do we have you on the line?

MR. BARD: Yes, I'm on the line now.

MR. COOPER: Please go ahead with your public comment.

MR. BARD: Mine is a general comment to the overall two days. I apologize if this comment seems out of order.

This is very much a meeting specific to urinalysis. There is an obvious need for alternative matrices. With the continuing discussion and not opening it up to alternative matrices, there is a stifling of development, scientific involvement, and the use of companies out there that could be looking at improving methodologies. But as long as the agencies involved won't accept additional matrices, my question is, why would anybody spend any time on it, and why won't any of the agencies look at alternative matrices at this time?

Thank you.

DR. STEPHENSON: The question that you have raised has been addressed in the publication of the Mandatory Guidelines last November. It's not a question of "won't" but a question of "when". Underlying concerns were raised both by public commenters and by Federal agencies in the internal review process. Any government regulation or final rule that we publish in the Federal Register must go through as a pre-clearance process. Thus, we had to focus on those parts in which there was sufficient agreement and consensus so that we could ensure clearance through the Office of Management and Budget. With Administration changes, there is a time when the door for approval closes. The clock then needs to be reset, resulting either in resubmission or reevaluation by a different Administration as they come into operational capacity. We believed that we had met the standards for the enhancements to the urine program to proceed. In the preamble to the Mandatory Guidelines, there was a declaration of intent to proceed. Given the urgent nature of what we must complete, implement, and have available by the first of May of 2010, we must focus the resources of both the staff and our contractor and of the DTAB, at least through the end of this calendar year, on the Mandatory Guideline changes. Because this is an executive call, it is a priority and one

that I am going to support. It doesn't mean that we are not going to move forward. I hope, in some way, that answers your question.

MR. BARD: Yes. I have a follow-on to that. Understanding that you are going to go for this calendar year, do you have a plan to initiate a working group of potential laboratories that would work with alternative matrices, manufacturers of equipment, and then any agency personnel? Is that a possible plan after this calendar year or during this calendar year or maybe just a future concept?

DR. STEPHENSON: Our intention is to publish a request for information from the public. When we do, individuals can submit what they know and what they have to offer. We need updates on both alternative specimens and the technologies that are related to them before we could reformulate. We have work we need to do inside the government. Our contractor must perform quality assurance testing and provide proficiency specimens for the alternative specimens that are consistent with the technologies. There will be future Drug Testing Advisory Board activities focused on these issues, perhaps including working groups, which will be developed in a transparent manner.

MR. BARD: Can you say whether or not there is a timeframe for that? Is that this year or next year?

DR. STEPHENSON: Through the end of this calendar year, we will not focus on anything beyond what we need to do to implement the urine-testing guidelines. What we do at the beginning of the next year will depend on how well we have met our timelines to get this work done. Our next stage is to publish a request for information on the alternative technologies.

MR. BARD: Thank you for those comments.

DR. STEPHENSON: Does that conclude your comment?

MR. BARD: Yes.

DR. STEPHENSON: Thank you.

DR. BUSH: The next commenter will be N.B. Varlotta.

MS. VARLOTTA: Hello. This is N.B. Varlotta speaking. I would like to know when the notice in the Federal Register will be available for the Custody and Control Form? When is that anticipated to be posted?

MR. LODICO: The anticipated process, as I stated in my presentation, is that at this moment SAMHSA is crafting the language to be posted for the proposed CCF in the Federal Register. After posting, you and the public will have an important opportunity to provide comments and recommendations. It is anticipated that the posting will occur within the next month to month and a half.

MS. VARLOTTA: Thank you very much. Is there any consideration for the indication of specimen validity testing that will be required in the process on that form?

DR. BUSH: N.B., the requirements and the details concerning specimen validity testing are contained in the Mandatory Guidelines themselves.

MS. VARLOTTA: I understand that. However, as an individual, I would like to make certain that every person that is tested knows that they are being tested for pH, creatinine, nitrites, and specific gravity. It should be put on the form.

DR. BUSH: Then I would suggest that you make public comment concerning that when this Federal Register notice is published.

MS. VARLOTTA: I guess this has not been considered at this time.

MR. LODICO: Ma'am, on the results section of the Custody and Control Form, the Laboratories are instructed to quantify any adulterated specimens. Also, there is a line on the remarks line which will allow the Laboratories to state any invalid results, such as low pH, high pH, the creatinine values, and specific gravity values.

MS. VARLOTTA: Thank you, Mr. LoDico. However, the donor is unaware that they are being tested for something like this.

DR. STEPHENSON: You are certainly welcome to continue with your public comment. As for engaging in questions and answers on this, as Mr. LoDico indicated,

you are welcome to make a public comment submission when it is posted for public-comment purposes.

MS. VARLOTTA: Thank you very much. I certainly will do so. I appreciate your time.

DR. BUSH: Mr. Eric Quilter is here.

MR. QUILTER: My name is Eric Quilter. I am the president of Compliance Information Systems and a past participant in the form-development process, as well as the working groups for electronic initiatives for federal drug testing. My company provides software, data-management imaging, and data storage services for the drug-testing industry.

First, I would like to compliment the Board and SAMHSA's continued efforts to improve the workplace drug-testing process. I have been involved in it a long time, as all of you have, and it is good to see it move forward. It is in this spirit that I would like to present my comments to the Board.

My comments pertain to the existing Federal Custody and Control Form and the current effort to revise the Federal form. You might be surprised to hear that, despite the fact that my company is hired by industry service providers to provide information technology solutions, I agree wholeheartedly with Bob Stephenson's earlier statement that a paper Custody and Control Form is still the best practice for our industry, for numerous reasons. I would like to suggest to the Board, however, the Federal testing programs could benefit from the current industry trend towards generating paper Custody and Control Forms at the collection site using software, laser or inkjet printers; barcode scanners; and signature-capture devices that also capture standard ink signatures. The vast majority of these transactions being conducted are non-Federal, laboratory-based urine testing and still rely on a paper Custody and Control Form with collector and donor signatures. While there are differences in the software systems being used, the initiatives share a common objective, which is to improve the integrity

and efficiency of the overall process.

Enough practical experience with these transactions, which now number in the thousands every single day, has been gained to achieve very measurable results. Those results include dramatically reduced collection-site errors, laboratory data-entry error reduction, improved reporting and distribution of information, and much reduced waste.

The software-driven collection processes provide these results because, one, they enforce procedure much better than a paper form by itself does. Visual instruction, like we saw earlier today in the video provided by DOT, can actually be incorporated into the collector's work environment on a day-to-day basis. Indeed, numerous software programs being used do this. They actually have a video presentation of collector procedure. It is very helpful for collectors that may not conduct a procedure very frequently.

They enforce training and qualifications. Software makes it far easier than paper processes to monitor individual collector and collection-site performance. This is a key concern of the DOT-regulated programs, the NRC-regulated programs, and the private-sector drug-testing programs. The performance of the collection site is always foremost in their minds, and software systems have really provided a huge benefit for doing that.

They improve the acquisition, management, and protection of donor demographic information, employer information, MRO information, and testing instructions. I am just going to run through a few quick examples that all will be familiar with who are familiar with drug testing.

For example, if an employer changes their medical review officer, all forms previously distributed must be discarded and replaced. When that doesn't happen -- and it doesn't happen on a frequent basis, in a timely enough fashion -- the verification process is delayed, as well as the results-reporting process being delayed. Those have safety implications, which is a key objective of this program.

Another example: A medical review officer changes their fax number. All forms previously distributed have to be discarded and replaced. When that doesn't happen, Copy 2 ends up getting faxed to places like Henry's Dry Cleaning. And it happens every day. So we have a serious concern with the privacy of the donor information being routed to the wrong place.

Another example: An employer can provide an electronic order using these new systems to the collection site. It makes sure that all the required information for the donor arrives at the collection site intact, especially the operating administration information for DOT testing or the Federal-authority designation for that particular test, and ensures that the right procedure and the right paperwork is used. This definitely decreases the paperwork burden currently associated with the Federal form, which is obviously a government initiative under the Paperwork Reduction Act and the ESIGN Act.

The demographic data from the collection site can be delivered to the laboratory LIS, the laboratory information system, electronically. The lab knows exactly how many samples are coming their way, what procedures are to be conducted on those samples, and less data entry has to occur on those samples when they come in. More accurate data gathering occurs, which again reduces their burden of using the form itself and increases the integrity of the event.

Those are just four quick examples -- and the list is very, very long -- on what we have learned through practical implementation of these. It is no longer theory; it is in practice. It is a process that has been used for several years now.

Laboratories and their owned and contracted collection sites are rapidly adopting this approved approach to manage the collection process and the custody and control form. Many collection sites now have the infrastructure required to support this type of technology, and the number is growing every single day. Unfortunately, collection sites have been reluctant to use these new tools for Federal testing programs because of the

assumption that a five-part form can only be produced using a heavy-duty impact printer. There are five parts to the Federal form that everyone is used to, because that form, the basic shape, has been around for 20 years now. You have to use a very heavy-gauge piece of equipment to go through all five parts.

I would like to suggest, however, to the Board that it explore, acknowledge, and take advantage of the proliferation of the information technology at collection sites currently that allows the Federal form to be produced in a more on-demand fashion. Even today many sites have the technical capability to produce a Federal custody and control form with a wet-ink donor and collector signature and produce identical copies for the donor, employer, and collection sites. Better still, it allows those copies to be distributed with far, far greater efficacy than their current paper counterparts which rely on physical distribution.

The most dramatic difficulties in this model have to do with the text that is on the back of the current five-part form, the Privacy Act statement, the Public Burden Statement for the Paperwork Reduction Act, and the collector instructions. These items can easily be addressed through simple formatting of the printed documents that come out of a laser printer or on-screen presentation. It is not a big leap to go that far, and it is not necessarily essential to the forensic nature of the collection event itself.

While not all sites can do this, those that have the capability should be allowed to do so, provided the custody and control form produced meets current and future HHS requirements. Those future requirements could further reduce the burden of the form by formatting options that can be even friendlier to collection-site form generation, such as finding ways to get the information in a laser-printed form. You can actually end up with a single piece of paper being produced for both Copy 1 and Copy 2, as opposed to two pieces of paper.

I actually brought an example. Most of the non-Federal testing is going to the laboratory on less than an 8.5-by-11 chain-of-custody form, with the wet-ink signatures

on it. Again, it's just because a laser printer can produce much smaller text in a far cleaner and more legible fashion than can a handwritten form.

Not only would the quality of Federal tests being collected in this fashion improve, but more collection sites would be willing to perform federal tests. An increasing number of collection sites are opting to not provide Federal collections or charging higher fees because paperwork issues remain unchanged, while the paperwork and recordkeeping requirements for non-Federal testing become more and more automated. It has created a gulf and a gap, both procedurally and economically, for the key service providers in our industry – that is the collection sites - and the hardest to regulate.

In addition, I would like to suggest that the Board reconsider its assumptions about the how the custody and control form is used today, specifically its use as a resulting document. It is our experience in working with so many of the industry providers out there that very rarely is this form currently used as a results reporting document. Results, at least for practical purposes, whether from the Laboratory or the final disposition from the MRO, must be transcribed on the form manually from far more reliable and accurate recordkeeping systems.

The time is long overdue to consider how the form is used in today's technology environment and make the necessary adaptations in these decisions with the forms committees, going forward.

Thank you.

DR. BUSH: Thank you, Mr. Quilter.

DR. STEPHENSON: Thank you for your comments. They are received with open minds and with an expectation that some of the issues you have addressed will certainly be a part of future discussions.

At this time, are there any other issues from the members of the Board or those at the table that need to be discussed?

(No response)

Donna?

DR. BUSH: At this time, I would like to close this open session of the Drug Testing Advisory Board. I look forward to seeing you next time. Thank you.

DR. STEPHENSON: Thank you very much for your participation.

(Whereupon, at 1:00 p.m., the meeting was adjourned.)