

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

**Meeting of**  
**SAMHSA's CSAP Drug Testing Advisory Board (DTAB)**

**May 20, 2016**

**Conference Room 16SEH02**

**5600 Fishers Lane**

**Rockville, Maryland**

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## **Call to Order**

Matthew Aumen, Acting Designated Federal Officer (DFO), DTAB

MR. AUMEN: Good morning, everyone. My name is Matthew Aumen, and I am the (DFO) for the Drug Testing Advisory Board or the DTAB. As DFO of the DTAB, I officially call this meeting to order.

This open session is scheduled to convene from 10 a.m. to 12:30 p.m. today. Thereafter, the Board will convene in closed session beginning at 1 p.m.

The DTAB has its own website which is located at the link shown 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.

If you have questions or comments concerning the material presented during the open session, please submit your questions and comments by pressing star one to contact the operator. The Board will consider submitted questions and comments during closed session. They will not be considered during the open session.

The public comment period is scheduled to begin at 12:00 p.m. today. The exact time will be dependent on our progression through the agenda. Currently, there are three attendees who have registered to give public comments. If anyone else wishes to give a 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 will be equally distributed among all the commenters. Public comments will be included in the meeting minutes as well as in the transcript, so if possible, please provide an electronic copy of your comments to accurately record those comments with the transcriptionist. The Board will not be responding to any public comments at this time but will take them under consideration in the 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 the Adobe Connect conference line that we have set up on the web using your computer speakers, or you may listen over the phone. If you use your phone, you must mute your computer speakers to avoid audio feedback. Board members and presenters may also want to mute your phones 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 they may interfere with the audio and visual as well as the transcription equipment in the room. This statement will also apply to public commenters during the public comment period later today.

I want to welcome our DTAB Board members: Jennifer Collins, Tony Costantino, Jim Ferguson, Ron Flegel, Greg Grinstead, Tony Iannone, Denise Johnson-Lyles, Patrice Kelly, Susie Mills, Madeline Montgomery, Christine Moore, Buddha Paul, and Jasbir Singh. I wish to extend a warm welcome to our newest Board member, Tony Iannone, who joined the Board in November. In addition, I wish to extend my deepest appreciation to Dr. Marilyn Heustis, who retired from federal employment, and thus the DTAB, in January. Marilyn had served on the DTAB for three and a half years. And finally on behalf of the Board and Division of Workplace Programs (DWP) staff, I wish to extend our sincerest condolences to the family of Bobby Bonds, a former member of the DTAB, who passed away last fall.

I also want to recognize our DWP staff: Ron Flegel, Sean Belouin, Deborah Galvin, Eugene Hayes, Giselle Hersh, Charles LoDico, Coleen Sanderson, and Hyden Shen.

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

The dates for the remaining FY16 DTAB meeting are July 26 and 27, 2016. Whether the upcoming July meeting will convene in open or closed session or on-site or by web conference only will be decided at a later date.

The following disclaimer, which applies to the remaining presentations that will be given today, I will read verbatim. Today's presentations do not reflect the views of The Department of Health and Human Services (HHS) or SAMHSA, nor does it constitute an endorsement of the presenter, the presenter's views, the presentation subject matter, the organizations mentioned during the presentation, or other entities, methods, products, and information referenced during the presentation.

Finally, I would like to introduce Ron Flegel, the director of DWP, who will be extending his welcome. Thank you.

### **Welcome and Introductions**

Ron R. Flegel, Director, DWP, CSAP, SAMHSA

MR. FLEGEL: Thank you, Matt. I do apologize for starting a little late. We wanted to make sure everyone was on the conference. I would like to thank the Board members, federal agencies, and the public for taking the time out of their busy schedules today to join us for the DTAB meeting. Over the next several hours, we will be updating the progress of the federal agencies and DWP on the final Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG) for urine and oral fluid.

I would also like to report we convened a scientific and technical (S&T) meeting on hair on May 11 to the 13th. In attendance are many industry leaders who worked closely together to answer the questions and concerns that have been expressed by the hair testing industry and the Board. The DWP staff was observers in this process.

We would also like to thank the public and industry representatives present with us today. Many thanks also to the government agency representatives who are providing today's updates and to the experts who have engaged and facilitated discussion surrounding the MGs for urine and oral fluid. We welcome and look forward to hearing the federal agencies' presentations, comments, and information.

The purpose of this meeting is twofold. First, in open session, several government agencies, namely the Department of Transportation (DOT), the NRC, the DoD, and the Federal Workplace Drug Testing Programs led by SAMHSA will provide updates regarding federal drug testing policies. Second, in closed session, we will review and discuss the final revisions to the final MGs for both urine and oral fluids. The resulting conversations with the DTAB members have a direct impact on the MGs for urine and oral fluid. The suggestions made in these DTAB meetings have provided some of the guiding principles for drug testing and federal government agencies. This meeting will ultimately benefit employers and employees of the federal government and the nation as a whole.

As mandated by Executive Order 12562 and Public Law 100-71, DWP develops and revises the MG. The DTAB was created with the intention of allowing experts in biochemistry, toxicology, hair testing, laboratory

operations, and others to advise the SAMHSA Administrator on the development of revisions to the MG, including new drugs of abuse and methods necessary to detect their presence.

Regarding the DWP status updates, the Office of Management and Budget (OMB) will review the final revisions to the MGs for both urine and oral fluid. In preparing these final revisions, SAMHSA considered comments and recommendations made by federal agencies, OMB, and the public. The final oral fluid MG and final revisions for the urine MG will serve to enhance this regulatory program, which is designed to deter illicit drug use in federal agencies and in the federally regulated industries. While the focus of the urine and oral fluid MGs is to develop the federal standards for workplace drug testing, these guidelines will also be important to private companies and other public sectors as well for establishing federal standards for oral fluids and oral fluid testing in other programs.

DWP staff and the Medical Review Officer (MRO) working groups have updated the MRO Manual to include the review of workplace prescription drug results. As you know, opioid painkillers are responsible for thousands for prescription drug overdose deaths each year. Workplace drug testing may now be one of the keys to early intervention and prevention.

DWP would also like to congratulate the laboratories that had been approved to implement the electronic custody and control form (eCCF). The list of approved laboratories is posted on the SAMHSA DWP website. We continue to work with those HHS-certified laboratories that plan to use the eCCF in the future.

DWP continues to focus on the special projects, including the research studies we have undertaken in conjunction with the National Laboratory Certification Program (NLCP). Some of the special projects include prescription opioids (oxycodone, hydrocodone, oxymorphone, and hydromorphone) for their oral fluid and urine excretion patterns; the passive inhalation of cannabis smoke; updated studies with high potency cannabis; oral cannabis consumption, pharmacokinetics, and pharmacodynamics; and the conceptualization design of a study to compare the effects of marijuana when administered by smoking and vaporization modes. Study results have been published in peer reviewed journals and presented at the 2015 Society of Forensic Toxicologists meeting. Additional journal articles will be published in 2016. Other special projects for hair scheduled in the coming years include the search for unique drug biomarkers in hair; comparisons of hair with other biomatrices, including oral fluid and urine; and development of hair proficiency testing (PT) specimens. Future projects will be designed and conducted to clarify and resolve issues with other specimen types, which may allow their use in federally regulated workplace programs.

I would also like to mention DWP's Prevention of Prescription Drugs in the Workplace initiative, which has several technical assistance products, including a series of one-page fact sheets, a Marijuana Toolkit that is currently under review by federal agencies, the Marijuana Smartbook, and several other DWP initiatives using oral fluid.

I would like to again thank you again for attending the DTAB meeting. I will turn it back over to Matthew.

MR. AUMEN: Thank you. I would like to do is introduce our presenter for this session who will provide the DOT drug testing update. Patrice Kelly is the Acting Director of the Office of Drug and Alcohol Policy and Compliance (ODAPC) with the DOT.

### **DOT Drug Testing Update**

Patrice Kelly, DOT

MS. KELLY: Thank you, Matt. This is Patrice Kelly, Acting Director of the ODAPC. Thank you very much to HHS, to my fellow members of the DTAB, and to the members of the public for the opportunity to talk with you this morning.

Shown here is a statement from DOT's Secretary Anthony Fox as to why this program is important. As many of you know, the DOT-regulated drug testing program is the largest of its type in the world. The Secretary is a firm supporter, and because of the issues and the scope of this program, we remain in the Secretary's Office and on the Secretary's staff.

Our function is to advise the Secretary and the DOT agency administrators on program issues, demand reductions, supply reduction, and DOT agency and U.S. Coast Guard drug and alcohol program activities. Even though the Coast Guard has been under Homeland Security since just after 9/11, they still remain part of our program. They have a Memorandum of Understanding with the DOT to use our regulations; they've never left our model roundtable.

We have ONE-DOT approach. For our procedures, including collection procedures, laboratory procedures, and return to duty procedures, we all follow 49 CFR Part 40. Our office also collects and analyzes data and information. During this presentation today, I will be providing to you information that we have gathered from the laboratories over the last several years, with the most recent data derived from the last six months of calendar year 2015.

Recognizing that we have some time constraints because we started late, I will move through my presentation as quickly as possible to get back on time.

ODAPC services include developing plain language regulations and providing consultation and liaison to other executive agencies as well as foreign governments. We do find that foreign countries have other testing methodologies that they have implemented, and we continue to have discussions, learn from each other, and exchange information. We also do presentations to industry stakeholders who we consider our customers, and that includes most everybody on this call. We see ourselves as very customer-oriented and strive to get the information and education out and be responsive to customer concerns.

Our program goal is ensuring the safety and security of the travelling public by reducing the demand for drugs, reducing alcohol misuse in the transportation industry, and creating prevention and treatment opportunities. Our regulations are not police actions. They are actions which deter drug and alcohol use. When someone is identified as having a problem, either through a test result or a refusal to test, he/she cannot be in a safety-sensitive position. Our regulations create treatment opportunities because the identified individual must be evaluated by a substance abuse professional (SAP) and successfully complete the treatment recommendation before he/she can resume safety-sensitive functions. It is not a ban on safety-sensitive functions as long as the individual has complied with that SAP process, successfully completed the treatment, and has a negative return-to-duty test.

We ensure the fairness and integrity of the testing programs. We maintain employee privacy and confidentiality. It is a balancing act under the 4th Amendment of the U.S. Constitution. We are doing a search and seizure. This is not a medical test. This is not a fitness for duty test. This is a search and seizure of individuals' urine so that we can determine whether or not they have illegally used drugs. We are also, in addition to the 4th Amendment balancing, bound by Omnibus Transportation Employee Testing Act. We often call it the Omnibus Act or OTETA.

Before the OTETA was enacted, we had regulations and maintained gatekeepers, who are the HHS-certified laboratories, to make sure the testing is reliable and accurate. We have evidential breath testing devices and MROs who find out whether or not the basis for the test result was due to a legitimate medical use or if the failed drug test is not due to illegal use. The MROs make their determination with SAPs, as I have discussed.

We make sure the systems are auditable and reviewable by the DOT agencies. We do thousands of inspections per year. Our office specifically works on plain language regulations, policies, and guidance documents.

Our program, with its focus on education and dissemination of information, requires our employers to have policies in place so that their employees know how our DOT programs works and what they need to know to stay in compliance. We also have employee prevention, education, and information to provide training on substance abuse. We have drug testing programs, licensed physician review of drug test results, alcohol testing programs to prevent alcohol misuse during safety-sensitive functions immediately before, during, or after removal from safety-sensitive duties for the violations as I discussed, the SAP evaluation, and rehabilitation before return to duty.

Our program history began with the regulations that predated the OTETA. We have had several rewrites of the regulations and several significant court actions. In addition, highlighted in green are the two marijuana statements we have issued - medical marijuana in 2009 and recreational marijuana 2012. In each of those statements, we told the MRO community that a state-issued recommendation for marijuana use, be it for medical reasons or recreational marijuana, is never an acceptable, legitimate medical explanation for a positive drug result. Not under the DOT program. We have made that clear to MROs, and you'll see in our data that the message has paid off. Transportation safety-sensitive employees know they cannot use marijuana and perform under our program.

The OTETA basically ratified what we were already doing, which I have already mentioned.

Here is what an overview portrait of how many employers and how many employees we have by DOT agency. This population has yielded about 6.3 million tests per year for the last two years. I will show you that data shortly.

In the DTAB world, the drugs currently tested are not a mystery. Outside the DTAB world, sometimes it is. People ask us if we have an 11-panel testing program. We do not. We have a five panel testing program with five drug classes for screening and 11 drugs being confirmed.

As you all know, laboratories are required to pass an initial NLPC review and semi-annual reviews thereafter with quarterly PT. We rely heavily on HHS SAMHSA's DWP, our partners who work with the laboratories to ensure the accuracy of the testing. DWP does investigate deficiencies in certified laboratories, and for that, we are truly grateful. We currently have 30 HHS-certified laboratories.

The assumptions with our data include that they are laboratory-reported results and are not MRO reviewed. MRO review is important in our program because if there is a legitimate medical explanation, the MRO will not report a positive result. The data we collect directly from the laboratory includes blind specimen results because a laboratory can not distinguish between a blind sample and a specimen.

Listed here are the drugs tested in order of prevalence. We found marijuana was the most frequently used, followed by amphetamine, cocaine, opiates, and phencyclidine (PCP). The overall annual positive rates have

remained below 2 percent with marijuana continuing to be the most identified. Amphetamines became the second most identified in late 2008. Before that, they were third. The positive rate for cocaine has remained the same as in 2014. The positive rate for opiates has been increasing since 2011. The positive rate for PCP remains low with fewer than 1,400 people testing positive each year. Both DTAB and today's audience understand the effects of PCP on an individual. Normally used as a veterinary tranquilizer, this is a drug that would cause tremendous concern in the transportation industries. We know that these are not just blind samples, but specimens from human beings who are testing positive for PCP under our testing program.

The results shown in these slides indicate tampering, which we consider to be possible cheating. Though it has remained below 0.5 percent, and we still consider it a concern.

Shown here is our laboratory-reported drug testing data by year from 2009 to 2015. In 2009, we had almost 5.2 million tests, and in 2015, that number rose to 6.3 million. Interestingly, the difference in the overall number of tests between 2014 and 2015 was just under 5,000. The actual number of laboratory-reported U.S. positive drug testing results from 2009 through 2015 is shown here. The data in red are PCP results, with the fewest number, followed by the opiates, cocaine, amphetamines, and tetrahydrocannabinol (THC). Highlighted are the total number of positive drug results between 2015 and 2014, 47,782 and 47,524, respectively, which are close in number.

Although we are finding that recreational drug use and drug-related traffic fatalities are increasing, in the transportation safety-sensitive regulated community, the use of THC is not increasing radically. I credit that to the information that we provided to the MROs. The MROs know that state reasons of medical or recreational marijuana use are not acceptable under our program. Therefore, we have a deterrent effect because employees know they cannot use marijuana if they want to participate in this industry.

Our laboratory testing drug positivity rates expressed as percentages are shown here by year and drug. Because of the small difference in positive results from 2014 to 2015, fewer than 5,000, the percentage positive results remained at 0.75 percent for THC. Next in prevalence are the amphetamines, followed by cocaine, opiates, and PCP. Note how the trend lines are very close to a crossover point for cocaine and opiates. Thus, it is possible that by the next time we report usage data that opiates could be above cocaine.

Shown here are the laboratory-reported data, expressed as percentages, for rejected, tampered, and positive results.

This slide shows the results for marijuana. To emphasize, we are not seeing a dramatic increase. For the years 2011 to 2015, notice the impact of permitting marijuana in certain states for medical and recreational purposes had on our program; we are not seeing exponential jumps.

Shown here are our horizon issues. The marijuana issues remain a great concern to us at DOT. Within the DOT, the National Highway Traffic Safety Administration (NHTSA) is funding research for determining marijuana impairment. The states have asked us what to do in situations of impairment. It has been ongoing program at NHTSA for about the last seven years to fund additional research. I know DWP is funding research, and DOT is also.

Other horizon issues include testing for additional schedule II drugs and the alternative specimen testing methodologies of oral fluid and hair. DOT and SAMHSA/DWP are closely aligned on these initiatives.

The driver clearinghouse database is a project of the Federal Motor Carrier Safety Administration. Publication of this project as a final rule is expected later this year. This database is DOT's answer to Congress' direction on how to address the problem with those individuals who test drug positive with one company and then relocate to another within the trucking industry. This has not been expanded to include other industries. Once the rule is published and implemented, it will be an area with a tremendous amount of discussion over the next few years.

For the eCCF implementation, we are working with SAMHSA/DWP to ensure that the eCCFs move forward effectively and efficiently. We have great hope at DOT that as the eCCF moves forward, more laboratories are approved to use it, more of our regulated employers implement it, and that this innovation will drive down the costs of testing, will improve collection site accuracy, and will make other matters easier for us, such as data collection. We applaud HHS for their hard work to implement this. We encourage the laboratories to submit their eCCF requests to HHS so that eCCF use increases. Then we can finally move into this century when it comes to IT issues. We at DOT look forward to that and also with our own regulations in the future.

The last horizon issue involves our drug impairment studies. As I mentioned earlier, both NHTSA and SAMHSA are working on those, and they are key to what our future is in terms of advising the states, etc.

Listed here is our staff. I am the acting director and Bohdan Baczara is the acting deputy director. Mark Snider and Cindy Ingrao are our senior policy advisors. Vicki Bellet and Maria Lofton are administrative personnel. Bob Ashby and Don Shatinsky are our consultants. Mike Smith is our attorney in the General Counsel's Office.

Our technical assistance numbers are shown here. We are a policy office with a strong emphasis on education and outreach. In 2015, we had 14,536 emails, phone calls, Ask ODAPC web inquiries, and other interactions with DOT program managers and our regulated public. Those numbers are almost double what we had in 2012.

We have 34,806 listserv subscribers as of April 27. This is important because it makes us the largest listserv of our kind in the world. We serve as a resource for other federal partners to submit their information to the antidrug audience. It is an area where we are always looking to increase. If anybody is interested, the listserv can be found at <https://www.transportation.gov/odapc>. I encourage people to sign up for our listserv because it keeps you abreast of the issues as they relate to DOT and our federal partners.

Finally is our ODAPC website data. It was interesting to us, because as a very small office, we are DOT's most viewed website. We are tremendously proud of that. We work very hard to keep that website up-to-date, user-friendly, and filled with very important information.

Shown here is where we live. We are on the southeast part of DC, not far from Nationals Stadium.

I thank DWP and DTAB for the opportunity to present. Thank you, everyone.

MR. FLEGEL: Thank you, Patrice.

MS. KELLY: You are welcome.

#### **NRC 10 CFR Part 26 Fitness for Duty Program**

Paul Harris, U.S. NRC

MR. FLEGEL: Paul Harris is from the U.S. NRC. He will be presenting on NRC 10 CFR Part 26, the Fitness for Duty (FFD) Program.

MR. HARRIS: My name is Paul Harris. I am the senior program manager representing the NRC staff, and with me today is Brian Zaleski. Brian Zaleski is our FFD Program expert on drug and alcohol testing.

Before I shift over to let Brian give the presentation today, I will say a few words. On behalf of the NRC staff, I would like to thank the members of the DTAB, members of the DWP staff, and members of the public for allowing us to present drug and alcohol testing information gained from the commercial nuclear industry in the US. The data that we present are pre-decisional data, the best data that we have currently. Brian will present the details of that. This is important because the NRC is responsible for the safe and secure operation and maintenance of our commercial nuclear industry, including fuel cycle facilities and many materials licensees. They are operated and maintained by a professional staff who needs to be fit for duty. By being fit for duty, I mean that they are unimpaired by any substance or any drug. They are not fatigued in their workplace, and they are mentally and physically capable of safely and competently performing their assigned duties and responsibilities. Another key element to the FFD Program is that all these individuals who have access to NRC-licensed facilities are required to be trustworthy and reliable. They have to have demonstrated character, integrity, and honesty to be afforded access to these facilities to conduct activities that are necessary to ensure that we protect the public and the environment. Brian will present data that will demonstrate why drug and alcohol testing is so vitally necessary to the safe and secure operation of these facilities, and with that, I am going to let Brian give his presentation now.

MR. ZALESKI: Good morning. Thank you, Paul. What I hope to accomplish today is to briefly talk about the mission of our organization. Paul already provided us with that information, so I will move through those two slides quickly.

The majority of the information I will present today is on 2015 performance. As Paul said, it is pre-decisional, which means that we have not yet validated all of our information. We receive results from the industry two months after the end of the calendar year. By the end of February, we have all of the data. What we are presenting here today is our best attempt and cleanest dataset that we have, but there will be some additional information that we will probably scrub out later.

We will provide a history of the Program in terms of our test results to give you a sense of the trending, especially in terms of substances that are being used. I will highlight subversions, which is a significant issue that we initially identified beginning around 2011. It continues to be a very significant issue for us. Then I will highlight our e-reporting system, which is the basis for all of this information that we are presenting today.

The mission of the NRC is to protect the public health and safety, and we do that by ensuring the individuals that are working there are fit for duty. The criminal background checks assess trustworthiness and reliability. The fitness for duty also implies not being impaired by any legal or illegal substance, not just the panel of drugs that we currently testing for, but any. For fatigue management, similar to what Federal Aviation Administration has in place, there are work hour controls for the cumulative effects of fatigue and acute fatigue.

This schematic shows a high level review, or what we call our defense in depth approach, to ensuring that we are protecting the public health and safety. Access authorization is on the top and includes the background

investigations, the psychological reviews, etc. The other approaches include drug and alcohol testing, fatigue management, and behavioral observation, where individuals are trained to identify impairment in the workplace and to report it so that the identified individuals are evaluated through a fitness determination process. A medical professional would assess them to ensure they can do their job safely and competently.

Shown here is the overall industry performance for 2015. Unlike DOT that tests over 6 million people, we tested 163,000 people this past year from 73 FFD programs, which is equivalent to a site. The majority of our sites are nuclear power plants. We also have two DoD fuel cycle facilities that enrich uranium, and a few corporate offices that manage their programs offsite and not inside a power reactor site.

We had 1,199 positive test results in the past year. The last time we had that many positive results in one year was in 2000. Comparing the number of positives without considering the total number tested is not an apples-to-apples comparison. In 2000, we tested 124,000 people while this year we tested 163,000 people. By percentage, we are considerably lower than what we were in the past.

The overall positivity rate in 2015 was 0.73 percent. Throughout this presentation, I will highlight the differences between licensee employees and contractor/vendors. This is important for us, because since the start of our program in 1990, we have noticed differences between the positivity rates and substances abused for these two groups. Licensee employees are generally fulltime employees while contractor/vendors are typically short-term employees. Contractor/vendors test positive at rates generally 2 to 3 times higher than our licensee employees.

The random positivity rate for the industry is 0.35 percent in aggregate, with a positivity rate of 0.14 percent for licensee employees, a number that has not changed from the prior 2 years, and 0.62 percent for contractors, which is the same as 2014. There has been a significant impact on the positivity rates over the last few years because of our two new construction sites. The majority of the fleet has been operating for a long period of time. Because we started a program to evaluate construction site workers in 2008, the majority of the fleet was not subject to these testing requirements. I will highlight those areas where we have noticed increases in detection based on that workforce.

This summary breaks down by both licensee employees and contractor/vendors. The most important thing is that roughly 70 percent of our positive results each year come at pre-access. That means an individual is identified before gaining access to a licensed facility. This is the proactive part of our testing program to prevent those that are using from gaining access. The remainder of the detections is either for random, for cause, post event, or follow-up testing. That means these individuals were performing their job and were on site at a licensee facility when they were identified with either drugs and/or alcohol in their bodies. Another notable item is the number of positive results by licensee employees and contractor/vendors. In 2015, the total number of positive results was 1,099, of which contractor/vendors numbered 1,068 and licensee employees 131. The majority of the industry positive results are from contractor/vendors.

For contractor/vendors, 78,000 tests were conducted for pre-access versus 9,000 for licensee employees. Our licensee employee numbers are fairly static. The licensee positivity rate is much lower, most likely because they are subject to testing fulltime in all the other elements of our program. Whereas, contractor/vendors are subject to testing for very short periods of time.

Finally, on this slide, notice the second table lists where are we conducting our testing amongst our personnel. For contractor/vendors, who are short duration employees, we primarily are conducting pre-access testing.

For licensee employees, we are conducting primarily random testing. The second part of that table talks about positivity rates. Most of the positivity rates for contractor/vendors are pre-access. For licensee employees, almost half of them are from random testing. The different elements of our program are identifying drug users in different ways, and that has policy implications for us.

This is a historical presentation of positivity rates by test type for almost the entirety of our program, dating back to 1993. I was unable to obtain data prior to that for this presentation. Notice the two separate lines in each of the exhibits. The top exhibit is pre-access testing. The dotted lines at the top represent contractors. The solid black line underneath represents the licensee employees. As I said before, there is a difference in positivity rates among all the test types across all the years, which is clearly evident in these testing tables. The middle chart is the random testing graph, which shows a slight increase over the last few years in contractor/vendor positivity rates. These positivity rates are tightly bound, ranging from 0.4 to 0.6 percent for contractor/vendors over the entirety of our program. The major reason why the contractor positivity rates have increased over the past few years is because of the new construction sites. It is helpful for us policymakers to understand that.

In 2009, we changed the way we collected data and started an electronic voluntary reporting system. We receive single event reports for each positive result, which contain a lot of information. Prior to that time, we received aggregate results in a licensee report. For instance, we would learn that we had 10 random positives by contractor/vendor and licensee employees. We would receive a table on the substances identified, but we could not crosswalk to identify which individual tested positive and in what area they tested positive. Was it a random test? Was it a pre-access test? We have that data now, and that has greatly informed our ability to assess risk and to inform our inspection process.

There is a difference between our employment types, the licensee employees and contractor/vendors, and the types of substance they use. These two pie charts present the relative percentage of positive results for each of those. It does not demonstrate the magnitude. The contractor/vendor pie chart is actually eight times larger, if you can envision that, than the licensee chart in terms of magnitude. The important notable finding for licensee employees is that the most tested substance is alcohol, a legal substance, at 43 percent. They are clearly misusing it and not complying with our requirements. For the contractor/vendors, the most used substance there is marijuana. There are similar percentages of use for amphetamines, cocaine, and opiates.

Looking at the 2014 versus 2015 test results, there was a decrease in the relative percentage of alcohol detection in both our populations. One of those reasons is because we lowered the cutoff levels for alcohol in 2008 to below 0.04 based on time dependency. If an individual has been at work for a few hours, we can lower that cutoff level. We have achieved about a 30 percent increase in detection. It is possible that we are achieving some deterrent effects, and that is why alcohol use is decreasing, though it is hard to say at this point. Another notable finding is that cocaine positivity rates increased in both of our populations this past year. Amphetamines use increased in our licensee population but not for our contractor/vendors. For marijuana positivity rates, our contractor/vendors decreased a little and our licensee employees increased a little, referring to single percentage points.

What this exhibit presents is the positivity rates for the substances identified in any given year, beginning in 1990, when our program began. Marijuana has always been the most detected substance in the history of our program, and it continues to be. Over 40 to 50 percent of our positive results each year are from marijuana. Obviously, the national issue of potentially rescheduling marijuana has large implications on our testing program because of the detection that we are seeing. The next highest substance that we identify is alcohol.

Third is cocaine. Cocaine and amphetamines crossed in 2014, with cocaine exhibiting a big uptick in the last year. Amphetamine and cocaine use are comparable over the last few years.

All the results in our presentation are MRO-verified results. These are not laboratory positive results, as DOT presented. These are verified results.

Some of the notable trends that we have observed from 2012 to 2015 include amphetamines and methamphetamines increasing in detection. The first column in the table to the right presents the total percentage of drug positive MRO-verified results each year for amphetamines and methamphetamines. They increased from 6.2 percent in 2012 to 10.6 percent in 2014 and then leveled off in 2015. Looking at the positivity rates for the amphetamines, from 2007 to the current year, we have seen a threefold increase in the testing positivity rates. In 2007, 0.021 percent of individuals that were drug tested tested positive for amphetamines and methamphetamines. In 2015, it was 0.065 percent, a threefold increase. That is a significant trend as far as we are concerned.

Subversion attempts are a very significant issue for us. Any individual that is identified as subverting a drug test is permanently denied access because it is a willful action against our regulatory environment. The trustworthy and reliability of an individual is significant and the most important thing that we look to in ensuring that someone can do their job safely. In 2011, we starting identifying subversion attempts as becoming an issue, in large part because of the way we collected our data. With this electronic reporting system, we have single event report information provided to us that affords us the ability to identify these subversion attempts. Between 14.7 to 19.3 percent of our total violations, which include alcohol, now are subversion attempts. If alcohol violations are removed and only the subversions to drug positives are examined, the percent subversions are over 20. In 2015, almost 25 percent of our drug violations were because of subversion attempts.

Another area where we can examine the details involves those individuals who test positive for more than one substance, the multi-substance positive drug users. Between 2012 and 2015, we saw between 34 and 61 individuals test positive for more than one substance, and of which, 83 to 93 percent tested positive for amphetamines, methamphetamines, and/or cocaine. The multi-substance drug users tend to be individuals using amphetamines, methamphetamines, and/or cocaine.

Supervisors serve as licensed operators, the individuals who are operating a power plant. If an individual in this critical group tests positive or violates the testing program, we receive a 24-hour event report immediately. That information is available to the public on our website within days of that occurring.

Another item that is unique about our regulatory environment is that we have licensed inspectors onsite at each of our nuclear power plants working fulltime with the industry.

Subversion attempts are a significant act in our regulatory framework. It is willful misconduct and results in a permanent denial. We have graduated sanctions for individuals that test positive. We have a minimum of 14 days for the first time an individual tests positive for drugs and/or alcohol, a 5-year denial for a second positive, and a permanent denial for a third positive result. In the case of a subversion attempt, the individual is permanently denied.

This slide also presents the magnitude for subversion. The percentage rates are interesting in and of themselves, but the numbers are more eye opening. In 2012, we had 177 individuals attempt to beat the test

through cheating, and in 2015 there were 231 individuals in the 1,199 violations. The picture shown on the right is of subversion devices, including medicine bottles, squirt bottles, and temperature measurement devices, that were obtained from one of our licensee sites. Anybody in this industry is aware of what individuals are attempting to use. The 2015 results also demonstrate prevalence. Forty-six of the 73 sites that reported information in 2015 had at least one subversion attempt. Subversion is occurring at more than half of our industry sites. Seventy-six percent of the subversion attempts occurred at pre-access testing because it is a predictable testing event. Ninety-five percent of the subversion attempts are by contractor and vendors. This problem is almost uniquely distinct to our contractor/vendor population, which is probably related to our permanent denial policy. A licensee employee, I am certain, does not want to lose this/her job. A contractor/vendor may have many different job options.

What kind of information can we gain from examining the data derived from those individuals who attempt to subvert the testing process? Two-thirds of the time they do not provide specimens for testing, but one-third of the time they do. Primarily subversion detected because of either a sound in the collection room or the specimen temperature is out of range and a second specimen is collected under direct observation. These are the results from those direct observation specimens from 2015, including the type of test that was conducted and the substances were identified in each of these individuals.

There are two important items to note here. One is that 55 results of the 73 occurred at pre-access; many of these individuals are identified at pre-access testing. Marijuana is the most prevalent drug identified with subversion, at least in the individuals that submit for testing. Fifty-two of the 73 specimens were positive for marijuana. The other identified substances are shown on this slide. The multi-substance users who are individuals testing positive for more than one substance are a much higher rate. The number of multi-substance users identified in the entire testing population is about 5 percent. In the multi-substance user population identified in subversion attempts, it is 17.8 percent. Individuals that subvert are three times more likely to be using more than one substance.

Last year when we presented our data, we talked about limit of detection (LOD) testing. NRC uses a unique testing methodology that is not in the HHS MG and that we use is one circumstance. If an individual produces a dilute specimen, the licensee has the option to lower the initial cutoff level to 50 percent of the initial cutoff level. If a positive result is found on that lower cutoff level, they can conduct LOD confirmatory testing. The table here presents the results from 2010 through 2015. The bottom line for this table lists the total number of individuals that tested positive with the dilute specimen. In 2010, there were 26 individuals. In 2015, there were 17 individuals. Though not a significant number of individuals, it is a measureable number. Secondly, this table is split into two segments. One provides the number of individuals who tested positive without this special analysis. Just because your specimen is dilute does not mean that you diluted that drug in your urine below the established cutoff levels. In 2015, three individuals tested positive on LOD testing. The remainder of them, 14, did not. That means that the urine drug concentration was higher than the standard cutoff level. In prior years, the LOD special analysis testing was more effective. It is variable based on year.

One other thing that is important to note is that we are detecting not only with pre-access testing. Obviously, we always want to identify these individuals. I wish every single individual we identified occurred at pre-access testing because they are not a risk before gaining access to a facility. If they are using drugs, we want to identify them. If they are attempting to subvert the process by diluting their urine, we want to ensure that their specimens are tested with the best methods that are available to us.

Finally, in 2015 we tested over a 166,000 individuals; 755 of their specimens were dilute. That is the dilution

rate we are detecting in our industry. If these results are paired with the subversion attempts, you learn that the preferred method is not to dilute your urine; it is to substitute your urine to subvert a test.

This slide provides the details on multi-substance positive results. These data were impossible five years ago. Now that we have results for every single individual that tests positive in our industry, and we can identify that risk. For the substances in our testing panel listed above the horizontal dashed line, we are drafting a proposed rule to lower our cutoff levels to make them in line with the current MG that are in place. Our testing standards for amphetamines, methamphetamines, and cocaine, and also how we test for 6-AM, the heroin metabolite, reflect what were in the MG prior to the 2008 update.

There are some opiate positives, including fentanyl, oxycodone, and oxymorphone. Our licensees are permitted, under our rule, to expand the testing panel, and some of them do that. We do have at least one licensee site that has expanded their testing to include semisynthetic opioid testing on for cause, follow-up, and post event testing. Sixty-one of the 1,199 identified individuals had multi-substance positive results. Twenty-three of the 73 sites did have a multi-substance positive result. Individuals who use a lot of drugs are attempting to gain access to our facilities, so a testing program is not a deterrent to these individuals. The big message is that individuals are identified at pre-access with more than one drug. Clearly, random testing and all the other testing elements that we had are very, very important to identify these individuals if they successfully beat our drug test on pre-access.

I wish I had quantitative data for drug testing positives, but I do not because we do not collect quantitative data, though we do for alcohol testing. In 2008, we lowered our cutoff levels for alcohol for time dependency. Shown in this exhibit is where positive alcohol results are detected. The lighter blue colors indicate results below the 0.04 cutoff level.

We conduct pre-access testing for all of our employees for both drugs and alcohol. We have a 50 percent random testing rate for both drugs and alcohol. We do not distinguish positive testing rates independently for alcohol and/or drugs. The question from a policy perspective is if you change the regulation, is it effective? Well, in this case, the takeaway message is that the time-dependent alcohol cutoff is 30 percent more effective. That has consistently been the finding for the past four years when we were able to identify that.

Shown here is some information on our resources. The OMB-approved forms that we use to collect information are depicted here. This is a voluntary system that the industry worked with the NRC to develop and utilize. Our reporting requirements, which are accessible on our website, are not as detailed as what are in these forms. Public trust in the nuclear industry is essential to us in doing our jobs effectively. All the information that the licensees present to us this year, including positive drug test results, single event reports, and the annual reports, are available on our public website for download. Our reports and the summary of those are a little easier for the public. The site-specific data are available on our website also.

In conclusion, listed here are our FFD Program staff, including Paul Harris, who began this presentation; myself, Brian Zaleski; and Will Smith, who is not here today. Please call or email us. We love to hear from people. Thank you.

MR. AUMEN: Thank you for that presentation.

MR. FLEGEL: I want to extend a formal thank you to NRC for allowing us to present to their regional senior leaderships on Tuesday. The dialogue and questions were great. I want to thank both Paul and Brian for

arranging that.

MR. ZALESKI: I hope you enjoyed seeing the information that we provide to our inspectors. The annual meeting at which Ron presented was for our regional inspectors who evaluate each of our testing programs. NRC evaluates each licensee program every three years. We present our data, our results, and our site-specific information to inform that inspection process. Ron had the opportunity to see the communication of that information for this year, and it was very well received. We were able to answer a lot of questions. That was great. Thank you.

MR. AUMEN: Our next presentation is the DoD drug testing update, given by Colonel Tom Martin, the deputy director, Drug Testing and Program Policy, Office of the Undersecretary of Defense for Personnel and Readiness, Operational Readiness and Safety, DoD.

### **DoD Drug Testing**

COL Tom Martin, DoD

COL MARTIN: I would like to thank everyone for giving me the opportunity to present a brief overview of our drug testing program. For the majority of this talk, I will focus on military drug testing. My office is also responsible for civilian drug testing for those identified in our testing designated positions (TDP).

Our number one mission is to deter illicit drug use as well as prescription drug abuse in our military service members, as well as our civilian personnel in TDPs. We consider this a military readiness and safety issue. In addition, our office and the services do provide drug abuse prevention education and outreach services to military personnel, their families, and the military community. Thirdly, we attempt to identify new drugs being abused within our population and develop testing procedures to detect their use. We have regulatory guidance, with our majority coming from DoD instructions as well as the Executive Order.

Some of the driving factors for our program and within the military are our recruiting population of 18- to 25-year-old males. It is estimated that 17 to 20 percent of that age group abuse drugs. In the population from which we recruit, 20 percent abuse drugs. That is an issue for us. We need to identify and separate out those individuals who are abusing drugs.

Our program resulted from Vietnam and the 1981 incident on the aircraft carrier Nimitz where there was an aviation mishap. Listed here are the number of servicemen killed and injured, the number of aircraft that were destroyed and damaged, and the total monetary damages - \$150 million in 1981 dollars. That incident shaped the nature of our program from a detection and treatment program to a more punitive program. If you test positive for drugs, you can be disciplined and discharged from the military. Just as in the general population, more recently we are seeing an increase in the abuse or misuse of prescription pain medications. The abuse of drugs is a safety issue, resulting in the potential loss of equipment, resources, and lives.

This general overview shows where my office is situated within the DoD. At the top is the Secretary of Defense with the different undersecretaries listed below. We fall under the Undersecretary of Defense for Personnel and Readiness. Within that office, we are under the Office of the Executive Director for Force Resiliency in the Personnel Risk Reduction Office. We provide the policy, advice, and guidance, with the execution performed by the services. There is a change there on the left for the Secretary of the Army. The Honorable Eric Fanning became the new Secretary of the Army this week; Patrick Murphy is no longer the Acting Secretary.

I have highlighted in green the key items in this chart. Within the Personnel Risk Reduction Office, there are three separate lines of activities - risk systems, accident reduction, and then my office, Drug Demand Reduction. From my office are the services, and each service has a program manager for the Army, Navy, and Air Force; the Marine program falls under the Navy. In addition, we have a quality assurance (QA) arm, the Division of Forensic Toxicology under the Armed Forces Medical Examiner System (AFMES) at Dover Air Force Base. From those, we have our drug testing laboratories, which I will touch on shortly. The overarching Board, which is very similar to the DTAB, is what we call our Biochemical Testing Advisory Board (BTAB). THE BTAB operates in a similar fashion as the DTAB.

Each of the areas has different responsibilities assigned to them. Within Personnel and Readiness, we provide the oversight. We issue policies, directives, and guidance to the services. My office advocates for funding for our programs. We assist in developing the procedures and standards for our drug testing laboratories. We maintain the certification as well as the inspection program for our drug testing laboratories. We established the BTAB.

The military services have two main responsibilities that they are charged with. They operate drug testing laboratories sufficient to meet capacity. These laboratories must be certified and must participate in a quality assurance program. All of the services must have a medical review process. On the collection side, they have to implement computerized random selection process.

The Division of Forensic Toxicology is the technical expertise for the Drug Demand Reduction Program. They manage our external quality control and PT programs. They provide both monthly blind and open PT to all our laboratories. In addition, they are responsible for administering our inspection program. They coordinate certification and recertification actions, and they make recommendations to my office for that. They evaluate our significant non-conforming events that are outside the ordinary course of business and require an investigation.

The chief of the Forensic Toxicology Division is the chair of the BTAB. The BTAB is organized into two different divisions. There is a technical or drug testing division and the personnel policy side, which is the collection side of the house. Each of the services has one representative on BTAB who is a voting member and who can be either military and/or civilian, depending on the service. The chair is a nonvoting member.

What are the functions of the BTAB? They evaluate new methodologies and new technologies for drug testing. They advise on the external PT, as well as our QA procedures. They oversee laboratory certification as well as decertification and recertification. The BTAB is extremely involved in evaluating our drug testing panel and whether to add or delete drugs on the panel. They recommend policy changes and drive our prevalence testing to identify what our service members may be abusing outside of our current testing panel.

How does the process work? BTAB makes data-driven decisions if at all possible. We perform prevalence testing to identify abused drugs and then make an evaluation based on that. We can minimize some of the bureaucratic paperwork or the red tape. This comes into play when we add or delete drugs from our testing panel. We can do that very quickly compared to the civilian or the federal program. Most important is we do not poll our customers, our service members. They do not have a say in what we test for and what we do not test for. It is a stepwise procedure. We begin with surveillance testing. We have a monthly surveillance program that is administered by Division of Forensic Toxicology at the AFMES. Literature reviews and congressional interest do drive some of our decisions. We evaluate what we find in media reports, etc. Then we evaluate what data we have, and the BTAB makes a recommendation to our office. That is driven by

technical capability, the capacity of our laboratories, and of course, cost. Following that, a policy change is approved, and BTAB provides the oversight.

I talked about our rapid response to changing threats. Listed here are our most recent additions to our panel, oxycodone and oxymorphone, hydrocodone and hydromorphone, as well as select benzodiazepines. We have also instituted synthetic cannabinoid testing for certain synthetic cannabinoids. We have added drugs and also deleted drugs that we were not identifying within our population. These included lysergic acid diethylamide (LSD), 3,4-methylenedioxy-N-ethyl-amphetamine (MDEA), as well as barbiturates.

This slide steps through the process of how we added hydrocodone and hydromorphone to our testing panel. As we are all aware, there was significant opioid misuse within the general population, and there were reports that it was also happening within our military population. In addition, we were beginning to see an increasing number of our service members testing positive for heroin. This issue had high visibility with Rear Admiral Mullen, the Chairman of the Joint Chiefs of Staff at the time. He wanted our program to evaluate the prevalence of this problem and determine whether we should add those drugs to the panel. We perform prevalence testing, testing a random sampling of about 16,000 specimens from our drug testing laboratories to determine the number of positive results for hydrocodone and/or hydromorphone. Of those positive results, we used our medical treatment facility and our electronic medical history to determine if any of the service members who tested positive had a valid prescription. When we analyzed and reviewed the results, the illicit positive rate of those who did not have a prescription was about a little over 0.2 percent. A recommendation was made to our office, and then we determined that we had the resources available. With the help of Rear Admiral Mullen, we obtained additional funds to implement that testing. With that decision, the Undersecretary for Personnel and Readiness issued a policy change to the services, notifying them that our testing panel would change within 90 days of the date of that letter. That 90-day notice allowed for notification service personnel of the addition of the drug. The notice provided personnel an opportunity to seek treatment if they so desired. At the end of that 90-day period, we added them to the panel.

If you are not aware, we have six DoD drug testing laboratories. There are two within the Army, one at Tripler Army Medical Center in Hawaii and the other at Fort Meade, Maryland. The Army laboratory at Fort Meade is also dual-certified for civilian testing by the NLCP. There are three Navy laboratories, one on the west coast in San Diego, California, one just north of Chicago in Great Lakes, Illinois, and one in Jacksonville, Florida. Finally, the Air Force has one laboratory in San Antonio, Texas at Lackland Air Force Base.

Here is a list of our current panel of tested drugs. Notice some of the differences. Every specimen is now tested for oxycodone and oxymorphone, hydrocodone and hydromorphone, as well as those benzodiazepines. We have also added random synthetic cannabinoid testing towards the end of 2013. For any drug that is not on our current panel, the services can request that testing. Those specimens are forwarded to the Division of Forensic Toxicology at the AFMES at Dover Air Force Base.

This slide lists our cutoffs for screening as well as confirmation testing and the breakout of what we test for, including the benzodiazepines as well as the synthetic cannabinoids at the moment.

This very busy slide is showing the distribution of drugs in fiscal year (FY) 2015. All the data have been medically reviewed and thus are all true positive specimens. The data are derived from active duty positive service members. These are unique positive members, indicating that if a service member was positive more than once during 2015, he/she is counted once. Similar to everywhere else, marijuana is our number one positive drug, followed by cocaine, and then amphetamine. Data highlighted in yellow are the opiates or

semisynthetic opioids. If we combine those, they would be higher in prevalence than amphetamines and be approaching our levels for cocaine. In 2013, we implemented 100 percent testing for those drugs. From 2013 to 2014, there was rapid decline, about a 40 percent decrease, in the number of unique active duty positive service members. Some of the rationale behind that rapid decline is twofold. One is the addition of added the drugs; members who were abusing them were discharged from the service. The real decrease was the result of our better oversight and guidance from the medical community on prescribing practices. This is a continuation of the drug positive result distribution for service members. In 2014 and 2015, synthetic cannabinoids were added; shown here are which ones were positive. There are differences in prevalence depending on the metabolite. We are still detecting those within our population, and the positive rate is approaching that of ecstasy. For synthetic marijuana, there are a large number of different variants, which presents unique testing challenges when we began our testing in December 2013. In FY15, the positive rate was 0.018 percent.

Our positivity rates, both historically well as in FY15, are shown broken down by the different services as well as the Reserve and National Guard. From 1987, when our program changed from a treatment program to a punitive program, our positive rate was close to 3.5 percent. That rapidly declined to near 1 percent. The annual positivity rate has fluctuated above and beyond since then. In 2015, the positivity rate was 0.84 percent overall for the entire military, which was our lowest rate in history. We think that is significant, especially since we added a significant number of prescription drugs over the last few years. Our overall positivity rate is steadily declining.

By component, including active duty, Reserve, Guard, as well as our applicant population, not surprisingly, our Guard and Reserve members have a slightly higher positivity rate than our active duty force. Our applicant rate is around 1 percent. Beginning in 2013, the active duty positivity rates for all the different services exhibited a downward trend. The Army has the highest positivity rate at a little less than 1 percent. The Navy and the Air Force are close to having the lowest rates at 0.38 and 0.35 percent, respectively. The Reserve positivity rate is highest for the Army Reserve at about 1.6 percent. The Navy Reserve has the lowest rate at about 0.4 percent. The trends mirror that of the active population but at a higher rate. For the Army and Air National Guard, the Army Guard positivity rate is a little less than 2 percent while the Air Guard is about a half a percent. That was a general overview of our military population.

On this slide are the results for our civilian testing for DoD agencies. All this testing is done at our Army Drug Testing Laboratory at Fort Meade, Maryland. The positivity rate has remained steady since 2012 for our agencies. For those in our random TDP testing pool, the positivity rate is about 0.35 percent overall. Our applicant rate declined since 2012 and now is about 0.27 percent. The combined positivity rate is a little bit over 0.3 percent.

The last thing I want to touch on is one of the efficiencies that we use within the military testing program called the automated MRO process. We link our laboratory data with our pharmacy prescription data to perform an automated electronic review. If a service member has an authorized prescription within a certain time period of the collection of his/her drug specimen, this is considered an MRO-negative result. In FY15, a little over 85 percent of those positive for oxycodone had a prescription. For benzodiazepines, 67 percent were considered MRO-negative results and for amphetamines, a little less than 50 percent had valid prescriptions.

I am open to any questions anyone may have.

MR. AUMEN: Thank you, Tom. Are there any members of the Board who have questions? Hearing none, we will move on.

MR. FLEGEL: Thanks, Tom, and I am glad you were able to take out time last week to be at the S&T meeting.

MR. AUMEN: Eugene Hayes, of our very own DWP, CSAP, will present on the Federal Workplace Drug Testing Programs.

### **Federal Workplace Drug Testing Programs**

Eugene Hayes, DWP, CSAP, SAMHSA

DR. HAYES: I would like to welcome everyone, including the DTAB members, our federal partners, and the general public. My name is Eugene Hayes. I am the Contracting Officer's Representative for the NLCP. Today I will to speak on the Federal Workplace Drug Testing Programs, specifically the NLCP results.

As of May 1, 2016, there are 31 certified laboratories. There are two category 0 laboratories. The largest group is category 1, with 10 laboratories, which includes one Instrumented Initial Testing Facility. There are six category 2 laboratories, three category 3 laboratories, three category 4 laboratories, and seven category 5 laboratories. Also, one laboratory is in the initial certification process. The application has been reviewed and accepted. The next step is the initial inspection. We could possibly have 32 laboratories certified under the program.

For regulated specimens tested from 2006 to 2015, the number of total specimens tested in 2006 was 7.5 million and rose to a high of 7.99 million in 2007. The number of specimens tested dropped to 5.47 million in 2009. A recovery began in 2010 with a continued rise into 2015 to 6.65 million tests. However, the number of specimens tested in 2015 at 6.6 million was only around 12,000 more than that tested in 2014. Therefore, there was just a slight increase from those two years.

The total number of specimens reported as drug positive, adulterated, invalid, or substituted non-negative increased from 108,000 in 2011 to 132,000 in 2015, a difference of roughly 24,000. The largest difference was from 2012 to 2013, with an increase of 11,449. The smallest difference was 2013 to 2014, with an increase of 1,705.

As shown in this graph of the distribution of specimens reported, THC remains, as in all the other programs, as the most often identified drug in urine. However, the number of specimens containing amphetamines and/or methamphetamine has continued to increase over the last five years. The percent of reported specimens found to be invalid decreased with the adulterated and substituted specimens remaining in the 2014 percentage range.

In this slide are the specimens reported as invalid due to immunoassay interference. There is a trending decline from a high in 2013. I think we will continue to see this trend.

Overall, the number of specimens reported as invalid dropped from 9,711 in 2014 to 7,796 in 2015. In 2015, there was decrease in all the invalid categories except for invalid pH, which increased from 2,238 to 2,909 in 2015. Note that the number of specimens invalid due to pH rises in the warm summer months and is lower in the cooler months of the year.

As shown by this chart, the percentage of specimens reported as invalid due to pH remains higher than other invalid categories. pH invalids demonstrated a seasonal increase from May through August, followed by a decrease from September through December. Other invalid categories include abnormal physical characteristics; abnormal creatinine and specific gravity levels; gas chromatography, mass spectrometry, or immunoassay interference; and oxidant activity. All varied from month to month, but overall remained at the 2014 levels.

In late 2011 and early 2012, the Program saw an increase in specimens reported invalid due to abnormally low pH. SAMHSA and RTI studies revealed that this was the result of a substitution product with a lower pH value than normally found in urine. This problem appears to have resolved in 2013 and 2014 when the percent of invalids due to pH was back to the 2010 levels.

However, in 2015, the percent of invalids due to pH rose well above the levels normally observed. The increase was primarily due to the number of specimens with high pH greater than or equal to 9 but less than 11. The NLCP and SAMHSA will continue to investigate why pH is a problem for our invalids within the federal program.

Of specimens reported as invalid due to immunoassay interference, the majority occurred with the 6-acetylmorphine (6-AM) immunoassay. This is because most certified laboratories use one 6-AM assay, the cloned enzyme donor immunoassay (CEDIA™), and there is a substitution product on the market that interferes with that reagent. Interference from that product is also seen with CEDIA's amphetamines and cocaine metabolite assays as shown in the previous slide. Overall, the number of specimens reported as invalid due to immunoassay interference decreased from 2014 to 2015.

This slide shows the decrease in specimens reported invalid due to immunoassay interference since the high in 2013. We continue to see that decline, as shown on one of the previous slides, and I hope that that trend continues downward. The strongest interference or invalids due immunoassay interference was reported with amphetamines in 2013.

The combined positivity nonnegative rates have increased slightly since 2011, from 1.89 to 2.06 percent in 2015. This has been primarily due to an increase in the combined drug positivity rate from 1.73 in 2011 to 1.89 in 2015.

The NLCP has several programs and projects, including the certification of all of our laboratories. The NLCP also works on special projects and programs with DWP as well. They work hand in hand with us on the urine and oral Fluid MGs. As you heard Mr. Flegel say earlier in his presentation, these two documents are in the current approval processes and hopefully, because they are so perfect, no one will have any more comments.

There are currently two approved eCCF applications and nine laboratories that are currently at some point in the review approval process.

Hair testing and the draft hair MG are progressing. Next week we are meeting to discuss the PT program for hair testing.

I would like to thank DOT for mentioning the laboratory investigations that we do. We investigate all of the anomalies that happen within our laboratories to make sure that our program is as strong as it can be, not only for the program's sake but also for the donors' sake.

We have studies that are on going in partnership with The Johns Hopkins University. The data from the newest study of smoked and vaporized marijuana will elucidate drug test results in urine, oral fluid, and blood specimens by the various routes of administration an individual can be exposed to cannabis. We continue to investigate and improve our stance on both urine and oral fluid drug testing.

The Marijuana Smartbook is one of the newest creations within DWP. Though not yet published, it is a resource guide that will help Mr. Ron Flegel, our DWP director, discuss marijuana and all the particular avenues that it may come up within any meeting or any discussion. The one charge that he gave us in preparing this document was to ensure that this book not only spoke to him but spoke to the general public as well. We included articles on popular culture and marijuana, on the science of marijuana, the laws and court cases on marijuana, congressional testimonies regarding marijuana, and which states have marijuana laws enacted. This resource, designed to help him and SAMHSA, will hopefully be published one day to help the general public, as well as anyone else who needs this particular document, to know about marijuana.

In summary, the number of regulated specimens tested by HHS-certified laboratories increased by 12.5 percent from 2011 to 2015. The number of regulated specimens reported as positive, adulterated, invalid, or substituted also increased 20 percent for that same period.

The factors behind the increase in the invalids due to low pH will continue to be investigated by the NLCP, as will the recent increase in the number of specimens invalid due to high pH. While we know that high pH in urine normally is due to bacterial contamination and increased temperatures during shipment, we are not sure that other factors, such as time in transit and the length of time in between collection and testing, may be important. The NLCP will be looking at these and other factors during the next few months to ensure that we stay on top and in front of anything that may be coming our way.

This is the end of the NLCP presentation. Are there any questions from DTAB?

MR. AUMEN: Hearing none, thank you, Eugene. Are there any other questions from the Board regarding any of these presentations this morning? Hearing none, we will move to the public comment period. We are about 15 minutes before the official public comment period time. Do you have anything, Ron?

MR. FLEGEL: Actually, I can talk more in detail regarding some of the information I presented initially in the opening remarks. We have several initiatives that DWP is working on. As Eugene mentioned, we have the Smartbook and the Marijuana Toolkit. We did several exposure studies in 2015 with published results due out in 2016. These data will assist other federal agencies in their understanding of marijuana and how we look at it. These studies have also been very useful for Driving Under the Influence of Drugs testing, especially for oral fluid. We have also evaluated some of the edibles to determine their potency. Hopefully, we will be able to publish those results in the future.

We also have a number of initiatives associated with our S&T meetings regarding hair. There were industry leaders, laboratory directors, federal agency representatives, and hair testing subject matter experts present. We have investigated the issues that have been put forward by the DTAB. We also discussed a number of issues submitted in response to the 2014 Request for Information. We will be summarizing all the information that we gained in this meeting in the near future. In addition, we re-evaluated the 2004 proposed draft MG for alternate matrices. We evaluated the questions posed within that document. We have made great start in understanding where we are and what we are currently evaluating. As Eugene mentioned, we will initiate the pilot hair PT program. That will be a discussion point at next week's meeting. The final revisions of the oral

fluid and urine MGs have incorporated recommendations from public commenters, federal agencies, and OMB. The documents had been resubmitted back to HHS and logged into the RISC and OIRA Consolidated Information System (ROCIS). We have received a few additional comments from federal agencies, which we are currently reviewing. Unfortunately, the public will not be able to view the documents until we have received all the comments back from OMB on the finals. Someone asked me where we are in the MG review process, shown in a previous slide. I believe we are currently in box 7. We will try to list that within the DTAB notes so we can point to where we are at the current time. That is most of the initiative updates that I had to talk about. In closed session, we will be examining some of the revisions that were made and the information from the S&T meeting. I want to again thank everyone for attending the DTAB and the federal agencies for their updates. I hope the updates were very informative to the public.

We will be adding a new a new ex officio to the DTAB with expertise in federal regulations, especially related to oral fluid and urine. Hopefully at the next meeting, we will have a third ex officio attending the DTAB.

I will turn it back over to Matthew for the public comment period.

### **Public Comment**

MR. AUMEN: For the public comment period, three individuals registered prior to the meeting for public comments. We have 30 minutes allotted, but I would like to keep public comments to about 5 minutes or less each if we can. I will begin with Judith Barrett from the International Paruresis Association. Judith, are you on the line? If so, please press star one to reach the operator who can patch you through to an open line. Okay, she is not on at this time. Next is Raymond Kubacki, CEO of Psychemedics Corporation. If you are on, please hit star one to connect with the operator.

MR. FLEGEL: Operator, are any of the individuals mentioned are on the line?

OPERATOR: I do not show anyone queueing by pressing star one.

MR. AUMEN: Our third individual who had registered is Sheila Harley, VP of Business Development at NetAmerica Corp. Sheila, are you on? If so, hit star one to connect to the operator.

OPERATOR: Again, no one queueing at this time.

MR. FLEGEL: Since we are a little ahead of schedule, let us wait another five or ten minutes and then re-announce for public comment. We will query those individuals again to see if they are available, and then if not available, we will adjourn the open session. We are going to mute our phones. Operator, if you do receive a star one from one of the individuals, please let us know.

MR. AUMEN: If anyone who did not registered ahead of time to give public comment and would like to give a comment at this time, please press star one. If we do not hear anything, we will mute our phones and wait about 10 minutes or so. Operator, is there anyone who pressed star one?

OPERATOR: No, sir.

MR. AUMEN: Okay, thank you.

(Pause.)

MR. AUMEN: Welcome back. This is Matthew Aumen, your friendly acting DFO. The registered public commenters will now have another opportunity to provide public comments during the scheduled public comment period, which began at 12:10. If any of those three registered individuals are on the line at this time, Judith Barrett, Raymond Kubacki, or Sheila Harley, please press star one to notify with the operator, and she will open your line for public comment. Not hearing from those folks at this time, are there any other members of the public who would like to provide comment at this time? If so, please press star one to be connected to the operator, and she will open your line up for you. Thank you.

Someone is asking a question on the web chat. I will give her a minute to finish typing. We do have a question from Tressa Johnson for Dow. Her first question is whether DOT is conducting international testing, and her second question is since DoD labs are certified by NLCP, can a federal agency under HHS utilize a DoD lab? Thank you for those comments. The Board will review them during the closed session. Are there any other comments at this time? Hearing none, we will conclude the public comment period and adjourn. Ron, did you have any closing remarks?

MR. FLEGEL: I want to thank everyone for taking time out of their day today to be with us at this DTAB meeting. As Matthew said, we still have not established whether the July meeting will convene either by web conferencing only or onsite; tentatively it is scheduled for an onsite meeting. That information will be provided to the public in the Federal Register Notice announcing the meeting. And thank you again. I will turn it back over to Matt.

MR. AUMEN: This concludes the public meeting of the DTAB. The Board will reconvene at 1 p.m. in closed session to review the MGs. Thank you all for participating, and we are now adjourned.

(Whereupon, at 12:20 p.m., the open session was adjourned.)