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Substance Abuse and Mental Health Services Administration (SAMHSA)
Center for Substance Abuse Prevention (CSAP)

Drug Testing Advisory Board
Meeting

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VTC Conference Room
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PROCEEDINGS

Welcome and Introductions

Dr. Cook: Good morning. I am Janine Cook, the Designated Federal Official (DFO) for the Drug Testing Advisory Board (DTAB). As a DFO of DTAB, I officially call this meeting to order. The meeting is scheduled to convene from 10:00 a.m. to 3:30 p.m. today. We do have an hour break scheduled from noon to 1:00 p.m. today, but the actual break time and ending time will depend on how we progress through the agenda.

The DTAB has its own website located at the link shown here on the slide. Posted on the DTAB website are the DTAB charter, the roster of Board members, and meeting information, including past, present, and future meetings. Dates for the fiscal year (FY) 2016 DTAB meetings will be posted within the next month or two.

You may use the Q&A pod on Adobe Connect to submit your questions. Submitted questions and comments will be considered by the Board during closed session. The public comment period is scheduled to begin at 3:00 p.m. today, although the exact time will be dependent on our progression through the agenda. Currently, no one has registered to give public comments. If anyone wishes to give public comment and has not registered, notify the Verizon operator by pressing star one. The public comment period is restricted to the time allotted, and the time will be equally distributed among the commenters. Public comments will be included in the meeting minutes as well as in the transcript. If possible, please provide an electronic copy of your comments to be shared with the transcriptionist to ensure that your comments are recorded accurately. The Board will not be responding to public comment at this time but will take them under consideration in closed session.

Guests are participating in listen only mode. If you need to contact the Verizon operator, please do so by pressing star one. You may either listen through Adobe Connect using your computer speakers or listen using your phone. If you use your phone, you must mute your computer speakers to avoid audio feedback. You may also want to mute your phone unless speaking if you anticipate any noise in the background.

For those Board members and speakers participating remotely, also please silence your electronic devices because these will interfere with both the audio/visual and well as with the transcription equipment. This statement will also apply to public commenters during the public comment period today.

I want to welcome our DTAB Board members: Jennifer Collins, Tony Costantino, Jim Ferguson, Ron Flegel, Greg Grinstead, Marilyn Huestis, Denise Johnson-Lyles, Patrice Kelly, Susie Mills, Madeline Montgomery, Christine Moore, Buddha Paul, and Jasbir Singh.

I also want to recognize our Division of Workplace Programs (DWP) staff: Ron Flegel, Sean Belouin, Jennifer Fan, Deborah Galvin, Gene Hayes, Giselle Hersh, Charlie LoDico, Colleen Sanderson, Hyden Shen, and our intern, Ana Donovan.

We treasure the relationship between the Board, the DWP, and our federal partners. The distinguished federal partners that I want to recognize include Paul Harris from the Nuclear Regulatory Commission (NRC), Tom Martin from the Department of Defense (DoD), and Ian Rucker from HHS Department of Office General Counsel (OGC).

The dates for the remaining FY 15 meeting are August 6-7, which is currently scheduled to convene face-to-face at SAMHSA. Whether that August meeting will convene in open or closed session will be decided once the agenda is finalized.

The following disclaimer, which I will read verbatim, applies to the remaining presentations. "Today's presentations do not reflect the views of HHS or SAMHSA, nor do they constitute an endorsement of the presenter, the presenter's views, the presentation's subject matter, the organizations mentioned during the presentation, and other entities, methods, products, and information referenced during the presentations."

There will be one change to today's agenda. Charlie LoDico will be presenting instead of Gene Hayes.

Before Ron Flegel, the Director of the DWP extends his warm welcome, I would like to present the results of an informal poll I conducted. I was curious as to whether the members of the Board could relate to donors who are subject to drug testing. I asked them anonymously to tell me about the drug testing that is performed in their workplace. I was very surprised to learn that of the 13 members, all but one work in an organization where drug testing is required. Besides asking them if their workplace did drug testing, I asked if all employees were in the drug testing pool. As you can see, 7 out of the 12 workplaces who offer drug testing require all employees to be tested. Next, I asked them for the reason for drug testing. Two of those 12 workplaces that perform drug testing test for all the reasons that are stated in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG). Another five workplaces test for pre-employment and reasonable suspicion; they vary as to whether they do random and post-accident testing. We have another group of five workplaces in which testing is performed for all the testing reasons but only for select testing designated positions.

I want to welcome Ron Flegel, the Director of the DWP, who will now give his opening remarks.

Opening Remarks

Mr. Flegel: Thank you, Janine. The poll was very informative. I appreciate the Board members who provided that information.

I would like to first welcome the Board members, federal partners, the ex officios who sit on the Board, invited guests who are present, and everyone from the public. Thank you for being here and taking the time with us this morning.

I did want to give some updates. There has been much happening within DWP, especially over the last month. The Request for Information (RFI) was published in the Federal Register (FR) less than a month ago. We have received some comments back on the RFI. Additionally, we have received requests from several entities seeking an extension of the comment period for an additional 30 days. We are currently in the process of extending the comment period. Hopefully, we should see that extension published by next week. Please look at the RFI and make your comments. We will consolidate all the comments for the Board members at our next meeting.

Additionally, the proposed MGs for oral fluid and urine were published in the FR with public comment periods that will end on July 14th. We have received comments on both of these proposed MGs. The public can visit the website and view the submitted comments and submit their own. As we receive public comments, we will consolidate those into categories and present them to the DTAB at the August meeting.

For the public's knowledge, the process for comments involves the receipt of the comments by DWP and consolidation of the comments. DWP will address all comments, including whether those comments were accepted or rejected, in the preamble of the final MGs. The draft final MGs are subject to an internal review process involving federal agencies and the Office of Management and Budget (OMB). All internal comments are returned to DWP to be addressed and then forwarded to the Administrator for hopefully final approval. I cannot provide an exact timeline for this process but can only offer when the public comment period will end. Once it does end, it will take some time to consolidate and write responds to all the comments. From that point, the MGs will be published in the FR as a final with a final implementation date.

For both the MGs for oral fluid and urine, we built in consistency between the two documents to ensure that sections are designated similarly. Section 3.2 in the urine MG will cover the same topic as Section 3.2 of the oral fluid MG. If there is a comment that you have on one matrix, it may also pertain to the other matrix. If so, make sure the comment is reflected in both documents.

I did want to provide a very brief update on the research studies performed to date. We have concluded a marijuana passive exposure study, and the results have been published as journal articles and given as professional society presentations. There will be many, many more presentations in the future, not only with federal agencies also but at public meetings regarding this study. In addition, we are concluding an oral ingestion study for marijuana which focuses on marijuana edibles, i.e., brownies. There are a number of findings from this study that the public, as well as other federal agencies, law enforcement, etc., will be very interested in learning as well. There are a number of synthetic opiate studies that we have also concluded.

Those results have been published in technical and scientific journals and will be presented at the Society of Forensic Toxicology (SOFT) meeting in 2015.

I also wanted to acknowledge a DWP initiative - Drugs in the 21st Century: Making the Science Actionable. With that, there will be a number of initiatives to come, including the MGs and where policy, regulatory, etc. issues are headed in the future.

With that, I conclude.

Public Comments to the Request for Information on Hair

Dr. Cook: Thank you, Ron. As Ron mentioned, three FR Notices (FRN) have been published. Today, besides reviewing the public comments received to date on the hair RFI, I will also review the comments received on both the urine and oral fluid proposed MGs.

The FRN announcing HHS's proposal to revise the MG for urine was published on May 15th. Public comments will be accepted until July 14th, 2015, making it a 60-day comment period. I have provided, at the bottom of the slide, the link for submitting public comments.

For both the proposed oral fluid and urine MGs, the Department has requested comments on any part of the notice. They also specifically targeted certain sections on which they requested the public to comment. For urine, this includes Section 3.4, which contains the table of the proposed new analytes: oxycodone, oxymorphone, hydrocodone, and hydromorphone and their proposed cutoff concentrations. Section 3.1 addresses medical review officer (MRO) qualifications, training, and re-examinations. The Department targeted questions on continuing education units, the optimum number of credits, and accrediting bodies.

As of Wednesday evening, seven comments were received. One commenter disagreed with urine testing unless that test is an observed collection because suspected substitution. One person agrees with adding the synthetic opiates. One agrees with MRO recertification occurring every five years by an authorized body. One commented that MROs should be required to contact the prescribing physician any time a laboratory reports out a positive result for any schedule II drug to verify that the donor is safe to perform their job duty. There were three other comments that were inappropriate; two were oral fluid comments that were submitted under the wrong document.

The FRN announced HHS's proposal to establish scientific and technical guidelines for the inclusion of oral fluid in the MG was also published on May 15th and has the same due date, July 14th, for the receipt of public comments. As with urine, the Department has requested comments on any aspect of this FRN but also had specific targeted requests. In Section 3.1, comments are requested whether on federal agencies should test oral fluid specimens for either albumen or immunoglobulin G (IgG) to determine specimen validity. In Section 3.4, comments on the appropriateness of the proposed cutoff concentrations are requested. Also in Section 3.4, the Department inquired whether laboratories are able to test the

tetrahydrocannabinolic acid (THCA) analyte at a cutoff of 50 pg/mL and whether THCA can be established as an accurate, sensitive, and valid marker in oral fluid to detect marijuana. Also in this section, comments were solicited on whether THCA could be used to extend the window of detection for marijuana use. Finally, in Section 3.4, comments on the lowering the cutoff concentration for tetrahydrocannabinol (THC) to either 2 or 3 ng/mL for the initial test cutoff and to 1 ng/mL for the confirmatory cutoff concentration is viable to extend the detection window for marijuana. In Section 7.3, targeted requests are solicited for the performance requirements of the oral fluid collection device. In Section 13.5, the MRO section, the Department inquired whether the concentration of 150 ng/mL of morphine or codeine should be used by the MRO to report a positive result in the absence of a legitimate medical explanation, such as a valid prescription, without requiring clinical evidence of illegal opiate use and to rule out the possibility of a positive result due to consumption of food products.

As of late Wednesday night, 16 comments were received. These included the two oral fluid comments that were submitted under the FRN for urine. Three commenters agreed with the proposed oral fluid guidelines. One agreed because it sped up the hiring process. The other one agreed because the urine specimen can easily be adulterated or substituted by the donor. One person disagreed with oral fluid testing because of the short detection time and believes that hair is the best matrix for drug tests.

One commenter disagreed with the collection requirements. The ten minute wait time increases the amount of time the donor is detained, hinders the collector from doing other work while supervising the donor, and is more costly for both the employer and the collector. This person also disagrees with the requirement to contact the agency for authorization to collect an alternative specimen when insufficient oral fluid is collected. He/she also disagreed with the requirement requiring tobacco users to rinse their mouths because the majority of truck drivers either smoke or chew tobacco. The collectors must find some place for the donors to expectorate that rinse.

One commenter provided comments on subpart M, saying the MROs should be required to contact that prescribing physician any time a laboratory reports out a positive schedule II drug to verify that they are safe to perform their duties.

One commenter commented on multiple sections. For Section 3.3, he/she disagreed with the validity testing for albumin and IgG, saying there is no scientific basis for that, the collection is observed, and it is unnecessary due to the limited amount of oral fluid that is collected. Regarding the cutoffs presented in Table 3.4, he/she believed that the THC cutoff of 4 ng/mL is appropriate but could be higher because of poor THC recovery from the current collection devices and also to avoid positive results due to passive exposure. He/she believed that THCA testing should be mandatory to avoid positive results due to passive exposure. The methamphetamine cutoff should be 50 ng/mL to avoid unnecessary confirmatory tests due to the use of the Vick's inhaler, phentermine, Adderall, or Vivanse. Also the same commenter on Section 7.3b2 said the volume diluent should be within plus or minus 5 percent of the target volume and not a specified volume of 0.05 mL of the diluent target volume because of the wide

range of target diluent volumes in the collection devices. In the same section but for another part, he/she stated the recovery of all analytes should be greater than 80 percent instead of what is currently stated as greater than or equal to 90 percent. Because of THCA, it is a very problematic to reach the 90 percent target. Since THC cannot attain this target, all drugs should have the same cutoff of 80 percent. In Section 11.9, he/she requested clarification on the initial test requirement, specifically asking whether Food and Drug Administration (FDA) clearance is required for all initial test methods. For Section 11.11, he/she stated that the quality control requirements for initial test batches should be higher, such as 50 percent above and below the cutoff instead of the 25 percent above and below that are currently stated because current immunoassay technologies for low cutoff assays are not able to perform robustly at those low levels. He/she provided a citation that FDA does recognize this and allows the plus or minus 50 percent for low immunoassay controls.

There were other comments received, but these were either inappropriate or not substantive.

Finally, the RFI for the hair specimen was published in the FR on May 29th. It is currently a 30-day public comment period ending June 29th. As Ron mentioned, we are pursuing extending the public comment period for another 30 days until July 29th. If approved, the extension will be published as a FRN.

The RFI format was divided into the following topic areas: hair specimen, collection, specimen preparation, analytes and cutoff, specimen validity, and testing. Within each of these specific topics that were identified by the Board members, specific questions were developed. For each of the topics, the number of questions within each topic is listed here. As of Wednesday evening, 11 comments were received on the hair RFI. Three commenters requested that the comment period be extended to a total of 60 days. Two commented on the reasons for testing for hair. One commenter said hair testing should be for pre-employment only. One commenter wanted hair testing for pre-employment, follow-up at the beginning and end of treatment, and when problems occur with the collection of a urine specimen, such as shy bladder, diluted specimen, and interfering substances. Three commenters disagreed with hair testing. One believed that urine is the best matrix for the Department of Transportation (DOT) testing due to detection time of urine when compared to hair or oral fluid. One commenter believed that oral fluid was the best matrix for drug testing and doesn't believe that hair is a viable option for the employer or for public safety. One collector disagreed with hair testing for the following reasons, stating that it is difficult or nearly impossible to collect hair from the crown of the head of those men and women who wear their hair very short, for men who have very little body hair because collectors are limited to a dry shave using a disposable razor or attempting to cut very short hairs with scissors, and for hair that is very dry and fine. He/she would also not recommend using hair without it being collected in conjunction with either a urine or an oral fluid test. The commenter gave a reason for this, stating that this collector had never seen a positive hair test alongside a positive urine test, stating that it is either a positive hair or a positive urine, but never both. One commenter recommended that SAMHSA solicit additional information from the court system, the Bureau of Justice Assistance Standards for

use of hair testing in drug courts, and Dr. Bob DuPont's research articles on hair testing. The two remaining comments were either inappropriate or not substantive.

There are three FRNs on which SAMHSA is requesting public comment. Please provide public comment! For the proposed urine and oral fluid MGs, the deadline is July 14th. For the hair RFI, the deadline for public comment is currently June 29th, but it will probably be extended to July 29th. Using the website link I have provided, I recommend that you navigate the site. For instance, you can place limitations on your search, such as selecting SAMHSA as the agency and the publication date as within the last 30 days. In doing so, these three FRNS will pop up right. I found this to be the easiest way to find these three FRNs. You can also make comments on comments. You also have the option to upload a document that is already typed to the site. Anything that is posted on the site can be viewed by the public. As instructed in the FRNs, submissions can be made outside of the web portal, such as by letter. Be sure to verify these other options by checking the FRNs. I did provide citations to each FRN so that you can search them.

DTAB's Process for Evaluating the Scientific Supportability of Alternative Specimens for Federal Workplace Drug Testing Programs

Dr. Cook: I have given a similar presentation before when we were discussing oral fluid. I believe it is time to present it again in the context of the hair specimen so you know where the Board is in the process of evaluating the scientific supportability of the hair specimen for Federal Workplace Drug Testing Programs.

Here is a little background on the DTAB. SAMHSA has seven Federal Advisory Committee Act advisory councils. DTAB is the only one within SAMHSA that is a scientific advisory council. Per its charter, SAMHSA seeks to improve the quality of the services for forensic workplace drug testing, assess the science and technology used in drug analyses, improve the quality of related laboratory services and systems for drug testing, generate standards for laboratory certification for Federal Workplace Drug Testing Programs, and guide national policy in these areas by the establishment of the CSAP DTAB.

DTAB has its own charter, which is posted on the DTAB website. Per that charter, it has very specific delineated duties, which I will read to you. The CSAP DTAB provides advice to the Administrator of SAMHSA based on an ongoing review of the direction, scope, balance, and emphasis of the agency's drug testing activities and drug testing laboratory certification program. It will recommend areas for emphasis or de-emphasis, new or changed directions, and mechanisms or approaches for implementing these recommendations. Periodically, the CSAP DTAB shall review specific science areas on new drugs of abuse and methods necessary to detect their presence.

Reviewing the history of the alternative specimens in the MGs, in 2004, a FRN of revisions to the MGs was published that proposed to establish science and technical guidelines for testing of hair, sweat, and oral fluid specimen in addition to urine. When the final MG were published

in 2008, only urine was included. The link to the 2008 FRN is provided here. The decision why the Department chose to only pursue urine was spelled out in the preamble of this 2008 FRN. Specifically, submitted public comments and additional comments raised by federal agencies during the subsequent internal review of the proposed changes to the MG raised significant scientific, legal, and public policy concerns about the use of alternative specimens. Their concern was that the scientific, legal, and public policy information for drug testing oral fluid, hair, and sweat patches is not as complete as it is for the laboratory-based urine drug testing program. In the 2008 preamble, three specific issues related to these alternative specimens were delineated. First, the data from the pilot proficiency testing (PT) program to date showed that not all participants had developed a capability to test for all required drug classes or to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others for any given type of specimen. Finally, the specific drug classes that are difficult to detect vary by type of specimen. HHS did state that it believes that the addition of these alternate specimens to the Federal Workplace Drug Testing Programs would complement urine drug testing and aid in combating the risk posed from the available methods of suborning urine drug testing through adulteration, substitution, and dilution. HHS then outlined an approach that SAMHSA, DWP, and the DTAB were to follow. This approach was proposed because each alternative specimen poses different concerns. The Department established a staggered timeline for issuing final guidance that allows for further study and research. Once that research and study are completed, then one or more final notices in the FR will be published for public comment. We have published the proposed FRN for oral fluid as an alternative specimen. Basically, the goal for the Department is to continue to pursue testing using alternative specimens. Once this research is done by the DTAB, HHS anticipates that further revisions to the MG will be issued and published in the FR for public comment.

For this alternative specimen process, DTAB has been tasked with following this HHS recommended staggered timeline for evaluating the scientific supportability of these alternative specimens. As you know from the publication of the recent FRN, the Board has completed its evaluation of oral fluid. It began its evaluation of the hair specimen in July 2013. The first step that the Board did was to assess the current state of the science for hair as an alternative specimen, which occurred during the July 15th-17th, 2013 DTAB meeting. In order to help them with this process, the Board identified scientific experts to assist DWP, and thus DTAB, to assess that science of the hair specimen. The scientific experts who were identified for hair testing were Jim Bourland, Yale Caplan, Ed Cone, Dennis Crouch, Rich Hilderbrand, Jeri Roper-Miller, Peter Stout, and Mike Walsh. I have an asterisk by Peter's name because he is no longer one of our scientific experts. The next step was to review the current science of hair, which occurred on July 16-17, 2013. The topics reviewed in that meeting included a historical perspective of hair as a drug testing matrix; hair specimen characteristics, collection, preparation, and stability; hair drug analytes, analyte stability, and analyte cutoffs; initial and confirmatory test methodologies; PT; best practices experiences from a hair testing laboratory; and actual hair testing drug data.

The next step was to perform an exhaustive literature search of peer-reviewed journals. It is amazing that our extensive bibliography contains 1,234 articles on hair. The reason we did this

extensive search was to be able to provide references in the proposed MG preamble, as we did with both urine and oral fluid. Any statement that we would make, we could substantiate it with a peer-reviewed journal article reference.

Next, topic areas regarding hair testing were identified in which DWP, the Board, and the scientific experts had reached preliminary consensus. That has occurred since that July 2013 meeting. We also identified those topics in which we were unable to reach consensus and decided that more research was required. The two major topics that were identified were hair contamination and the preferential binding of basic drugs by melanin. These two topics, as well as others, have been discussed at length by the Board for almost two years now. The topic areas that were specifically identified as requiring further research included the hair specimen itself, collection, specimen preparation, analytes and cutoffs, specimen validity, and hair testing. These topics might look familiar to you because these are included in the RFI. Under each of those topics, the Board developed specific questions for which they felt they did not have the answers. For each one of these questions, possible outcomes include a consensus answer; a request for a more in-depth literature review; a request for information, which we have sent out; and a request for research studies. Also, any issue that has significant scientific, legal, or public policy concerns has been forwarded to the appropriate federal officials for their input. Most people don't realize that representative experts from the Department of Justice (DOJ), the HHS OGC, FDA, DOT, NRC, DoD, Federal Bureau of Investigation (FBI), and National Institute on Drug Abuse (NIDA) are present with the Board in real-time so that they understand the issues.

As I mentioned, we have identified other nonscientific issues. Because the Board is scientific in nature, any other issues that they uncover are forwarded to the appropriate persons, including OGC and DOJ.

Another step in the process involved soliciting feedback from industry stakeholders. At the February 5-6, 2015 DTAB meeting, we asked those laboratories that are enrolled in the National Laboratory Certification Program's (NLCP) pilot PT program to attend this meeting. We provided them in advance with a list of detailed questions on which the Board wanted to solicit information from them. Each industry representative was given an hour to meet confidentially with the Board and to provide their confidential responses to the questions that the Board had provided each representative in advance. This format allowed for a give and take of communication between the Board and the laboratory representatives.

Currently, we are soliciting feedback from the public in the form of a RFI. I have already reviewed the comments that we have received to date. At the August DTAB meeting, all the received public comments will be reviewed. With the public comment period being extended to July 29th and DTAB is convening the first week of August, please do not wait until near the end of the closure of that comment period to provide comments because it will not provide the DWP staff enough time to process all received comments for the August meeting. Once all of the public comments to the hair RFI are reviewed, the Board will deliberate on the scientific

supportability of the hair specimen for Federal Workplace Drug Testing Programs. That will happen, if all goes as planned, at that August meeting.

Per its charter, DTAB provides advice to the SAMHSA Administrator. OGC recommended that the best way for the Board to do that is in the form of an official written recommendation. There is an official process that must be followed for the Board to put forth a recommendation. This process was followed for oral fluid, as well as for the synthetic opiates. The recommendation must come from a voting member or the chair of the DTAB. The language of that recommendation is clearly proposed in writing. The Board will deliberate on that recommendation in open session. A quorum of the Board members must vote by closed ballot on the recommendation in the open session with a majority needed for approval. Since this is a closed ballot, only the final tally of the vote will be presented in the open session. If passed, all voting Board members sign a recommendation letter that is addressed to the Administrator for her approval or disapproval.

During this two-year process, the Board has evaluated the scientific supportability of hair. DWP and its federal partners also have to address other significant scientific, legal, and public policy concerns that will be raised by the public commenters and federal agencies. The Board will or will not recommend proposed revisions to the MG to include hair as an alternate specimen. If the Board produces a recommendation and that recommendation is approved by the SAMHSA Administrator, the proposed revisions to the MG will be drafted by DWP, reviewed by the Board, and then published in the FR for public comment.

Mr. Flegel: Thank you, Janine.

Dr. Cook: Our next presenter is Commander Jennifer Fan, who will be talking to you about the HHS approval of entities that certify MROs.

HHS Approval of Entities that Certify Medical Review Officers

CDR FAN: Good morning, everyone. I will provide a really brief overview on MRO-certifying entities and where we are in the process.

What are MROs? MROs are licensed physicians who have earned either a Doctorate of Medicine, M.D., or Doctor of Osteopathy, D.O, degree. They must also have knowledge regarding the pharmacology and toxicology of illicit drugs, have completed the training that is necessary to serve as an MRO, and have satisfactorily passed an examination administered by a nationally-recognized entity that certifies MROs or subspecialty board for physicians performing a review of federal employee drug tests results, which has been approved by the HHS Secretary. All of this information can be found in in Subpart M, MRO, Section 13.1.

What are MRO-certifying entities? They are nationally-recognized organizations. They must submit their qualifications, as well as a sample MRO examination with answer key, to us for review. We provide our recommendation to the HHS Secretary, who in turn will review our

recommendation and approve or not approve the organization. The latest group of entities was approved on May 26, 2015 and includes the American Association of Medical Review Officers, AAMRO, as well as the Medical Review Officer Certification Council, MROCC. In the past, we have evaluated those organizations that only provide training, but it is out of our scope to approve those since they don't administer examinations. Thus, this time we did not list those entities in this FRN.

For the next cycle, an MRO entity that seeks approval from the HHS Secretary must have its information submitted to SAMHSA by July 31, 2015. Once we review the submissions, we will provide our recommendation to the HHS Secretary. Once the Secretary has approved those organizations, the approved list will be published in the FR.

I also provided some key references that relate to MROs. Please note that the latest MRO Manual, dated May 31st, is currently on the website. That concludes my presentation. I will hand it off to Charlie LoDico.

Dr. Cook: Our next speaker is Charlie Lodico, who will present on the federal custody and control form (CCF).

Federal Custody and Control Form

Mr. LoDico: Thank you, Janine. Good morning everyone. This presentation will focus on an update to the electronic CCF (eCCF). As a background, the CCF is a document that is OMB approved. Because the CCF has an expiration date, it must be reviewed by OMB every three years. As part of that review, we must justify its continued use. There are changes required by OMB to reduce burden per the Paperwork Reduction Act. The latest iteration of the CCF allowed for the use of an eCCF. This slide shows the OMB Notice of Approval with an approval date of May 28, 2014. On August 24, 2013, the eCCF was officially available for use in our program. Listed on the bottom is the current expiration date of May 31, 2017. Before that date, DWP must provide documents to OMB requesting continuation of the form.

One of the most gratifying things was the publication of DOT's final rule concerning the CCF in the FR (80 FR 19551) on April 13, 2015. From that rule are two summary points that I want to iterate. First of all, DOT's definition of the CCF will include both the paper and electronic form. Secondly, DOT made it very clear that the laboratory eCCF must be reviewed, approved, and inspected by the NLCP before implementation. That requirement goes to the heart of the rest of this presentation.

To support the laboratory's request to receive review and approval, we created several related eCCF documents, which are listed here and also posted on our DWP website. The first two are guidance documents, relating to how the laboratories should proceed and what the requirements are to get approval. The other three documents are ongoing, such as the MRO Manual that Jennifer Fan mentioned. The MRO Manual includes language that allows for the use of eCCF. The Collection Handbook also contains language about the eCCF. The updates to

the Laboratory Checklist and Inspection Manual are very close to final, with minor editing and wordsmithing remaining.

There are two versions of the CCF. The first one is the paper CCF, which has not been eliminated. As both OMB and all of us are aware, we cannot create a digital divide. Thus, the current CCF is still acceptable and will be acceptable until told otherwise. There are two paper CCF options. First is the preprinted, multiple-part carbonless form, which is the current way it is done today, or there is the option for a multiple-part CCF that is printed at the collection site. For the paper CCF, both the collector and the donor must sign using wet signatures. The hardcopy CCF that accompanies the specimen is the chain of custody.

Then there is the eCCF. For this version, as we have defined it, it is an all eCCF. It means that all gathered information is in an electronic format. Information fields are only assessable through a computer. During the specimen collection process, the collector fills in all the designated demographic fields. Once that is completed by the collector, it is submitted to the laboratory as electronic transfer. The electronic signatures are digitized for both the donor and the collector. The test facility attests to receipt and certification of test results electronically. It is also received and handled electronically in the laboratory. Test result information is in the form of an electronic report. The eCCF is the chain of custody. The eCCF is an electronic auditable trail. Any action that is performed with that particular document is captured. The eCCF information will be reviewable and auditable. Therefore, it creates concrete information.

The last condition is a combination. In this situation, the collection of information is performed electronically, but at the collection site there is the option to print the CCF, Copies 1 and 2 at a minimum. Copy 1 is the donor copy and the other is the collection copy that accompanies the specimen to the laboratory. In this situation, both the collector and the donor must sign using a wet signature. The hardcopy CCF sent with the specimen is the chain of custody.

The value and the efficiency of the electronic system is that there is a better collection process for the collector in terms of the completeness of the information that is gathered. Unlike a paper CCF where there could be missing demographic fields, in the electronic version the information is complete. More importantly, this information, once it is complete, is immediately sent and distributed electronically to the interested parties, including the MRO, the employer, and the laboratory, which will receive a copy in advance to the specimen arriving. Once the specimen is received in the laboratory, the eCCF is married to the specimen.

These are the three conditions that we have explained and informed the laboratories about. What are the first steps? At the NLCP Workshop at the SOFT Annual Meeting, we will and have informed inspectors and laboratory directors about these CCF requirements. We informed the laboratories that before a federal eCCF can be used for regulated specimens, the HHS-certified laboratory must submit documentation for NLCP review, undergo an NLCP inspection, and obtain HHS/SAMHSA approval to prior to implementing the eCCF. After eCCF implementation, NLCP inspectors will review the procedures, practices, and records, including verifying the Inspection Checklist Section P self-assessments. Laboratories must also notify the NLCP before

major changes are made to their eCCF process. We have provided the laboratories with an opportunity to apply and use the eCCF. As of today, there were only three applicant laboratories that have submitted information and expressed their desire to use an eCCF.

I will review the process for handling eCCF applications requests. First, the laboratory submits specific information to the NLCP. Eight different information submissions are required. The first is the general review of the whole process, which includes a topic outline of proposed standard operation procedures (SOP) for eCCF use. The SOP is the bible by which the laboratory performs all of their processes. For a certifying body such as the NLCP, the SOP is a foundation for inspectors to ensure that laboratory actions are in compliance with its SOP. An inspector reviews the process that is described in the SOP and evaluates in real-time whether the laboratory personnel are adhering to the SOP in the performance of their duties. When there is disconnect between the SOP and practice is an area of concern for the inspector. We also review training plans. Every new process must have a plan for training personnel, both internally in the laboratory and outside relevant personnel. How will electronic documents be received? How are the collectors trained in using a digitized process for collecting information? That is a responsibility of the laboratories to produce for us a training plan for the specific personnel if they are implementing new processes. Another important document is a System/Network Diagram, which details how information is received and how it is transmitted. Critically, the most important of all of these information submissions is the System Security Plan. A security breach is in the news every day. Our own federal government was hacked recently, exposing our personal information. We are very sensitive to the need for defining and describing in very specific detail the Laboratory Security Plan to ensure that information is kept to a minimum and the firewalls are secure. We also evaluate their Validation Plan. Also of vital importance is the Third Party eCCF Provider Agreement. This agreement is required if a laboratory relies on a secondary provider for support. We need to know that the third party agreements are legally binding whereby the provider is accepting responsibility and liability. Lastly, we request that the Laboratory Information Checklist is consistent with what they propose to do.

This slide provides a bullet by bullet overview of the process review for the federal eCCF from initiation until final disposition. For the SOP outline, we evaluate the outline content, including accessioning, result certification, and reporting. We review the instructions for other eCCF users. The SOP will also have instructions on what collectors should do to release information to the MROs. For ease of inspector review, we recommend that the laboratories include eCCF software screenshots. If a collection is performed, each of the collection steps is accompanied with a screenshot. Thus, inspectors evaluating the collection site can visualize what is happening, as well as read the information as it is described.

Again, we require training plans. The training plans extend to laboratory staff, the collectors, and if applicable, the MROs. We evaluate any training that involves individuals that are given access to regulated specimen data, such as the IT staff. This is critical if the laboratory is using an external service provider for storing its electronic data. It is important to know that training

of those who not part of the laboratory staff is occurring. It is very important to know that there is a staffing and training plan.

The responsible person (RP) must document the review and approval of all training plans and materials. The RP currently does that for other changes in their laboratory processes. We are simply mandating what is currently be required of them, only this time extended to electronic CCF.

The network diagram contains the details for the required information. The logical network diagram must include, at a minimum, the following: firewalls, network security, servers, workstations, primary routers, remote access devices, and internet connections.

The NLCP is very specific and detailed in what it requires. If a laboratory submits information that is only a peripheral description, the Program will follow up and request more detail. The approval delay will fall on the laboratory if its submitted information is not all inclusive up front. We rather that the laboratories provide too much information and let the NLCP whittle it down rather than missing information than has to be tracked down and result in delays in the implementation of the eCCF.

The system security requirements are critically important to us. I highlighted the compliance requirements that are industry standards. Though I couldn't tell you what they represent, this information is requested as part of an IT review. Our NLCP contractor, RTI International, which has the contract for laboratory certification and inspection, asked their internal IT security component to review some of these submitted applications. We are utilizing baseline industry standards, not exceeding them, and asking the laboratories to provide us with detailed information consistent with the industry standard for security clearance to review.

The validation plan requires that any new process be checked, validated for accuracy and reliability, and work according to the stated plan before implementation.

The third party agreement applies to services that are outside the control and the ownership of the laboratory. If the laboratory relies on a server, call service, or external data storage, there must be an agreement that shares the concerns of the Program as well as the liabilities.

Finally, NLCP laboratories are all familiar with the checklist information process. The Laboratory Checklist Manual will include and require applicants to use the federal eCCF. The Manual will address CCF annotation, computer system validation, security, electronic record, electronic signatures, electronic reports, audit trails, system monitoring, incidence responses, disaster recovery, and personnel training.

This is not a simple change in a current process done every day without much concern or fanfare. This is a monumental difference between what was done in the past. As a consequence of this, the NLCP must perform a detailed due diligence. Even though only three laboratories have submitted applications, there are many more that will submit their

applications. Once the NLCP receives the application information, it will respond quickly. The NLCP is offering to do an advanced inspection of an eCCF applicant laboratory before its scheduled inspection, which is typically every six months, because of the benefit the eCCF brings to the Program. I will end here.

Dr. Cook: Do any members of the Board have any questions for Charlie? If so, please state your name and then your question. I forgot to ask do any members of the Board have questions for Jennifer and the MRO approved entities or process?

Because we are running ahead of schedule, Charlie has kindly agreed to continue with his next presentation, originally scheduled as the last presentation of the day. He will present about the Federal Workplace Drug Testing Programs data from 2014.

Federal Workplace Drug Testing Programs

Mr. LoDico: Good morning again. This presentation is of value to the public because they can evaluate the federal drug testing program through the statistics I will present.

This slide, which looks very confusing to some people, is very simple to those of us who have seen it repeatedly. It depicts the distribution of NLCP laboratories by category. There are 31 laboratories in our program, with each laboratory of a different size, ranging from category 0 through 5. Laboratory fees and inspection review criteria are based on laboratory size. A category 0 is considered a very small laboratory. Typically, the laboratory doesn't perform any federally-regulated drug tests. Their sole reason for being certified by our Program is for other reasons, such as a marketing tool or certification credentials for other contracts. For category 0 laboratories, two inspectors are dispatched to inspect these laboratories every six months. Category 5 is our largest laboratory classification. Typically, they are the high volume laboratories. Currently, there are five of them. The category 5 laboratories are subject to more inspectors at each inspection, typically four inspectors plus two auditors for a total of six inspectors at one time versus a category zero with only two inspectors. The reason for the increased number of inspectors is to review the required percentage of records. That is how we established the program in terms of categories. We review the laboratory's work volume on a semi-annual basis when they submit their non-negative specimen list. If we see a change in work volume, then that means we might have to change their category. The laboratory could change from a category four to a five or, conversely, from a four to a three.

This slide depicts the volume of federally-regulated specimens tested over the years in our certified program. Between 2005 and 2007, there was an increase in total specimen received, reaching a high of almost eight million specimens in 2007. After the crash in the economy, there is a gradual downturn in the volume of specimens tested. Now, testing volume is beginning to increase. In 2014, there were close to 6.5 million total specimens in analyzed HHS-certified laboratories.

This slide is a snapshot of positive results only. As the volume of total specimens tested increased, there is a correlating proportional increase in the number of positive specimens. In this a bar graph for the regulated specimens that are positive, adulterated, invalid, or substituted between 2010 and 2014, there is a slight increase between 2012 and 2014.

This graph illustrates the distribution of the positive results. The drug which yielded the most positive test results on an annual basis is THC. It is followed secondarily by amphetamines. Notice the sizable increase in amphetamine positives, primarily the result of Adderall, which is the most prescribed amphetamine. The remainder of the drugs exhibited flat trends. There was a decrease in the cocaine metabolite benzoylecgonine while the trend for opiates was steady. A slight increase occurred for invalids/unsuitable for testing specimens, which I will explain later.

Shown here is a bar graph distribution of invalid pH results. Notice the increased bar height between 2010 and 2014. Notice too that the invalid high pH distribution in the summer months from March through July. The number of high pH invalids increases in the summer months and decreases thereafter. This is thought to be related to specimens not properly stored during transport to the laboratory; the resulting increase in bacterial growth results in an increase in pH.

In the specimen invalid category, the emphasis for the laboratory is to define what constitutes a specimen that is consistent with normal human urine. The laboratory uses different tests to identify what is considered a valid urine sample. I will break these down. There are physical characteristic criteria for the invalid classification. There are also clinical criteria, including creatinine and specific gravity. If the confirmation gas chromatograph (GC)-mass spectroscopy (MS) is invalid or a GC-MS error is unresolvable, the test is reported as an invalid. One of the major invalid categories results from immunoassay interferences, which I will explain further. Invalids can also result from oxidant activity causing an invalid pH. Listed here are all the invalid categories.

Interference in a specimen that causes an immunoassay test response that is outside of specific parameters defined in the laboratory SOP results in a test being reported as an invalid due to that particular specimen-related analyte abnormality. Laboratories are required to establish assay criteria for those interference conditions. For 6-acetylmorphine (6-AM), notice the large rise in the number of invalid results. This is related to a specific manufactured kit producing an abnormal response to an interferent. An unknown substance present in the specimen reacted with the kit components to cause the majority of tested specimens to be reported as invalid.

I wanted to provide the public and our Board members an understanding of the positivity rates. Even though there is an increase in the number of specimens being tested and an increase in the number of positive results, between 2010 and 2014, our drug positivity rate only increased from 1.54 to a high of 1.80.

The percent positivity rates are further broken down by category – drug positive, adulterated, invalid/unsuitable for testing, and substituted. Also shown in this table are the combined positivity rates by year. Between 2010 and 2012, the average combined rates for drug positive, adulterated, unsuitable/invalid, and substituted ranged from 1.7 percent in 2010 to 2.0 percent in 2014. Under the invalid/unsuitable column for 2012, the positivity rate was 0.10 percent. In 2013, that rate jumped to 0.15 percent and decreased to 0.14 in 2014. The immunoassay interference I discussed earlier is thought to have caused this increase in invalid results between 2012 and 2013.

The next two slides summarize the key points of this presentation. The number of regulated specimens tested over the period from 2010 to 2014 increased by 15.2 percent. The yearly increases ranged from 2.5 to 5 percent. On an annual basis, there was a five percent increase in total specimens that were tested at all the laboratories. From 2010 to 2014, the number of regulated specimens being reported as drug positive, adulterated, invalid, and substituted increased by 41.7 percent. The yearly increases ranged from 1.4 to 13.7 percent, an overall total increase in positive results. The positivity rates are flat, ranging between 1.5 and 1.8 percent, if the adulterated, substituted, and invalid results are removed. Specimens reported as invalid due to a low pH have decreased from the levels seen in 2011 and 2012. The proportion of specimens being reported for this reason in 2014 returned to 2009 rates. Lastly, the specimens reported as invalid due to immunoassay interference increased in 2013 but have since decreased, yet remain elevated, in 2014. The immunoassay interferent is still an issue. Overall, positivity rates still are not that elevated. That concludes this presentation.

Dr. Cook: Do any members of the Board have questions for Charlie? If so, please state your name first.

I forgot to announce prior to Charlie's presentation that each year at DTAB we have what I call the "state of the union", in which the federal programs, DOT, NRC, and DoD present their drug testing data from the previous year. Charlie just presented the federal update while the other updates will be heard this afternoon.

We do have one question. (Question off mic)

Mr. LoDico: The point you made refers to amphetamines and opiates. I will refer this to Jim Ferguson. It is my understanding that if the laboratory reports a positive amphetamine result to a MRO and that amphetamine is Adderall, or in the case of the opiates, it is codeine, and there is a qualified medical explanation with a valid prescription, the overturn rates on both of these are probably in the 75 to 80 percent rate. Dr. Ferguson, are you on line? Can you validate this as the MRO?

Dr. Ferguson: Yes. I am on the line. I can validate that. Actually, the amphetamine rate is around 84 percent. It always varies in that 70 to 80 percent range for those two.

Mr. LoDico: These results are laboratory-reported results that subsequently are reviewed by the MROs. When we capture this reported information from the laboratories, it is laboratory positives that have not yet been MRO-verified. These data are the represented graphically. You are right though. If MRO-verified positives were overlaid on laboratory positives, this slide would change dramatically.

Dr. Cook: I just want to remind people who are on site that we are having problems with the microphones on the east side of the room. We are getting comments from several people that they are having difficulty hearing you.

Ron, do you have any comments?

Mr. Flegel: No, not at this time.

Dr. Cook: We will now break for lunch.
(Lunch)

AFTERNOON SESSION

Dr. Cook: Welcome back everyone. I apologize for the confusion. The decision was made to adhere to the published schedule and begin at one o'clock as originally planned. Before Patrice Kelly of DOT gives her 2014 update, Ron Flegel has a few announcements.

Mr. Flegel: Thank you Janine. Before we start the federal partners' updates, I wanted to extend a big thank you to our federal partners for their comments on the two proposed MGs and everything else that they have done, helped us with, answered questions about, etc. There are a number of challenges going forward. SAMHSA will help our federal partners, too, with their notices of proposed rulemaking, whether for urine, oral fluid, or anything else in the future.

Dr. Cook: Thank you, Ron. Our next speaker is Patrice Kelly, Acting Director of the Office of Drug and Alcohol Policy and Compliance (ODAPC) for the Department of Transportation.

DOT Drug Testing Update

Ms. Kelly: Thank you, Janine. Again, thank you to SAMHSA and thank you to DTAB for this opportunity to provide our 2015 program update.

This slide explains why this program is important. Shown here is a picture of our DOT Secretary, Anthony Foxx. The Secretary supports this program, and ODAPC is part of the Secretary's staff.

We view drug testing as an important safety component. Two accidents were the catalyst for the creation of this program: the 1985 subway accident in New York City that was as a result of

marijuana use and the Chase, MD accident in 1987, again attributable to marijuana use. No such accidents have occurred since this program began 25 years ago. The Secretary recognizes that safety is our highest priority. Across the different modes of transportation, our regulated industries are expected to follow our regulations and maintain this level of safety, if not better. We are always seeking to improve.

The ODAPC program advises the Secretary and the DOT agency administrators from the Federal Motor Carrier Safety Administration (FMCSA), the Federal Aviation Administration (FAA), etc. regarding issues at the national and international level. Though our office only regulates nationally, we are often asked to advise in international situations and share our experience. We are involved in supply reduction and demand reduction issues. We work closely with the White House Office of National Drug Control Policy as well as our colleagues in other federal agencies to bring those issues to the forefront and to work to reduce the supply and demand for drugs.

DOT agency and U.S. Coast Guard drug and alcohol program activities are another area where we advise the Secretary and the DOT agency administrators. We strive for a one DOT approach where appropriate. For example, our regulation under ODAPC is 49 CFR Part 40, which are the procedures for workplace drug testing. Our science is based on the HHS MG. Yet, we move beyond the MG to tailor our regulations for the transportation industry. In addition, the FAA, FMCSA, and others have their own individual regulations that tailor that further. However, ours are the procedural regulations, for instance, for how testing is performed; the use of HHS-certified laboratories; and instructions to the laboratories, MROs, and substance abuse professionals (SAP). That is followed throughout the modes.

We also collect and analyze data and information submitted to us every six months from the regulated industries' HHS-certified laboratories. I will review that data with you later.

Our staff develops plain language regulations, guidance documents, and policy interpretations. Ours is a very active office. We receive incoming calls on a daily basis to the tune of just over 12,000 calls last year, in person appearances, and consultations with the DOT program managers. We provide consultation and liaison with the executive branch, federal agencies, and foreign governments. We are working very closely with HHS on the proposed oral fluid MG, the changes to the urine MG, and the hair testing initiative. All of these are in proposal stages. Listed on this slide are examples of foreign governments with which we have consulted, including Mexico, Canada, Australia, England, Germany, Nigeria, China, New Zealand, and others in our not too distant horizon. We meet with industry stakeholders and customers and support issues, conferences, and training events. As the Acting Director of ODAPC, this is one of my initiatives. This Administration, especially Secretary Foxx, is strongly predisposed to more outreach and to communicate with our regulated industries about initiatives, priorities, and their importance. ODAPC can enact all the regulations it wants, but they mean nothing unless people are actually implementing them.

Our public outreach is an important aspect in that overall picture of communicating. We have the largest regulated testing program in the world with roughly eight million employees at any given time subject to testing. Last year, 6.3 million tests were conducted. This is a very large industry. We strive for outreach to communicate information.

Our program's goal is to ensure the safety and security of the traveling public, reduce the demand for drugs by transportation workers, and reduce alcohol misuse in the transportation industry. Though the focus of DTAB is on the drug side, we also have a very active alcohol misuse prevention program.

We create prevention and treatment opportunities. Our program has always had a very strong SAP rehabilitation aspect to it. An individual who is determined to be drug positive or has refused the test will be removed from safety-sensitive work and cannot return to the performance of safety-sensitive work until after receiving an evaluation by a SAP, successfully completing the SAP's recommendation, and being ready to return to duty test for regulated employer. For many of the folks to whom I am speaking to right now know this is as elementary because of your experience with our program. When we began talking with this Administration seven years ago about that aspect of our program, they were fascinated. It creates an incentive to recovery because the individual knows that he/she has something to go back to in the transportation industry if he/she can get cleaned up. That is an important component that we have worked closely with other federal agencies to discuss and to see how they can integrate it into the other programs they administer.

Our program goals include ensuring the fairness and integrity of the testing process and maintaining employee privacy and confidentiality. We speak to the Fourth Amendment constantly in this program because what we do is not a medical test. It is a Fourth Amendment search and seizure. Over 90 percent of the individuals who are subject to these searches are innocent. Still, whether you are innocent or guilty, you deserve the same protections. This is a warrantless search. We strive to balance our transportation safety needs with the privacy concerns of the individual in this otherwise intrusive search. That is another reason why we strongly support DTAB and HHS in their efforts to look at alternative methodologies. Urine specimen collection is somewhat invasive. When our scientists state that alternative methodologies are scientifically defensible and forensically defensible, we are very interested in determining how those can be applied in the transportation industry.

The Omnibus Act sets the cornerstone for our program. Our regulations existed before the Omnibus Act, but Congress wanted specific parameters to further reinforce what we were already doing.

We have gatekeepers in place to ensure due process. They are the HHS-certified laboratories, which are a very important piece of what we do. The evidential breath testing devices for the breath alcohol test provide a certain degree of due process. We utilize the MROs to review laboratory results and SAPs.

We maintain that all systems must be auditable and reviewable by the DOT agencies. The different DOT agencies have very active inspection and audit forces. We are out there every day. A few thousand inspections occur in any given year. Records must be auditable and reviewable, which is why we have worked closely with, and applaud the efforts of, SAMHSA on the eCCF. SAMHSA has not forgotten our need for auditable and reviewable records.

In addition, we develop plain language regulations, policies, and guidance documents.

The components of our program include employer policies. It is very important to us that employers communicate information to their employees about what the employees should expect with respect to testing, to educate the employees regarding anti-drug initiatives, and to inform why drugs are not a wise choice. Other components are employee prevention education and supervisory training on substance abuse so that supervisors are better educated as to the signs and symptoms. Credible drug testing programs require physician review of laboratory drug test results. We don't allow just anyone review a drug test result as a MRO. The MRO must be a M.D. or a D.O. We have the alcohol testing programs in place. Other aspects include the removal from safety-sensitive duties, the SAP evaluation, and rehabilitation before return to duty, which provides the treatment opportunity and the incentive for the employee to strive for recovery so he/she can return work.

Part 40 in the DOT agency rules came into effect in 1988 and 1989 with our early proposed rules and final rules. This was followed by the Omnibus Transportation Employee Testing Act of 1991, which reinforced the regulations we already had in place plus added additional parameters to ensure that any of the concerns about drug testing in the late 1980s could be addressed. What about the false positives? What about the possibility that there be favoritism at a laboratory toward a particular donor? All of those issues were addressed in our program. Congress liked what we were doing and put in additional protections. Another thing the Omnibus Act did was give us the authority to test for alcohol. Though alcohol is a legal substance, we are testing for impairment. That is not what we have the authority to do with respect to drugs. We needed the Omnibus Act to give us the authority to move forward with alcohol testing. So 1994, three years after the passage of the Act, we moved forward with the Alcohol Testing Rule. We did a Final Rule major rewrite in 2000 of our Regulation 49 CFR Part 40, for which we received the Vice President's Plain Language Award. It makes me feel old because there are only three of us left at DOT who worked on this rulemaking in 2000. It doesn't seem like it was that long ago. For many people, it was a whole career ago. The remaining team members are Mark Snider, who is in ODAPC' and Patricia Sun, who is an attorney with the Federal Railroad Administration; and myself. We have a lot of background in that regulation and why it is the way it is. We moved forward in 2003 with the One DOT Management Information System, which ensures that all data among the different transportation modes collected from employers are reported in the same format. The 2008 Final Rule authorized the semi-annual laboratory data collection. This rule is important because it provided the authority to perform the laboratory data collection that I am about to discuss with you. These laboratory data are obtained from HHS-certified laboratories and are not MRO-verified. It is laboratory confirmed, but not MRO reviewed.

In 2009, we had litigation before the U.S Court of Appeals for the D.C. Circuit, which is a level below the Supreme Court, on the subject of direct observed collection. Our direct observation is what we call our “up, down, turn around” to verify that the donor is not wearing a Whizzinator. That up, down, turn around was upheld unanimously by the D.C. Circuit Court as an important step in our battle against cheaters in the federal drug testing process.

In 2009, we published our medical marijuana statement and later in 2012 our recreational marijuana statement. Those two documents together, I am told by transportation employers across the country, have been tremendous tools for them to let employees and MROs know that any excuse for marijuana is not acceptable. It is a Schedule I drug. Even if a state has authorized its use for medical or recreational purposes, that is not an acceptable response for safety-sensitive employees regulated under DOT.

In 2010 we published our Final Rule, thus harmonizing with HHS. Our rulemaking on the eCCF was issued on April 13th, 2015 and was immediately effective

The Omnibus Transportation Employee Testing Act of 1991 requires us to use HHS laboratories, their protocols, and their drugs. DOT does not have authority to test for different substances because we must utilize HHS-certified laboratories.

Another important requirement is the split specimen collection for drugs. We are required under our program to collect a split specimen, that is one subdivided specimen, for testing; consecutive specimens are not allowed. This requirement is considered another step toward due process for the employee. Another requirement under the Omnibus Act is that we prove drug use by an employee and not exposure. This ensures safeguards for alcohol testing. Remember, before the Omnibus Act, alcohol testing wasn't authorized. Because Congress recognizes this is Fourth Amendment search and seizure, and not just a medical test, we were given parameters regarding privacy for testing and confidentiality of test results.

This slide depicts what our current DOT drug and alcohol testing regulated industry program. Motor Carriers has about 700,000 employers and just fewer than four million employees. FAA has 6,900 employers and 450,000 employees. The other programs fall in between.

Shown here are the drugs for which we test. The number of drugs in our panel confuses our industries. They count 11 drugs in the panel, but we correct them by explaining it is a five panel test because we screening for the five drug classes and confirm for the 11 individual drugs. In this particular slide, the Schedule I drugs are shown in red and Schedule II drugs in black.

The 30 HHS-certified laboratories report data to us as laboratory-confirmed positives, and not MRO-verified positives, every six months. There were approximately 6.3 million tests last year, continuing a trend of increasing employment since 2009. During the second half of last year, there were about three million tests performed. Approximately 57,000 were laboratory-

confirmed positives. The overall positive rate, again, for laboratory-confirmed results rose slightly from 1.75 percent to 1.79 percent for these results.

THC continues to be the most identified drug. The positive rate rose slightly for the second half of last year. The second most identified drug was the amphetamines, including methamphetamine. The positive rates for those are currently at the largest percentage ever. Cocaine was the third most frequently identified drug. The positive rate for cocaine has dropped slightly from the last reporting period. This is the second reporting period in a row in which cocaine has declined. The positive rate for amphetamines has remained above that of cocaine since 2009. Being able to collect this data every six months has really helped DOT to identify trends and work with other federal agencies on those trends. For instance, after we began collecting these data in 2008, we noticed that amphetamine trend in January 2009 and alerted the other federal agencies. At the end of this month, the laboratories will start gathering their next six months of data to send to us. It won't be until the fall before we have that data to report. I am not sure if we will have it ready for the August DTAB, but it should be shortly after that. Data receipt every six months helps with our trends analysis. The positive rate for phencyclidine (PCP) continues to be higher than the ecstasy drugs combined. That is significant to us. DoD dropped PCP testing because of low incidence. Unfortunately for us in the transportation industries, we are still detecting individuals who are using PCP. While the numbers are by no means exponential, over 600 employees who are using PCP and perform safety-sensitive functions is completely unacceptable. Remember, all told, PCP tests positive more frequently than the ecstasy drugs combined.

The rate of specimen results reported by laboratories for fatal flaws remains low. The rate of tampered specimens stayed the same for a second reporting period.

Shown here are our total results. This increase, we believe, implies that the economy has been recovering and more people are applying for and obtaining jobs. Shown here are our results as percentages. Percentage positives are represented as the top line, tampered specimen percentages are shown as the red line, and the percentage of rejected specimens is the bottom green line.

On this slide, the number of positives is listed by drug. The top line represents THC, which continues to be higher than the other drugs and exhibits a steady, but not radical, increase. We credit these two guidance documents as reasons why our numbers have not increased radically. The guidance we published on medical/recreational marijuana six years ago instructed MROs that they must not change a positive to a negative result for a medical marijuana excuse. The individuals in our regulated industry know they are subject to testing and know that there are no excuses for the use of marijuana.

The amphetamines, represented by the blue line, are increasing with time. Cocaine continues to drop. The opiates and PCP, with six month numbers around 600, trend consistently. Annually, we detect about 1,200 PCP positives, which is absolutely inexcusable in the transportation industry.

This slide depicts percentages instead of positive test results. The THC positivity rate is at 0.76 percent, amphetamines at 0.56 percent, cocaine at 0.23 percent, opiates at 0.22 percent, and PCP at 0.02 percent.

The eCCF is a tremendously popular subject in our industry. Folks were very, very interested in its implementation. We issued our Final Rule on April 13th. In that rule, we informed employers, collectors, laboratories, and MROs that they can use the eCCF, but only when the employer's laboratory has been approved by the HHS NLCP. The eCCF requires the same collection and distribution of information to the relevant parties as the paper eCCF requires. That is an important point for our industry because they inquired whether they would have to report more or less information. How does this change the basic requirements? As we have explained to everyone, this is a HHS form and not a DOT form. HHS was required by the OMB to provide an opportunity for an eCCF. It was not necessary for us to do separate rulemaking because we were not changing any elements of that form since that was an HHS determination. It was also important for us to remind our industry that nothing changes because the same data are collected and the same processes apply. We have been very clear with the public that this Final Rule does not require entities to use an eCCF. On April 14th, the day after the rule was published, we received phone calls into our office from individuals asking whether they were required to convert to the eCCF. We said, first of all, you would follow your laboratory's instructions. You will receive information as to whether or not your laboratory is approved to use an eCCF. Secondly, the eCCF is not required. Rather, it will be available for use. We believe that the efficiencies of using the eCCF should encourage a tremendous number of companies into eCCF reporting. The eCCF, ultimately, will provide us better data and more information that we can use in our safety-related rulemaking. Overall, it is a tremendous initiative. Again, we applaud SAMHSA for their leadership on that. Through our rulemaking, we wanted to remind employers that the use of the eCCF requires that they must establish adequate confidentiality and security measures to ensure the confidential employee records are not available to unauthorized persons. Charlie LoDico specifically mentioned this during his presentation today. We discussed about how this includes protecting physical security records, access controls, and computer security measures to safeguard confidential data in electronic form. We require the same kinds of procedural safeguards to be put in place with respect to paper records. We posted this on the listserv. Many of the points I am covering today are examples of items that we post in our listserv to our 32,000 listserv recipients so that they would know and understand that the same confidentiality and security measures that are attached to the paper form will be in place for the electronic forms.

An employer who uses an eCCF must ensure that the collection site, the primary and split laboratories, and MROs have compatible systems. If not, they need to use the paper CCF. We place more of a burden on the employer to communicate with the others. It is important to note that electronic signatures are not acceptable throughout the rest of Part 40. We tried to make this clear through the rulemaking. One amusing anecdote was the number of people who contacted us afterwards inquiring why they couldn't use electronic signatures. They were assuming that there was some provision to allow electronic signatures. We clarified that for

everyone by stating that no, this is the one exception we have made so far. The rest of Part 40 has not turned to electronic signatures. For example, when an MRO reports a result under our Section 40.167, electronic signatures are not allowed on those reports. Again, it was a reminder to our industry and probably a good refresher.

Shown here is our ODAPC staff. I serve the Acting Director. Bohdan Baczara is our Acting Deputy Director. Mark Snider and Cindy Ingrao are our Senior Policy Advisors. Vicki Bellet and Maria Lofton constitute our administrative staff. John Sheridan, Bob Ashby, and Don Shatinsky are our consultants. Anne Bechdolt serves our General Counsel Attorney.

Our website is <http://www.transportation.gov/odapc> If you don't already subscribe to our listserv, I would strongly encourage you to go to our website to sign up for the listserv on the right hand side of the page. You will get pertinent updates regarding our rulemakings and SAMHSA rulemakings. We worked in close partnership with SAMHSA to make sure that we inform everyone about the proposed changes to the urine MG, the oral fluid MG proposal, and the hair testing RFI. Again, I encourage you to sign up for those.

Our technical assistance includes 12,000 emails, phone calls, Ask ODAPC, and other interactions with the DOT Program Managers and our regulated public. Now, our listserv has approximately 32,000-33,000 recipients. Last year, we had almost 600,000 visits to our website, making ODAPC's webpage one of the most consistently popular at DOT, which is pretty amazing when you consider how tiny our staff is. Our website is heavily relied upon by the transportation industry.

Our horizon issues include the drug impairment studies, testing for additional Schedule II drugs, and oral fluid alternative specimens. We support National Highway Traffic Safety Administration (NHTSA) and SAMHSA in their research efforts. When I submitted these slides, not everything was in full motion. I applaud our very, very busy HHS scientists, who have been moving forward with all of these issues at once.

Shown here is our headquarters building. Thank you all for the opportunity. Does anyone from the Board have any questions?

Dr. Cook: If any of the Board members have a question for Patrice, please state your name and your question.

Dr. Ferguson: Could you give me your definition of tampered specimen?

Ms. Kelly: That would be substituted, adulterated, and invalid, Jim.

Dr. Ferguson: So it is all of the invalids from both immunoassay and GC-MS.

Ms. Kelly: Exactly.

Dr. Ferguson: Even though there could be medical explanations for some of the reasons for the invalids.

Ms. Kelly: Yes, because remember this is the raw laboratory data and pre-MRO.

Dr. Moore: You mentioned that you can only test for use in your program. Could you comment a little more on that with regards to potential passive exposure for oral fluid and hair?

Ms. Kelly: Yes, I definitely can address that. Under the Omnibus Act, Congress limited us to testing for the use of the illegal drugs. We have to be very careful at DOT to make sure that any testing that we bring in to our purview will detect only use and could not possibly detect exposure. If it is testing for exposure, then our position is that it could result in all positive test results being overturned for that specific drug if we can't prove that it is use only. We could end up with situations where private employers have positive test results that may get overturned. When our cases are heard at the D.C. Circuit Court, it is not just one case that is involved and one individual. It starts out that way, but when a court makes a ruling, it affects all similarly situated people. The Omnibus Act tied us more tightly than our own regulations had by saying we had to prove use. As we move forward, we recognize that we have a constitutional principle to protect the Fourth Amendment search and seizure requirement as being a reasonable one per the principles laid out by Congress in the Omnibus Act. There is also a moral end to this where we know that we must not go beyond the authority that Congress has given us. It is an area that DOT is watching with much interest and hoping very much that we can utilize alternative methodologies. Those issues of use versus exposure must be absolutely resolved scientifically so there is no explanation that somebody might have been exposed and not using the drug that they tested positive for.

Dr. Moore: Thank you.

Dr. Collins: For your PCP data, I am assuming the data are based on laboratory-submitted data. Do you have any additional information that would show a geography relationship in those positives?

Ms. Kelly: We don't have anything on that right now. The way the laboratory data are submitted to us, it is not sorted geographically. Any information we have is anecdotal, for instance when somebody says, yes, I see more of that here versus there. No, the data are not sorted that way, unfortunately. As we move forward with the eCCF, it will become easier to track data that way because it will be reported by the laboratories electronically. The laboratories won't be rekeying it to determine the geographic aspects. That is another reason why we are so eager to see the eCCF implemented.

Dr. Cook: Are there any other questions from the Board? Thank you, Patrice. Our next speaker is Paul Harris, Senior Project Manager in the Fitness for Duty Program (FFD) in the U.S. NRC.

NRC 10 CFR Part 26 Fitness for Duty Program

Mr. Harris: My name is Paul Harris. I am the Senior Program Manager for 10 CFR Part 26, which is the FFD Program, particularly the drug and alcohol provisions within those regulations.

I wanted to thank HHS, and especially Ron Flegel and Janine Cook, for inviting the NRC to make a presentation to the DTAB. We have been presenting this annual update for about four or five years now. I also appreciate listening to the Board and its deliberations.

Throughout my presentation, feel free to interrupt me. If I have a slide up there or I make a comment and you have a question, please interrupt and I will take your question at that time.

Also with me today is Mr. Brian Zaleski, NRC's Fitness for Duty Program Specialist.

Consistent with the President's National Drug Control Policy, the NRC continues to coordinate with federal partners and NRC licensees to enhance the identification of deterrents of substance abuse at NRC-licensed facilities and affected contractor/vendor organizations. We do this to provide reasonable assurance that the nation's commercial nuclear power industry maintains a drug-free work environment and that the people working at these facilities are free from the presence and effects of both legal or illegal drugs and alcohol so that they can perform their duties safely and confidently.

I have ten slides today discussing the FFD Program and results from our 2014 drug and alcohol testing results. However, there are three primary messages that I want to stress right away. The first one is the prevalence of drug and alcohol use and abuse in society continually challenges the effectiveness of the 10 CFR Part 26 FFD Program. Number two, subversion and adulteration of urine specimens exist in the commercial nuclear industry, and this represents a significant staff concern. We fully support HHS's concerted efforts to publish the oral fluid MG and continuing efforts to assess the effectiveness of hair testing. The third message is that we cannot test our way out of this box. In the next few slides, you will see the breadth of the FFD Program, which incorporates other elements above and beyond drug and alcohol testing.

The hundred car freight train rolling along at 100 miles per hour is filled with impairing substances. Testing and after the fact testing and deterrence will not stop it. As a result, we have tirelessly worked to ensure that human performance errors caused by impairment do not result in the conditions adverse to public health and safety. In addition, persons who have access to strategic special nuclear material (Category 1A material (bomb grade material)), controlled information, and unescorted access to energy facilities must be trustworthy and reliable.

Today's topics include our mission, a summary of industry performance, historical trends, subversion trends, and the FFD Program electronic reporting system. All presented data in this presentation are MRO-verified. Therefore, our data are different from those presented by Charles LoDico and Patrice Kelly.

For Part 26, we have a mission statement: provide a direct contribution to public health and safety through effective regulatory oversight. This mission helps us in the development and support of licensing, rulemaking, and inspection of licensees and other affected entities. The NRC must establish and maintain a regulatory framework that effectively enables NRC licensees to meet or exceed the FFD Program performance objectives listed in 10 CFR that require a licensee FFD program to provide reasonable assurance that persons are trustworthy and reliable, not under the influence of any legal or illegal substance or physically impaired from any cause, and not fatigued or in a state of diminished mental or physical capacity. We also require the licensees to maintain a drug-free and alcohol-free work environment that is consistent with President Reagan's Executive Order, which established the Federal Drug-Free Workplace Programs.

We are working diligently to propose a proactive rule for substance abuse issues that challenge human performance at NRC-licensed facilities. For example, we want to enable more effective MRO access to prescription drug monitoring programs that are being implemented by the states. This access should help inform MRO determinations, such as whether or not individuals are drug shopping or not declaring prescription medications that could cause impairment.

We look forward to working with local and national labor unions to supply a trusted nuclear worker to help the commercial nuclear industry conduct maintenance and surveillance at these facilities. I will discuss why I mention that.

Thirdly, we are working to enable a fitness determination process prior to the conduct of safety and security significant work activities if a worker's physiological or mental baseline performance changes. I will discuss that more in another slide.

In 2014, we had 75 programs within the industry, which covers approximately 100 nuclear reactors throughout the country, supplying approximately 19 percent of the baseline electrical generating capacity in the U.S. In 2014, 166,000 individuals were tested; of these, 1,132 were tested positive. The graphs indicate the trend associated with these data. Sixty-seven percent of all of our positive tests occur on pre-access testing. This is why I mention the concept of a trusted nuclear worker within the contractor-vendor arena. The majority of our positive, adulterated, and substituted test results are occurring on pre-access testing. This number has remained consistent over the years, ranging from 60 to 70 percent. Twenty percent of all testing violations occur on random testing. I will discuss what is happening inside the power plants when we conduct random testing. The overall industry positive rate is 0.68 percent. The industry rate for licensee employees is about 0.23 percent. The positive rates for contractor/vendors that are helping with the maintenance and surveillance of these facilities and the construction of a new nuclear reactor are significantly above this at about three times the rates for licensee employees. This trend has been consistent for the last five to ten years. The random testing rates are similar. The random positive rate is 0.14 percent for licensee employees, indicating that the permanent employees at these nuclear power plants are testing approximately three to five times lower than the contractor/vendors that are coming on site for

temporary work activities. The commercial nuclear industry is a mature and highly professional industry. These testing rates demonstrate that. The employees of these facilities are dedicated to safe operation of their nuclear power plants and materials licensees. They are definitely the silent heroes who keep these power plants operating safely and competently. If we remove contractor/vendors from these overall rates, we see an approximately 10 percent reduction in the overall industry testing rates. We could supply those specific numbers to the DTAB at another meeting.

On this slide depicts the numbers broken down by test category type, licensee employees, contractor/vendors, and the total. There are only a few key elements that I want to point out. Under pre-access testing row, approximately 9,500 licensee employees were tested, resulting in 27 positive occurrences. We tested about 82,000 contractor/vendors, resulting in 735 positives. At the bottom of that table are the relative percentages and the totals. Licensee employees tested positive 118 times in 2014. With approximately 100 reactor plants in the U.S., this equates to approximately one positive test per site in 2014, indicating the maturity and the professionalism of this workforce. The contractor/vendors, even though they are approximately ten times the testing rates, have three times the positive rate. Approximately 1,014 or 90 percent of all the positives that occurred were because of the contractor/vendors on pre-access.

Post-events are a significant indicator for the NRC because we are concerned about the types of events that are occurring at these power plants and whether or not they are caused by individuals who might be under the influence of a drug or alcohol. For licensee employees, we had one positive. For contractor/vendors, there were 12 positives. Those numbers are relatively low and have been pretty consistent. We are seeing a small increase in the number of post-events for contractor/vendors. That is primarily due to the increase in construction activities that are occurring at the two new reactor construction sites down south. Thus, we don't find these numbers to be very surprising.

On this slide, notice that the percent positive rate for licensee employees is 0.23 percent. Whereas, the percent positive rate for the contractors/vendors is 0.88 percent. The NRC staff is highly focused on pre-access testing because we want to stop the users from coming on site. The NRC staff believes that by pursuing a more proactive approach on drug and alcohol testing and screening of individuals prior to coming on site, we can drive these numbers down to provide a safer, more secure facility.

This next slide shouldn't be too surprising to anyone who has looked at drug and alcohol testing results. Alcohol and marijuana continue to be the most prevalent drugs. For licensee employees, alcohol is number one. As Patrice said, it is a form of a self-medication. We have indications that individuals are using alcohol and testing positive. Approximately half of all the positives are alcohol followed by marijuana. For the contractor/vendors, marijuana tends to be the drug of choice. This doesn't surprise me as well because of a general societal acceptance of marijuana. This is followed by alcohol, cocaine, and the amphetamines.

The refusal to test is always a concern for me because it represents the subversion and adulteration of the urine testing process. Therefore, the NRC staff anticipates the oral fluid initiative that HHS is proceeding with. Furthermore, the NRC staff is pursuing efforts to evaluate the conduct of hair testing to provide further assurance that individuals are trustworthy and reliable prior to coming on site.

We enabled the commercial nuclear industry to test for drugs above and beyond the federal drug testing panel of five drug panels. We are not seeing too much of an indication of other drugs in the contractor/vendor pie chart. In the far lower right hand corner is the other drugs category, which includes oxycodone, oxymorphone, hydrocodone, and methadone. We have seen one propoxyphene.

This graph is a pie chart represented linearly. Focus specifically on the y-axis where each one is a relative percentage off of 100 percent. For marijuana, there was a dip in the 2006-2007 timeframe followed by an increase in 2008. In 2008, we issued a very substantial change to 10 CFR Part 26. The identification of additional marijuana use is probably due to the implemented change in testing methodologies.

In addition, around that same timeframe, we saw a significant decrease in the amount of cocaine within the commercial nuclear industry. Was this a success of the Rule? I would like to say it is, but more work must to be done in this area.

Alcohol continues to be prevalent, as evident by my pie charts where a bump up increase was seen. The NRC has implemented time-dependent alcohol limits such that if an individual is on site for one hour, two hours, or three hours, the blood alcohol concentration limits are different at those timeframes. Therefore, we account for biological metabolism of alcohol in individuals and we, by regulation, lower our limits to ensure that we identify individuals who might be under the influence of alcohol when they first report to duty and when they are on duty within the station.

Next are amphetamines. Similar to what Charlie LoDico and Patrice Kelly mentioned earlier, we are seeing an increase in amphetamine use. The NRC has not yet lowered its amphetamine cutoffs to match the HHS MG cutoffs for amphetamines or for cocaine either. Once our rulemaking becomes proposed and final, which should occur in 2015, we should expect to see an increase in the cocaine and amphetamines identifications. In 2014, the prevalence of amphetamine positives finally exceeded cocaine.

Though opiate positives are low, we continue to track those. In addition, we are looking forward to the changes in the urine MG for the additional semi-synthetic opiates.

One of my key elements that I want everyone to remember is listed as item number two - subversion attempts and adulteration products. We do see these in the commercial nuclear industry. I am concerned about that, the rest of the staff is concerned about that, and the industry is concerned about that. There are some good collection processes to help identify

subversion and adulteration at the collection facility. We have very few adulterated products or adulterated test confirmations returned from the laboratories. The preponderance of subversion identifications are occurring at the collection facility, demonstrating the effectiveness of the collectors.

Since 2012, we have implemented an electronic reporting system. This system is the most sophisticated and accurate drug and alcohol reporting system that I know of that is being utilized by a private entity such as the commercial nuclear industry. Shown here is a snippet of some of the subversion information that we receive. For every subversion attempt, the licensees provide this voluntary information and submit it to the NRC for evaluation. We have very detailed data on how these subversion attempts are being caught. We have very detailed data on what the licensees are doing to detect subversion and what kind of corrective actions they are implementing. The licensees check off the appropriate blocks, such as refused to provide initial specimen; refused to provide a second specimen; temperature was out of range; paraphernalia was identified; specimen characteristics such as color, odor, or precipitant were identified; invalid test results; and refusal to follow instructions. Shown here are subversion attempts from 2012 to 2014. For the past few years, we have been consistently around a 15 percent subversion rate. Of our 1,100 positive adulterated substituted test results, about 15 percent are due to subversions. These are the ones we are catching; I would like to know about the ones we are missing. In 2014, 72 percent of all subversion attempts are detected at pre-access testing. Ninety-six percent of those subversion attempts are made by contractor/vendors, who are the short-term workers who come to nuclear power plants to conduct maintenance and surveillance activities or to help build the nation's commercial nuclear power reactors. This is why we are focused in on this employment category.

Because we receive this detailed information from the industry, we can better inform our inspectors. If we know what kind of subversion is occurring and when that subversion is occurring, we can timely inform our inspectors before arriving at the facility on when and where that type of subversion is occurring. Inspectors can focus their inspections to ensure that licensees are consistently implementing good collection processes that are based on the HHS MG to identify those individuals who are trying to subvert a drug test.

This table provides additional detailed information from 2013 on the first collection, second collection, and the subversions. I did not have time to update it to the 2014 data. The number of subversions was 145. With about 100 reactor plants in the U.S., this equates to about one per reactor site. This is still a concern because the donor has definitely demonstrated that he is untrustworthy, unreliable, and should not be within an NRC-licensed facility.

We typically see a large number of specimens being out of temperature, either high or low, indicating that the individual is trying to subvert the temperature, whether by an adulteration material or by submitting another's urine. About 104 of the 145 specimens collected indicated out of temperature. Mapping of subversion attempts this way has been possible since about 2012. Inspectors are very familiar with this type of information. The majority of all of our subversion attempts are identified on collection. Very few are being detected by the

laboratories. In fact, based upon 2013 data, only six of 145 subversion attempts were laboratory-identified.

Concerning electronic reporting, on the NRC's website are OMB-cleared forms that the licensees voluntarily use to report to us required information, demonstrating commendable licensee performance. These electronic forms are voluntarily used by the licensees to not only provide us with the required information but also to provide detailed amplifying information by which we can inform the inspection process and our rulemaking based upon their corrective actions and the information that they are providing us in the comment blocks on these forms.

In addition, we have a desktop application, which allows us to extract the information from these forms. We can present the information in a manner in which we could target specific areas within the nuclear industry for inspection.

A DTAB member previously inquired whether we can examine the data geographically. Well, I can search the data by site, geographically, by all the construction reactors, and by all the multi-unit reactors. Two years ago, at a meeting with the International Brotherhood of Electrical Workers, they were interested in the specific drug prevalence within their unions based upon the geographical location of the union. We can now provide the union halls with this type of information so that the unions can test their workers prior to entry to the nuclear power facilities to conduct maintenance and surveillance. The utilization of these forms demonstrates the industry's commitment to openness, transparency, and continuing improvement.

You are free to call or email us if you have questions regarding program implementation. Will Smith is not here with me, but Brian is.

In summary, I want to review my three key points one more time. First, the prevalence of drug and alcohol use and abuse from society continually challenges the effectiveness of our program. We work with HHS and other federal agencies to ensure that the workers at nuclear power plants are trustworthy and reliable. Secondly, subversion and adulteration continue to exist and are a significant staff concern. We are working to address those, primarily in the collection area because that is where the boots hit the ground and we can really have an impact. Number three, I don't believe we can test our way out of this box. This is why we need a defense in depth process by which we ensure that we have trusted nuclear workers prior to granting them access to NRC-licensed facilities. The only way we can do that is through aggressive pre-access testing and good outreach programs with the unions, such that they supply the nuclear industry with trusted nuclear employees or workers. We are pursuing a proactive regulatory approach to ensure that our MROs have open and unfettered access to state prescription drug monitoring databases to ensure that individuals are not shopping for prescriptions or not declaring prescriptions to the medical staff at the nuclear power plants.

That is my presentation. Do I have any questions from the DTAB members?

Dr. Collins: I have a couple of questions. The first is that you indicated that your licensees have the ability to test for additional drugs. What percentage of your licensees has incorporated that into their program?

Mr. Harris: I will defer to Brian Zaleski to answer that question.

Mr. Zaleski: It is a handful of licensee operations that are testing for additional drugs. A few licensees are testing for the semi-synthetic opiates. One licensee has been testing for as long as I have been looking at the data for the benzodiazepine diazepam and methadone. We also provide the opportunity for licensees to test at more stringent cutoff levels, but no one is currently doing that. In addition, they are permitted to test for Schedule I through V drugs. Most indicate that they have difficulty doing so because of primarily union issues.

Dr. Collins: Thank you. In your rule, licensees are permitted to test to the limit of quantification (LOQ) on a specimen when it is reported as dilute and there is an elevated immunoassay response. Do you track what percent of your overall positives are found as a result of that additional permitted testing?

Mr. Zaleski: Yes, we do that as well. Off the top of my head, I think between 10 to 20 positives a year are found that are associated with dilute specimens that are tested at the limit of detection (LOD) or LOQ. Unfortunately, we don't collect data on the drug quantification. I couldn't tell you if that LOD testing was the result of that or whether it was a dilute specimen that was also positive at the normal cutoff level. The majority of the individuals that are identified as diluting their specimens are marijuana users. That is not surprising because more than 50 percent of our contractor vendors are using marijuana or identified as using.

Mr. Harris: For the rest of the individuals listening on this conference, the LOD and LOQ testing that we do on dilute specimens is a voluntary program enabled by regulation under Part 26. However, it is not a requirement.

Mr. Zaleski: Ninety percent of the licensees are testing to LOD/LOQ for dilutes. I don't think many donors are using dilution as a method to beat the testing process anymore. They prefer substitution, as we noticed with our identified subversion attempts.

Mr. Harris: Any other questions? Well, thank you very much.

Dr. Cook: Thanks Paul. Our next speaker is Colonel Tom Martin, Deputy Director of the Drug Testing Program Policy in the Office of the Undersecretary of Defense for Personnel and Readiness in the Operational Readiness and Safety in the Department of Defense. I just learned today that Tom received a promotion to Colonel.

DoD Drug Testing Update

Dr. Martin: I appreciate everyone being on the call today. I am looking forward to presenting a short overview of the DoD Drug Demand Reduction Program (DDRP), some military testing data, and our DoD agency civilian testing data.

First, my office, which is part of the Personnel Risk Reduction Office, resides within the DoD. Ours is a drug demand reduction program where we do policy, direction, and oversight. We also have another function, which is a safety analysis program as well as mishap avoidance.

Of course, we have a mission and vision. Overall, we want to drive preventable mishaps as well as illicit drug abuse to zero. Listed here are a variety of different venues by which we are able to do it within the department.

Ours is a very small office, with a director, Mr. Litton, an assistant, and the three different areas. I am the director of the DDRP and have two individuals who work for me. That is our entire program. We also have the accident reduction program as well as the risk systems, which is essentially a database for monitoring accidents, assessing trends that occur, and developing different avoidance techniques or systems to minimize those mishaps from occurring in the future.

I fall under the Office of Personnel and Readiness. Drug abuse in the military affects individual and unit readiness. We consider it both a readiness and safety issue. To have an effective program, we must deter drug abuse, detect use within our individuals, and then hold those individuals accountable for the choice to use or abuse drugs. Drug abuse does cross all ages and ranks. Drug testing does consume the limited resources that we have in the department. We strive to maximize our efforts in our deterrence mission. Since we invest much time and money in our service members, there is a significant loss on that return on investment if these individuals test positive and are removed from service. Overall, in FY14, a little over 15,500 service members were MRO-verified drug positive.

Dr. Cook: Do you have a percentage for that number?

Dr. Martin: Overall in the entire department, we were at 0.088 percent positive rate in FY14.

Our mission is to deter illicit and prescription drug abuse in both our military service members as well as our civilian agencies. We also have prevention, education, and outreach missions as well. As new drugs come into the system, we strive to identify those and develop or adapt testing procedures to detect their use. There is a variety of regulatory guidance that we follow.

The majority of our recruits are 18-25 year old males. They have the highest positive rate within the department. Before we instituted the program, there was significant drug abuse among service personnel. Starting in Vietnam, there was an estimated over five percent of service members returning to the U.S. who were addicted to heroin. An incident in 1981 that drove or changed the program from a treatment-type program to a disciplinary program was the accident on the aircraft carrier Nimitz.

We have been testing synthetic or semi-synthetic opiates for quite some time. We are seeing an increase in their abuse and misuse amongst our personnel, especially those outside that 18-25 year old group.

Personnel that abuse illicit or prescription drugs poses a safety hazard, resulting in the potential loss of equipment, resources, as well as lives.

Recapping a short summary of our history, in 1971 our program began in response to our returning addicted Vietnam veterans. In 1981, the aircraft carrier Nimitz aviation mishap results in 14 servicemen killed, 48 injured, 7 aircraft destroyed, 11 damaged, and over \$150 million in damages in 1981 dollars. Autopsies revealed detectable levels of marijuana in six of those deceased service members. They couldn't definitively pinpoint marijuana as the cause of the crash, but that information alone changed the tenor of the program for the department. Later on in that year, authorized punitive actions, including court martial as well as military separation, were instituted for those individuals who test positive. We formalized as a program with a directive. We have the Executive Order for federal civilians. In 2010, the Chairman of the Joint Chiefs of Staff requested a review. He requested more funding and provided more funds to expand our program to include prescription drug testing for the opiates and benzodiazepines.

If you are not familiar with our program, we have six DoD laboratories as shown here. There are two Army laboratories, one in Hawaii and one at Fort Meade, MD. The three Navy laboratories are located in Jacksonville, FL; San Diego, CA; and Great Lakes, IL, which is just north of Chicago. The Air Force laboratory is in San Antonio, TX. I want to highlight our new facility at Great Lakes, IL, which opened on April 27th for business. This picture was obviously taken during the construction period this winter. I was there a few days ago.

Listed here is our current panel of drugs and their screening and confirmation cutoffs. There are some differences between the civilian and military programs. In particular, for the amphetamines as well as methamphetamine, we only report a concentration for the d-isomer of both.

Shown in this slide is the drug distribution for our active duty service military members who tested positive. These are the unique numbers; if a service member tested positive more than once in that fiscal year, it is only counted once. Marijuana is our number one drug amongst the military population followed by cocaine. The third most prevalent is d-amphetamine followed by oxymorphone.

We have been testing oxycodone and oxymorphone since 2006. For the most part, that was at about a 35 percent testing level; that is only about 35 percent of specimens submitted to any of those laboratories were tested for oxycodone. In 2013, all specimens are tested at 100 percent for those drugs. The semi-synthetic opiates results are highlighted to show that there are significant numbers of individuals or service members who have tested positive for those. Not

surprisingly, the majority of those who tested positive were outside that 18-25 year old male age group or category. In FY14, we saw a large decrease in positives overall for those drugs. We are keeping our fingers crossed that this trend will continue. That is a good news story for us.

Shown here is the overall military positive rate since 1987. The positive rate in 1987 was around 3.5 percent. A significant decline coincides with when we implemented punitive actions. Since then, the positive rates have stayed steady somewhere between 1 and 1.5 percent over the years. As drugs were added to the testing panel, we see an increase, but overall, we are right around one percent. In FY14, positivity was 0.88 percent.

Breaking the data down by component – active duty, reserve, National Guard, and military applicants - a difference in the positivity rates are evident. It is not surprising that our National Guard and reserve members have higher rates considering that the majority of their time is spent on the civilian side. The active duty rate is much lower. For the military applicants, we have seen a very significant decline since 2009, which is good news for us. However, I need to caveat that the testing panel for our military applicants is different than for our active duty or service members. For our military applicants, they are only tested for marijuana, cocaine, amphetamine/methamphetamine, and the designer amphetamines.

We have are also trying our best to address the synthetic marijuana or Spice problem. We are aware there are a large number of Spice variants out there, and they continue to change. The challenge is developing a low cost screen to test large numbers of specimens. At the end of December 2013, we started random testing. In calendar year 2014, the positive rate was almost exactly the same as what we saw for Ecstasy or 3,4-methylenedioxy-methamphetamine (MDMA). We are in the process of adding testing for five additional metabolites. We anticipate starting right around July 1st.

On the military side, we have the ability to rapidly change our testing panel as we respond to a threat. For example, with Ecstasy, oxycodone, oxymorphone, and the other drugs listed here, we were able to change our testing panel. We adjust our panel based on prevalence testing. We use results from a random sampling of service member specimens to determine what is there and whether it meets a criterion. If a drug does, we go directly through my office to the Undersecretary of Defense for Personnel and Readiness and ask him to sign the policy to change the panel. Typically, it is less than a year for that whole process to take place.

We are very proud of our ability to capitalize on our automated MRO review process. All military members who use Tricare insurance have their prescriptions tracked within that system. We are able to compare our laboratory results to that system to essentially perform an electronic medical review. This allows us to replace the actual MRO review. This process has been in place for a little over three years now. In FY14, a large number of positive specimens were not subjected to an actual MRO review but rather an electronic review.

For our DoD agencies, all testing is performed at the Forensic Toxicology Drug Testing Laboratory at Fort Meade, MD. That laboratory is dual certified for the military testing component and a completely separate civilian testing component.

Over the past three years, the overall positive rate has stayed about the same. For those in testing designated positions, a little less than 0.4 percent were positive. Applicants were a little bit higher.

On the next few slides are the actual laboratory-reported positives and the true MRO-verified positives. On the left side of this slide are the total number of positives reported by the laboratory and further broken down by unauthorized use, authorized use, and then total. A large majority, or about 25 percent overall, are considered unauthorized use for all the reported drugs except for a spike in 2011. By drug, it is not surprising that the majority of the methamphetamine positives are unauthorized use. Looking at each drug individually, in 2012 there was a large spike in the number of amphetamine positives. However, the majority of those was authorized use. That has remained constant throughout. Methamphetamine is just a little bit different. There was very little authorized use for methamphetamine from the MRO perspective. For codeine results, there is very minimal unauthorized use as well. Morphine had a little bit higher number of unauthorized use.

That concludes my presentation. I am open to any questions from the Board members.

Dr. Cook: I was very interested in the synthetic cannabinoid metabolites for which you are testing. Can you describe that process and how you selected those metabolites?

Dr. Martin: We performed prevalence testing at two of our laboratories. At the Air Force laboratory in San Antonio, they have the capability to test for synthetic cannabinoids. They took a random sampling of the specimens submitted to that laboratory and tested those to see what was the most prevalent based on what they could test for at that time. We also utilize the Division of Forensic Toxicology at the Armed Forces Medical Examiner System as our quality assurance arm. They perform our PT and manage our inspection process. They also performed the prevalence testing at the same time with specimens from several different laboratories. Based on the results from those two laboratories, the most prevalent drugs that they were able to test for were determined. We continue to monitor them in real time and try to change as the metabolites change. We are definitely behind. The manufacturers change things much faster than we can test for them.

Dr. Cook: Thank you. Does any Board member have a question for Tom? Tom, thank you very much.

Public Comments

We have now come to the public comment period of our agenda. At noontime, no one had registered yet to give public comment. Is there anyone who has not registered but would like to

give public comment at this time? If so, please press star one to alert the operator so she can open up your line.

Operator: Currently, there are no participants in the queue.

Dr. Cook: I will officially adjourn this meeting. Thanks everyone.

(Whereupon, the meeting adjourned at 2:30 p.m.)