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

# Drug Testing Advisory Board (DTAB) Meeting

## Open Session

**June 13, 2017**

**SAMHSA**
**5600 Fishers Lane**
**Rockville, Maryland**

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**P R O C E E D I N G S (9:00 a.m.)**

**Agenda Item: Call to Order, Brian Makela**

**Designated Federal Official,**

**CSAP, SAMHSA**

MR. MAKELA: Good morning, everyone, and welcome to the June quarterly meeting of the Center for Substance Abuse Prevention's Drug Testing Advisory Board. My name is Brian Makela, and I am the designated federal officer. I officially call this open session of the DTAB to order. Today's open session is scheduled to start at 10 a.m. and end at 1 p.m.

I would like to welcome our board members, the Division of Workplace Program staff, our federal partners, contractors, and members of the public. Today's meeting is an open session with presentations from our federal partners at the Department of Defense, Department of Transportation, and the Nuclear Regulatory Commission providing annual updates on the drug testing programs.

We will also hear an annual update on the division's National Laboratory Certification Program, or NLCP. SAMHSA has asked the public to register for comments and no one registered to make public comments during this particular meeting.

Today's presentations are available through Adobe Connect. The web conference address was provided with the

meeting registration. For those of you who called into the teleconference, you will be in listen only mode. For our presenters, please make sure to mute any devices and minimize background noises during your presentations.

There is one more meeting scheduled for the fiscal year on September 19 and 20. The meeting will take place on site with the option to attend by web conference. The topics to be presented are yet to be determined and it has not been determined if the meeting will be open, closed, or a combination of both.

A notice with the description of topics and the open or closed nature of the meeting will be published in the Federal Register approximately two weeks prior to the meeting date. You can find public information about the board, its past meetings, presentations, transcripts, and summaries at the website listed here. Information from this meeting should be available approximately three to four weeks from today. Thank you again, everybody, for attending.

I would now like to introduce the director of the Division of Workplace Programs as well as the chairman of the Drug Testing Advisory Board, Mr. Ron Flegel. He will get us started with introductory remarks and a quick update on advisory board and program activities.

**Agenda Item: Welcome and Introductory Remarks**

**Ron Flegel, B.S., MT (ASCP), M.S.**

**Chairman, Drug Testing Advisory Board**

**Director, Division of Workplace Programs**

**(DWP), CSAP, SAMHSA**

MR. FLEGEL: Thank you, Brian. I'd also like to welcome everybody to the third Drug Testing Advisory Board meeting for fiscal year 2017. I would like to thank the board members, ex officios, industry representatives, and members of the public for taking the time out of their busy schedules today to join us for the Drug Testing Advisory Board.

Over the next several minutes, I will be updating you on the progress of the mandatory guidelines for both urine and oral fluid, the progress of the mandatory guidelines for hair, the Division of Workplace Program's initiatives and other programmatic information that the HHS-certified laboratories, federal agencies, the drug testing industry, and the public may find helpful and interesting.

We have a number of presentations today, as our federal partners will be providing annual updates on their respective drug testing programs and the impact on the government and the industry. As mandated by Executive Order 12564 and Public Law 100-71, the Division of

Workplace Programs develops and revises the mandatory guidelines for federal workplace drug testing programs.

The Drug Testing Advisory Board was created with the intention of utilizing experts in biochemistry, toxicology, laboratory operations, and testing for drugs in various matrices, and donor advocates to advise the Assistant Secretary for Mental Health and Substance Use, formally known as a SAMHSA administrator, on the development and the revisions of the mandatory guidelines.

SAMHSA seeks to improve the quality of service for forensic workplace drug testing, assess the science and technology used in drug testing analysis, 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.

The CSAP DTAB provides advice to the Assistant Secretary for Mental Health and Substance Use based on the ongoing review of the direction, scope, balance, and emphasis of the agency's drug testing activities and the drug testing laboratory certification program.

The CSAP DTAB shall review SAMHSA's program for National Laboratory Certification Program for federal workplace drug testing as required by Public Law 100-71 and

as described in the mandatory guidelines for federal workplace drug testing.

It shall recommend areas for emphasis or de-emphasis, new or changed direction, and mechanisms of approaches for implementing these recommendations. This includes new and emerging drugs, new technologies, alternate matrices, the future program objectives, as well as other issues.

Periodically, the CSAP DTAB shall review specific science areas on new drugs of abuse, specifically the synthetic drugs, and the methods necessary to detect their presence. Again, the purpose of this particular meeting is to provide updates within the program as well as updates from our federal partners on their programs under their specific authorities. I will briefly address the status of the urine and oral fluid mandatory guidelines and details around the October 1 implementation date in the PowerPoint presentation I will show. Again, I would like to thank you again for attending the Drug Testing Advisory Board.

The mandatory guidelines for urine were published in the Federal Registry on January 23, 2017. It was 82 FR Notice 7920, pages 7920 to 7970. The effective date, more determined, was October 1, 2017. Some of the changes within the revised mandatory guidelines for urine were the

addition of synthetic opioids, the oxycodone, oxymorphone, hydrocodone, and hydromorphone.

MDEA was removed from the testing panel. Additionally, MDA was added as an initial testing analyte. Also, we raised the lower pH cutoff for determining an adulterated specimen from 3 to 4. This was through many evaluations in the NLCP program looking at different specimens that came into the program and what they were effectively made up of.

A number of these were synthetic urines and other additional things that were added to the specimen. Additionally, to note was the Department of Transportation's Notice for Public Rulemaking was published also on January 23, 2017.

Under the National Laboratory Certification Program, the implementation of the urine mandatory guidelines. We're currently revising the program documents. This includes the NLCP manual, the NLCP checklist application for the laboratory application for a certified HHS certified lab, the C tables, which mostly are all due in July or August of 2017.

We've also assessed and looked at the federal agency collection site assessment documents. Those are also being revised and updated based on the revised mandatory guidelines. We've also finished the HHS medical

review officer guidance manual and it's going through the final review process. We've also finished the HHS specimen collection handbook. All of these program documents will be put on the website prior to the actual implementation date.

Real quickly, to talk about the implementation of the proficiency testing samples, there are three qualifying sets of the proficiency testing samples. These three sets were sent out on May 1, June 12, which was yesterday, was the second set, and July 24 are upcoming in 2017.

The laboratories have completed the first set and reviewed that and we feel very confident that laboratories can perform the testing on the synthetic opioids, among other things. The verification PTs, post implementation, will be October 9, in 2017, so after the implementation date of October 1. We're currently also working with drug program coordinating training and we're trying to get this training acceptable so that we can put this out in the last part of August or September. We also plan on doing inspector training in September 2017 around the new revisions to the mandatory guidelines.

Again, the proficiency testing cycles, just to update all the matrices, urine, we've integrated the new analytes and the pH changes in the quarterly PT's at -- or we will integrate those into the quarterly PT's as of

January 2018. The oral fluid, we have three occasions, including the new analytes beginning in January 2018.

We've suspended one of those proficiency testing PT samples. One was financially, and the second was we needed to concentrate on urine. And the last was with hair, and we continued to develop an inventory of user hair specimens to look at the federal drug testing programs regarding hair.

Within the drugfree workplace program, DWP continues to brief agency drug program coordinators and senior leadership of these federal agencies on the upcoming changes. We've also briefed a number of unions on the upcoming changes, specifically around the synthetic opioids.

Again, the implementation of the revised urine mandatory guidelines is October 1, 2017. DWT and DWP interagency coordinating group briefing, which is basically the federal agency's drug program coordinators, was set for June, which has currently been postponed. We have revised that schedule. We are now currently looking at doing a web or teleconference presentation and it is tentatively scheduled for late August or early September.

Within the agency briefings, again, this is to occur in September 2017, both webinar attendants as well as onsite here in the location for SAMHSA, some of the agenda

items, we will be looking at the scientific background and implications of testing for synthetic opiates, the status of the oral fluid testing, some of the studies in progress toward inclusion of other alternate matrices, the electronic chain of custody formed as well as both the revised form, including the synthetic opiates and also the old form.

We also are looking currently at the annual survey report, better known as the ASR for federal agencies, and we're trying to streamline the reporting of that data or the federal data so that we can look at that almost on a daily -- if we wanted to look at it onsite or on a daily basis. The next step for agencies and drug program coordinators, and that again will be the briefing.

Within the mandatory guidelines for the oral fluid, we are currently under final review by SAMHSA HHS. Within the hair, the mandatory guidelines for federal workplace drug testing, using hair is currently under review. Comments from both DTAB and HHS are being considered at this time.

DTAB recommendations, one of the issues with the recommendation on hair is currently being addressed, and those two within the recommendation were decontamination and hair color impact.

Some of the ongoing studies that the program had both completed and ongoing, an ongoing study we are looking to start in August 2017 to finish up a number of the studies we had done around marijuana would be the cannabidiol study. A number of, I guess online, there are a number of products you can buy around cannabidiol. So the tentative start date for this study would be August 2017.

Some of the pharmacokinetics and pharmacodynamics studies that we've used for oral, smoked, and vaporized cannabis, two presentations I just wanted to note for SOFT members, Society of Forensic Tox members, in 2017, we've had three of these presentations accepted. The first is the disposition of cannabinoids in oral fluid and whole blood after vaporized and smoked cannabis. Very interesting study.

The next would be the pharmacodynamic comparison of acute cannabis effects following oral, smoked and vaporized administration, and through route of administration, there is a significant difference in what you see as the testing. Also, I also want to bring up, which was briefly talked about in the last Drug Testing Advisory Board meeting, was around hair and this presentation has been accepted. It's on opioid glucuronides. It is the detection and quantification by

LC/MS/MS of opioid glucuronides in hair of opioid users, and again, that revolves the unique metabolites within hair for these specific drugs.

So with that, I will close and if there's any questions from the Drug Testing Advisory Board, I will take those at this time. Otherwise, I will turn it back over to Brian Makela.

MR. MAKELA: So Carol, if there are any questions from board members for this particular presentation, could you open up their mics?

OPERATOR: Thank you. And if you have a question or comment from the phone, please press star-1. Make sure your phone is unmuted and record your name to introduce your question, and to withdraw that request, you may press star-2.

We'll stand by for questions or comments.

MS. KELLY: Hello, this is Patrice Kelly from DOT. Could we go back to slide 20 for a moment? Thanks. So on mandatory guidelines for federal workplace drug testing, you're saying it's under review. So there is something that's drafted?

MR. FLEGEL: Currently there is a proposed draft of the mandatory guidelines for federal workplace drug testing. There were a number of issues within the recommendations, and those issues are being addressed

mostly by literature. Currently there could be a number of studies that we've looked at or we need to proceed with, but most of those issues, again, we're looking at addressing by literature.

MS. KELLY: Thank you for that clarification.

OPERATOR: I am currently showing no questions or comments from the phones at this time.

MR. MAKELA: Thank you. Thank you, Ron. What I will say is that since there were no public comments, any questions or comments about the next presentations from our federal partners, we are going to -- I would ask the board members to hold their questions or comments until the time after the last presentation, and we can address them all there. It will make it a little easier, and since we have the time allotted now that there are no public comments.

So moving on.

OPERATOR: We do have one question that just queued up from the phones. Jennifer Collins, your line is open. Please go ahead.

DR. COLLINS: Thank you. Hey, Ron, I did have one more question, and that is whether or not you can provide an update on the status of the revised custody and control form. It doesn't appear that that has been finalized yet. Is that correct?

MR. FLEGEL: That is correct. Again, Charlie did a presentation in our last Drug Testing Advisory Board. Currently -- I didn't give a status update, but the status of the chain as well as the electronic portion and the old CCF that we are currently -- is now at Office of Management and Budget, and it has at this current date, it has not been approved.

We have given guidance to the laboratories as to how to proceed with that once the approval for the new chain as well as the old CCF. Then we'll again give further guidance, and I'm assuming that within the programs we will also work with DOT to give guidance for the Department of Transportation's, the regulated samples themselves.

So currently status is that there is no requirement of a memorandum of understanding or memorandum or MFR for those samples that are coming in, and Patrice can address that in her update if there's questions regarding that. But currently we are hoping shortly it will be approved by OMB.

OPERATOR: I am currently showing no further questions or comments at this time.

**FEDERAL DRUG TESTING UPDATES**

MR. MAKELA: Okay, so we'll move on. I would like to introduce Ms. Patrice Kelly. She's the acting

director of the Office of Drug and Alcohol Policy and Compliance within the Department of Transportation. Please welcome Patrice.

**Agenda Item: Department of Transportation Drug Testing Update**

**Patrice Kelly, J.D., Acting Director,**

**Office of Drug and Alcohol Policy and Compliance**

MS. KELLY: Thank you, Brian. Thank you very much, everyone. Again, I'm Patrice Kelly, the acting director of the Office of Drug and Alcohol Policy and Compliance.

This is our secretary, Secretary Elaine Chao. She returns to us after being away for many years. She was here at the start of the program, about 25 to 27 years ago, as the deputy secretary. Secretary Chao has a very strong interest in this program. She was there with the early litigation and she has remained actively interested. So we were particularly pleased to welcome back somebody who had been a strong proponent of our program for so long. Her number one bottom line is safety, and again, we're grateful for that and her support.

Our program services, most of you are very familiar with what we do. We advise the secretary and the DOT agency administrators and by the DOT administrators, it's specifically the modes that we cover and I'll talk

about that a little bit later. Our program issues are at the national and the international levels. We do a lot of international consultation and discussion with foreign governments who are either implementing drug testing for the first time or are grappling with the concerns and interests in their communities regarding gaining workplace drug testing.

We work with the Office of National Drug Control Policy, as do most of the folks in this room, dealing with supply reduction and demand reduction issues. We have the DOT agency in the U.S. Coast Guard drug program activities and those are the various modes that implement our drug testing regulations throughout the transportation industries.

We strive for a ONE-DOT approach. We recognize that each of the industries are very different and what works for an airline does not necessarily work for a railroad, nor does it work for a transit administration who has people out on the streets and dealing with situations where their employees are exposed to individuals who are out and about in states, for example, where marijuana is legal.

So we have a lot of unique situations and yet we strive for a ONE-DOT approach, to bring everyone together under our regulation 49 CFR Part 40 so that people can

actually, across the transportation industry, have one way of doing the testing. Obviously, we follow HHS as a science-based organization for our testing so that's, again, a common place where we all come together in the ONE-DOT approach. We also collect and analyze data and information and I will be going through our data during this presentation.

We develop plain language regulations, guidance documents, and policy interpretation. The plain language regulations, I usually explain to people, if they don't think 49 CFR Part 40 is plain language, they might want to try reading the IRS code first, and then they'll see that it's actually pretty readable and pretty workable.

So we're very proud of our regulation and we did get a plain language award for it when we rewrote it back in the year 2000. Actually, of that original rulemaking team, only three of us are left, myself, Mark Snider in my office, and Patty Sun, an attorney with the Federal Railroad Administration, but that's also a wonderful thing because we still have institutional memory as to what we've said in part 40 and exactly why. That's very helpful not only to our management and our colleagues, but also to the public. A lot of times, a regulation is a lot easier to implement if you understand why things are a certain way

and certainly a lot easier to remember when you've got that basis.

We provide consultation and liaison with executive branch agencies and as I said, foreign governments. Our executive branch agencies that we interact with the most are ONDCP, here at HHS, Department of Homeland Security, DHS, United States Coast Guard falls under Homeland Security, Department of Defense, Nuclear Regulatory Commission who have representatives here today, DOJ, DEA, et cetera.

With respect to foreign governments, some of the ones we've talked with, Mexico, Canada, Australia, England, Germany, Nigeria, China, New Zealand, et cetera. The Nigerian federal air surgeon told me herself that they actually use part 40 for airline pilots in Nigeria. They want to make sure that the testing is done in accordance with part 40 and therefore also very similar to the central protocols.

The industry stakeholders and customers, we have a tremendously large regulated industry out there and I'll show you some of the numbers. But basically, we anticipate any given year that we'll have between 5 and 6 million tests. That means that we probably easily have at least 5 million people subject to testing, but because that number fluctuates and because with a lot of small businesses out

there, it's hard to get the actual numbers of people subject to testing, I can tell you pretty safely, it's upwards of that.

So there are a lot of industry stakeholders, a lot of customers we have out there. We take a lot of phone calls. We do a lot of education to try to get the word out there. Unions, employers, service agents, the more information we can get out there about our program, the better we can achieve compliance without having to take enforcement action. So our office also strongly supports issue conferences and training events.

We ensure the safety and security of the traveling public. We reduce the demand for drugs by transportation workers by having this program in place. It does make a difference. Reducing alcohol misuse in the transportation industry is another piece of what we do, because we are the Office of Drug and Alcohol Compliance. So alcohol misuse is a component of our program.

Create prevention and treatment opportunities. Ours is not designed to be a punitive program nor is the HHS program designed to be punitive. In our program, it's important to remove people from safety-sensitive functions when they have a non-negative result or a refusal, but to be able to get them the help they need so that when they are ready to return, they can return safely.

Here are the various modes of transportation, or sometimes as we affectionately refer to it, our family portrait. Part 40 is our regulation in the Office of the Secretary under Secretary Chao. We have the Federal Motor Carrier Safety Administration, FMCSA. I'll just read down the modes. Federal Railroad Administration, the Pipelines and Hazardous Materials Safety Administration, the Federal Transit Administration, the Federal Aviation Administration, and the United States Coast Guard.

So they're all the folks who are covered under our regulation who utilize part 40 but who have their own distinct regulations that cover who's subject to testing, what employers, what employees, under what circumstances. All of those are clearly defined so that they work well in the specific industries. They're tailored to match. Again, they incorporate by reference our 49 CFR Part 40.

The current drugs tested. We often get the question from industry and individuals out there about how many drugs are in our panel. We screen, we all in this room, screen for five, and we confirm for 11. We find that it's very helpful information to get out to folks because they'll say, well, now you've increased to an 11 panel, and it means HHS is increasing to a 15 panel, and that's not true. We go by the panel categories and the four synthetic

opioids would fit into the opiates for us, would be presumably the opioids category.

The schedule I drugs that are listed in red, those are the drugs for which there is no legitimate explanation.

Moving onto our data, we have the data I'll provide to you from 2009 to 2016. First, the assumptions. We collect the data; our office, ODAPC, collects the data from the laboratories, not from all the regulated employers. It's up to each of the modes of transportation, remember, FAA, Federal Motor Carriers, et cetera, to collect it from the individual employers.

Some of our modes are smaller, and they can collect the data from all of their employers. Some of the modes are larger, like Federal Motor Carriers that has way more than 4 million regulated employees, and they figure more than 800,000 regulated employers.

The cost of collecting that data individually from each of those employers today is cost prohibitive. I really hope that the electronic CCF goes fully electronic, because then that data will not be cost prohibitive for us to see from the end user, but today, we can collect the data from laboratories.

So what I present to you today will be not MRO reviewed data, but the raw data right from the

laboratories, and it does include blind specimens because the laboratories of course do not know which ones are the blinds. The drugs tested for the five, in order of prevalence of what we're seeing, marijuana is the most common, for us amphetamines comes in second, cocaine, opiates, and PCP.

Our overall positive rates have remained below 2 percent, and again, marijuana most, amphetamines second. Moving down my list, cocaine rose a little bit after it had been declining for the past three years. The positive rate for opiates, somewhat ironically, declined slightly after rising over the past six years. So cocaine and opiates almost crossed with opiates becoming a little bit higher on the list, but then opiates declined a little and cocaine rose a little. The positive rate for PCP remains low.

Admittedly, fewer than 1,400 people test positive for each year and they are not just blind specimens. We through inspections have actually found individuals in the transportation industries who used PCP. That is purely terrifying because it is a hallucinogenic and pain-suppressing drug. It kills your nerve endings so while you're using it, you don't feel pain. That's a very, very dangerous situation that can be posed in the transportation industries. So we are grateful to SAMHSA for keeping that in the panel.

The number of tests indicate some tampering as possible has been declining for the past three years, but those are still results we work with SAMHSA on.

Here, for most of you who are scientists, you love the bar data. For those of us who like the background first, that's the background. Now you can see the actual data: 5.4 million tests were done last year. That's down from 2015. The reason for that is because last year, the Federal Motor Carrier Safety Administration had moved from a 50 percent to a 25 percent testing rate. So as I said, remember they're the largest of the modes and they would have the largest number of the tests.

So seeing the decline in data is not something to be alarmed about. It just simply shows that fewer tests are being done through the FMCSA's regulation and that does have an impact on the overall. Yet, it's still just under a million fewer tests. So we're not talking about half the number of tests.

The lab reported U.S. drug testing data, number of positive results for each calendar year, and the top line is the PCP, the smallest of course, the blue line being the opiates, the cocaine, the amphetamine, and the THC are listed, THC being green of course. So if anyone wants to see those numbers, those are our actual numbers

that we're getting back from the laboratories. Again, remember, before the MRO verifies.

So you're going to see a lot of amphetamines out there. Unfortunately, they're using that to treat a lot of the adult onset ADD, ADHD, those types of things. So we are seeing more of those, but a lot of those go away with verifications.

Then this is by percentage, the positive rate based on total test results for each year. And this is our slide about the percentage positive versus tampered versus rejected. The positive is your highest of the lines, with the tampered being the dark pink, the middle line, and then the rejected for testing, the purple. Again, as we find them tampered, as we find them rejected, those are communications, conversations we have with SAMHSA, and DWP is very, very responsive to us as we raise those questions.

Our horizon issues, the marijuana issues, we're continuing to track what's going on with marijuana. As most of you know, the DEA decided to keep marijuana schedule I which was very important for our program from a safety standpoint so there would be no legitimate medical explanation for actual marijuana use. However, another part of that initiative from DEA was to change the requirements regarding research, regarding who they would allow to grow marijuana for research purposes. So we

really do hope that that's going to bring a tremendous amount of marijuana research into light so that we can deal with the various impairment issues.

When our colleagues at DOT under the National Highway Traffic Safety Administration, NHTSA, were testing to see what the impairment levels could be, should be, it was pretty difficult to do considering the fact we were growing things that were far weaker than anybody was actually using in Colorado, Washington, Oregon, et cetera. Essentially, the private users had just much more potent stuff. So hopefully the DEA's changes will help us to get research to a better level, and I know that affects DWP, too.

We're also on a federal interagency working group dealing with marijuana issues. As we track what's going on on the state level, we're also very interesting on what's happening on the international level. Somewhat paradoxically, a lot of foreign countries are challenging us, saying we have treaties that say we will not legalize these things, and yet here we're moving forward at a state level and allowing this to go on.

So there have been a lot of times when Department of State has had to be called to task as to what's going on here in the United States. So again, it's important that we as federal agencies continue to communicate with each

other, and this working group has been of tremendous importance to us in our office.

Going around the alternate specimen testing methodologies, again we're looking to our scientists here in this room and at SAMHSA to provide us more information about when oral fluids and hair are ready for actual mandatory guidelines to be published. We can use them after SAMHSA decides that they are scientifically reliable, forensically defensible, and as long as the outcome fits within our Omnibus Transportation Employee Testing Act of 1991. So that's a lot of details to be going forward with, but just to kind of give you that idea.

Also, oral fluids, we're starting to get a lot of questions in my office from the public regarding October 1 implementation of oral fluids. That has never been a date DOT has given out. We have not reached final rule. Until we reach a final rule, we do not have a publicly available date. People have even gotten to the point of asking me, how can we make it effective without having published final rule? And that is, of course, the key point. We have not published a final rule.

I'm sorry, that's on the opiate side. I jumped across on the opiate side. On oral fluids, again, we're waiting for SAMHSA.

So those two sides of it are the SAMHSA sides, driver clearinghouse database, job-hopper database, final rule, Motor Carriers moving toward implementing, it's still got another about two and a half years before that's finished, public interest exclusions, an active area we follow up with service agents. And then finally reaching the bottom, eCCF implementation, extremely important to us. We continue to work closely with DWP, and that's pretty much it on the horizon issues.

Our staff, myself, our acting deputy Bohdan Baczara, Cindy Ingrao who is here with me today is our senior policy advisor. Mark Snider, chief of inquiries and audits, works in large part on the PIEs also. And our administrative staff and our website.

Our technical assistance, last year we had just under 15,000 phone calls, emails, Ask ODAPCs, and interactions with DOT program managers and our regulated public. That's more than double what we had in 2012 and I've been acting director since 2013.

We have almost 39,000 people on our list serve as of April 29, 2017. That was the last list serve that we sent out to let folks know about a Take Back the Drug Day at DEA. That's almost 17,000 more subscribers than we had in 2012, so again, as we get out there, as we provide more information to the public, we raise awareness through the

list serve and we've put out list serve announcements for DWP before also to let folks know when things are out for public comment and what have you.

Finally, on our website, we are the DOT's most viewed website with 650,000 some-odd sessions in 2016 and, at one point, 1.7 million subpages viewed.

Then finally, we encourage everybody all the time to join ODAPC's list serve because that's really how you're going to get the information, how you're going to stay informed about changes to the DOT regulations. And finally, that is actually what our webpage looks like. Again, just to clarify, the October 1 date is for the opiates, and to let you know that that is the DWP date and we have nothing public yet for the DOT.

Thank you, and that's it.

MR. MAKELA: Thank you, Patrice. Actually, if you could stay up there since we have a couple more minutes, we can actually take any questions from board members about this presentation, any questions or comments. First, we'll open it up to members present in the room and then if anybody on the phone wants to question or comment, we can take that.

Anybody in the room? No comments here. Operator, can you find out if any members have any questions or comments on the phone?

OPERATOR: Certainly, and if you have a question or comment from the phone, please press star-1 at this time. Make sure your phone is unmuted and record your name to introduce your itself, and to withdraw that request, you may press star-2.

One moment, please. We do have a question or a comment from Jennifer Collins. Your line is open. Please go ahead.

MS. COLLINS: Hi, Patrice. I know that you just addressed the fact that there is no final rule on the anticipated October 1, but do you have any information on when we might see that rule, by the way?

MS. KELLY: No, unfortunately, Jennifer, we can't release any information about pending final rules, just that we don't have it out yet, but thank you for that question.

OPERATOR: Thank you and I'm currently showing no further questions or comments.

(Pause.)

I am currently showing no questions or comments from the phones at this time.

MR. MAKELA: All right, well, thank you, Patrice, for your presentation.

Up next, we'll turn our attention to the Nuclear Regulatory Commission. Today's presentation will be split

between Paul Harris, who is the senior program manager in the Fitness for Duty Program, and Brian Zaleski, a Fitness for Duty specialist within the program. Here's Mr. Harris.

**Agenda Item: Nuclear Regulatory Commission 10 CFR Part 26**

**Fitness for Duty Program, Paul Harris,**

**Senior Program Manager, Fitness for Duty**

**U.S. Nuclear Regulatory Commission**

MR. HARRIS: Good morning. My name is Paul Harris. I'm the senior program manager at the Nuclear Regulatory Commission here in Rockland, Maryland, and with me today I have Brian Zaleski who is an FFD program expert. He'll be speaking after myself on FFD performance data.

On behalf of the Nuclear Regulatory Commission, I'd like to thank the Drug Testing Advisory Board, and in particular, Ron Flegel and staff for inviting the Nuclear Regulatory Commission again to present at the DTAB meeting.

We noted that the DTAB charter has five specific program objectives and these are commendable program objectives as summarized by Ron during his opening statements. But I find what's most important about these program objectives is not the statement of them but the outcome of the objectives.

DTAB's efforts are definitely the silent force in authority behind the conduct of millions of drug tests that

are conducted in the United States of America every year. These drug tests are designed to help detect and deter illicit drug use, thereby enabling drug treatment and assistance and precluding events that are adverse to public health and safety.

The Nuclear Regulatory Commission was established basically in 1954 with the Atomic Energy Act. Congress wanted to promote the peaceful use of nuclear energy throughout the United States, and the Nuclear Regulatory Commission was absorbed at that time within the Department of Energy. In 1974, the Nuclear Regulatory Commission was removed from the DOE and formed as an independent agency regulating the commercial nuclear industry in the United States. That occurred in 1974.

Our mission is to regulate in a manner that protects the public health and safety and promotes a common defense and security through the regulation of special nuclear material. We provide minimum regulatory oversight and requirements as necessary to ensure that programmatic mission.

Today, I would like to discuss a quick overview on what our program is. It's on 10 CFR Part 26 Fitness for Duty Programs. I'd like to discuss what is Fitness for Duty, what the program objective is, what's some of its key elements, some overall performance observations, policy

considerations. Then I'm going to have Brian Zaleski go into performance and operating experience, which should be very insightful. Last topic will be a little bit about electronic reporting.

Fitness for Duty is a defense in depth program. It's a strategy that utilizes multiple programs to identify not only drug users and individuals who are illicitly using impairing substances, but also identifies what we call the insider. It identifies individuals who may be untrustworthy and unreliable to safely, competently perform assigned duties and responsibilities.

So the strategy that we employ is a four-pronged approach. One utilizes access authorization and that basically is a program that does background checks of criminal employment in academic and financial histories, personal history, a psychological assessment, character and reputation reviews, and it also queries a national database that we have been maintaining for a number of years to identify whether or not these people can be afforded unescorted access to our nation's nuclear facilities.

We also employ fatigue management as an element of Fitness for Duty program. We also employ behavioral observation. All individuals who have unescorted access authorization to our nation's nuclear facilities are required to perform behavioral observation on their peers.

Therefore, if they identify an individual as being potentially impaired for any cause, mental or physical, that individual should report, and I may say is required to report, to the licensee that that individual may be impaired. That individual would then undergo a for cause drug and alcohol test and evaluation by a reviewing official medical review officer and potentially a substance abuse expert.

Our program applies to not only commercial nuclear facilities that generate about 20 percent of our nation's nuclear energy, but it also applies to what we call fuel cycle facilities. These are facilities that generate, that process and form nuclear fuel.

So we have a number of facilities out there, namely, two of them. One processes primarily Navy nuclear reactor fuel, and the other processes primarily -- well, both of them do the fuel, but one element is Navy nuclear fuel and the other is commercial nuclear industry fuel. So our program also applies to that element there.

The overall program objective, I don't want to read through this but I do want to highlight two key elements that I already mentioned upon. If you notice, in the second line there, the program is for any substance in which an individual may be impaired, legal or illegal, mentally or physically impaired from any cause is what's

included in our program, which in any way affects his or her ability to safely, competently perform assigned duties.

So therefore, this program goes above and beyond drug testing. I'm a firm believer that drug testing cannot get us to safety and security 100 percent of the time. We need other elements of the defense in depth program that prevents the actual individual from actually conducting the activity.

Drug and alcohol testing at pre-access is probably the best, strongest method to assure public health and safety because you're identifying those individuals prior to them conducting those activities that can be adverse to public health and safety. So we're a big program supporter of oral fluid testing and anything to improve the pre-access evaluation of individuals such as pre-access hair testing.

Once they get inside the power plant, now we have to do a for cause behavioral observation program. This applies equally to Department of Transportation -- I know that they are very aware of this -- that once that individual is impaired doing an activity within the public, that individual has a potential consequence that could be dire for a number of individuals.

Nuclear power facilities are the most heavily defended and fortified commercial operated and licensed

facilities in the world. Up in the left-hand corner is a spent fuel pool. Top center is what we call an independent spent storage installation. Those big canisters are containing spent nuclear material. We have robust security and safeguards around all these facilities.

In the bottom left hand picture, is what's called a research and test reactor. That right there is a trigger reactor which pulses through probably, well, I don't want to get into that because I might say something wrong, but that's a research and test facility. The center bottom of course is a nuclear power plant, and then the right bottom of course you see some of the security features that we require licensees to employ to defend against what we consider the design basis of threats.

The seven key program elements that make us sort of different than DOT program. I'm going to go through right here really quickly. The first one is that we do a lot of testing at lower cutoffs if the licensees establish a policy and procedure that enables lowering of cutoffs.

We allow for testing for additional drugs. We do what's called dilute specimen testing. If the specimen shows dilute characteristics from the laboratory, we enable licensees to test for drugs and metabolites down to the limit of detection.

Brian's going to talk a little bit about time-dependent alcohol limits, which is a very strong and valuable tool that we enable licensees to identify individuals who may be on alcohol or are impaired from alcohol.

We require behavioral observation both onsite and offsites. Offsite is primarily associated with illegal drug use. Required sanctions, we do require sanctions. Sanctions are utilized for two purposes. One is to enable the time period for treatment of the individual who has been identified, but secondly, it's a trustworthiness and reliability issue.

If the individual is identified once, that results in a small sanction on the individual who is now afforded access to the power plant, for about 14 days. On a second occurrence, however, it's a 5-year denial. The person is not allowed to go to the site of a power plant for 5 years. On a third denial, he's permanently denied forever. He cannot get in.

We also issue a permanent denial for a subversion attempt. We take subversion attempts extremely seriously in the Nuclear Regulatory Commission and again, Brian Zaleski will talk a little bit about subversion attempts and show you why it's such a regulatory concern.

So we do scale our sanctions to severity. We do take a graduated approach to it, but I, as a senior program manager, I have little tolerance for drug and alcohol use in these facilities.

Next slide here is four overall performance objectives. Brian will describe these in more detail. I just want to go through, point this out really quick, positive rates in the nuclear industry continue to be very low, and affected individuals have not contributed to any significant nuclear events. You've got some sub-bullets there that you can read on your slides. For timeliness, I'm going to move on.

Pre-access testing directly contributes to the safety and security as I previously mentioned. Brian's got the data, but about 65 percent of our substance-using individuals are caught at pre-access testing. Anywhere we could strengthen that program, we're all for that.

Training and vigilant collectors are identifying the majority of subversion attempts. We cannot drum this home enough. It is the collectors who are identifying the subversion attempts. We get very few subversion attempts identified by laboratories.

I have talked to DTAB on that before in previous presentations and to HHS on a number of presentations. We've got to get in front of these before these individuals

are actually doing these duties and responsibilities. I already talked about behavioral observation.

Future policy considerations, really quick, I'm at my 10-minute point, I've got to move on. First one, the changes in the Department of Health and Human Services mandatory guidelines for federal workplace testing is a regulatory burden. Whenever these changes occur, the supporting federal agencies have to undergo rulemaking to implement these changes. So that's a regulatory burden upon the staff of the agencies and upon the affected individuals inside the regulated community.

So we're taking a look at how we could better enable that such that when the guidelines change, we can seamlessly and transparently progress to the changes without a lot of regulatory burden. So that's what we're working for there.

Number two, timely enable effective licensee response to changes in societal substance abuse. So what we see is, let's say we stand back and we see changes in drug use and prevalence use outside in society, how does that impact our industry? Brian has some data on that, but clearly we want to do something the Department of Defense is doing. They do what's calling prevalence testing. They're actually surveying their affected work force to see what drugs they're actually using.

The second thing we're looking at is a proactive assessment on prescription drugs. A number of commercial industries out there, namely Exxon and large oil facilities, require the announcement of prescription medications. A number of commercial nuclear industries are also announcing prescriptions. That's one way to get in front, so we're looking at that.

We already talked about oral fluid testing. We're looking at alcohol portal monitors to keep alcohol outside the power plants because that's pretty high as well. We're also looking at hair testing for schedule I drugs on pre-access testing. Why do I focus on schedule I? Because I think that's the easy way to go right now until the guidelines get issued.

Number four, detection of subversion attempts; you could read that. Oral fluid testing, Brian will talk about the data there and give his thoughts.

The fifth one, enable medical review officers to access the state prescription databases. We cannot state more strongly the need for timely MRO access to state prescription databases to evaluate an individual's drug use at power plants. So right now, we're getting the donors' consents to have the contemporaneous medical doctor for the individual to access that database, to get that information, but if we could facilitate the commercial

nuclear industry and probably the DOT MROs to have unfettered access to that information, in the conduct of the requirements, I think that would be a strong area to go. So that's something I know I would like to work for and would work with my counterparts to help facilitate that.

Next slide is we're getting into Brian. Let me introduce Brian Zaleski. Brian, if you could, come up here real quick. Brian is new to the agency, been into the agency for about three years. He's been doing department of tests, auditing, inspection of the drug testing programs for decades and probably has been a contractor for the NRC for a decade as well. Lots of experience. Here's Brian.

MR. ZALESKI: Thank you, Paul. Good morning, everybody. What I hope to accomplish today is to provide an update on the 2016 test results for Fitness for Duty testing programs in the country. Our presentation is reflecting the entire industry's data. There is draft all over this presentation because we received the results at the end of February, so we're still using some QA/QC on the results.

We collect individual-specific data on every testing violation. This is based on a voluntary reporting system that we put in place in 2009. Since 2014, we have 100 percent use. That's given us a lot more precision and

the ability to dig a little deeper into our testing program and to try to characterize the risk categories better.

Hopefully in this presentation you'll see some of that information, and we use this information for a variety of things. We use it for reflecting the current performance of our industry, for the individual utilities to take this information and to evaluate their own program in comparison to their peers. We use this to inform the public.

We also use this to inform our inspectors. Every Fitness for Duty program in the country is inspected every two or three years. It's changed, I think it's three years now, every three years by an NRC inspection team. So there's vigilance in that regard. There are also a lot of donor protections that are put in place, just the same as DOT, in terms of making sure that individuals that are subject to testing are given the ability to appeal test results. They are trained annually. That's one thing that our program does, everyone that is subject to testing gets an annual refresher training.

As Paul said, this is a Fitness for Duty program, so it's beyond just testing for a few drugs and alcohol. It's also what about my consumption of Benadryl or anything else in the normal environment could affect my ability to do my job?

Okay, 2016. So we have a small industry. We have 73 different FFD programs. We have about 100 different sites with 73 programs. That 73 programs indicates that some of the corporate entities manage their programs under an umbrella. We test about 150,000 people a year. It varies from year to year. Last year, it dropped about 6 percent from 2014.

One thing that I'll be talking about a lot today is the impact of the two construction sites on the industry. So when federal testing came to the NRC, this was in 1990, most of the construction sites in the United States had already been completed. We had I think two or three that were in the final stages.

So our data right now is new to us in terms of characterizing the constructions industry. We have had two power plants that have been under construction, one since 2009, the other since 2011, and they're definitely impacting our test results.

So it's important when we look at high level trends, such as this slide, to keep that in perspective, and I'll try to drill down because some of the rates are starting to bump up, but they're primarily the result of these two construction sites, not the majority of the industry. It's an important message for the public and

it's an important message for the regulators so that we can strategically apply our resources in the right place.

So 1,163 individuals tested positive. As Paul said before, 65 percent of those were identified in pre-access. We'd love to have every single one of the individuals identified on pre-access because that's a zero risk to us. That number has fluctuated between 65 and in the low 70s. So we do a very good job of identifying individuals before they're provided unescorted access to a power plant.

That means that everybody that's been identified was clearly undeterred by the fact that they were going to be drug tested and alcohol tested. Another thing to keep in mind about our test results is that we have a 50 percent random testing rate. That's both for drugs and alcohol. I don't think you'll see that elsewhere in normal regulated industries, including the federal employee program, much lower, much lower.

Overall, industry rate is 0.76 percent. That's all the tests for all the different testing categories. I personally dislike presenting that number because it's really -- it aggregates things at too high of a level. But it is a telling one in terms of the overall risk, less than 1 percent of the individuals that are subject to testing in a year are going to test positive.

Industry random positive rate is also very low. It's 0.42 percent, but this breaks out in two ways. Our licensee employee population, these are generally full-time employees, which there's not a ton of turnover in the industry, very, very low positive rates.

We're talking 0.14 to .16. The highest I think it's ever been was 0.2 percent in the whole since 1990 testing. So that population is very low in terms of drug use. Contractor, vendor population is much higher. This has been historically the case across test types and across years. They're generally 3 to 4 times, that employee category, to test positive 3 to 4 times higher than the licensee employees. I think in part that has to do with temporal employment or short term, and they're not a well-characterized group.

The industry does have outages. Each power plant, there's going to be an outage every two or three years. They do a lot of maintenance. They require a lot of maintenance workers to come on the sites at that point. That surge of work sometimes presents greater levels of positives.

This is a busy table, but I present this because you can track the results through some of the exhibits later in the presentation. This presents the test results by employment category, the licensee employee and

contractor/vendors, and by the testing categories. There really are two distinct categories of individuals that we see. We see the licensee employees. We primarily identify them on random testing. We see the contractor/vendors, we primarily identify them on pre-access testing.

That is very helpful to us in terms of where our policies are working correctly and where we may need to be improve upon. This has always been the case with our program.

Licensee employees, you'll see on the data table, there is much lower hiring. So pre-access, there are about 8,000 individuals in the year compared to 75,000 for contractor/vendors. Because of our data that suggests 65 to 75 percent are pre-access, you'll see why the contractor/vendors are drawing a lot of the positives. If we stop hiring so many contractor/vendors, you'd have many fewer positives in the industry.

Okay, one thing that I'm going to highlight here that was a little unusual this year is in the for-cause testing. The rates are always the highest in many of the test categories because it's contemporaneous impairment or credible information about use. We saw a dip in the for-cause testing rates for contractor/vendors, much lower than we had in previous years, and it's associated with the construction sites. I'll show you an exhibit of that to

explain that a little bit more thoroughly, but in general, for-cause testing is going to have a much higher positive rate for the obvious reason that you're only doing it when an individual is impaired.

These three charts present historical information on the positive rates for the three test types that we're reflecting here. The top chart is pre-access testing, middle chart is random testing, and the bottom chart is for-cause testing. You'll see the separation between each of the lines, the bottom line in each of the charts are the licensee employee positive rates, and the hash marks on the charts are the contractor/vendors. So as I said before, 2 to 3, 3 to 4 times more often positive, you'll see those separations in the charts.

The licensee employee category is pretty well-characterized and very tight in terms of their detection. We're talking 0.2 to 0.4 percent on the pre-access testing. Contractor/vendors, it's starting to move up. It's moving up in the pre-access. It's definitely moving up in the random, the middle chart. The important thing to understand about that move on the random testing is it's related to the construction sites. If you remove the construction site data from 2016, you get the exact same positive rate that you did before construction started in 2009.

So the public needs to be aware that most of the delta there is related to a large, large group of individuals being tested at construction sites. That's not to say that there's a higher level of risk because we're identifying most of these individuals at pre-access, but we're testing a large, large number of individuals, and they tend to be using drugs at a higher rate than the normal industry that's supported by contractor/vendors.

The bottom chart, the for-cause testing, you'll see the lines cross over there in 2016, and that's the dip where we saw these two construction sites testing an inordinate amount of people in comparison to the previous year and not having a lot of positives. That could be a variety of reasons. It could be that they're being overly protective; it's an industrial site and people are getting injured or they're functioning under strenuous work conditions so they may be demonstrating signs of impairment. They also may be using substances that we're not testing for. That's a possibility as well.

The good news is that in our program, if you're identified as demonstrating signs of impairment, you'll be drug and alcohol tested, and then if the individual is negative and they still are demonstrating impairment, they will be evaluated by a medical professional to ensure that

they're able to get back to work to do their job. If they're not, then they will be denied access.

This is one of the types of analyses that we do in an annual report that we publish. This is the pre-access testing rates and this is site-specific testing rates. So it's nice to show an industry trend of 0.4, 0.5, but really, when you drill down into it, how are the sites looking individually? So we broke the positive rates out by the two testing populations, contractor/vendors, licensee employees, and in this chart, the darker burgundy color or red color, those are the contractor/vendors, and the greyish color is the licensee employees.

Okay, so the vertical axis shows you the bins that we're using. It goes from 0 to 4 percent. So we've had a range of 0 to 4 percent positive rates per site in 2016.

The top horizontal line shows you a 0-positive rate and so that indicates that 57 of the 72 -- so the legend in the chart shows you the n, the number of sites. Licensee employees are 72 sites that tested an individual on pre-access in 2016; 57 of them had a 0-positive result. Conversely, only 8 of the 72 sites that tested a contractor/vendor in 2016 had a 0-positive result. That's telling because pre-access testing is a very effective

method of identifying drug users in the contractor/vendor population.

The second piece of information that I think is pretty interesting here is you'll see that while there is some movement in terms of the bins, the majority of the positive rates for the contractor/vendor populations are well below 1 percent. Occasionally, you're going to see something higher, 2.5 to 3 percent, 3.5 to 4 percent. Looking into those bins, some of those bins are related to the construction sites, but some of them are also related to operating power reactor sites. So we are seeing some higher positive rates at operating reactor sites. There could be some regional impacts associated with that.

We need to look more into that. We're starting to have the ability to do that with the data assessment tools that we've been developing over the last few years. But the good news here is that this gives you underlying information about the sites, positive rates, and the spread throughout the industry, which is important for the public because they need to know is use rampant through our industry?

I'm going to go through this a little bit more quickly. Random testing, again, we do 50 percent random testing across the industry. Drugs and alcohol, top line, 0 percent positive rate. You see there it's almost 50/50,

34 of the 72 licensees and 32 of the contractor/vendors, 0 positive rates. So in part, that tells me that we're doing a real good job of screening out a lot of drug users on pre-access testing, but this exhibit also shows you that random testing is definitely detecting a lot of use.

So it is a good programmatic element to ensure that our population, we're getting a reasonable assurance. That's the standard that NRC uses. It's not no drug or alcohol use, it's reasonable assurance. We use defense in depth to mitigate risk and ensure that there is no safety or security consequence to that use.

The vertical distribution is from a 0 to 2 percent. So in 2016, we had between a 0 and 2 percent positive rate for any individual site, broken down by contractor/vendor and licensee populations. Only one site on the licensee side of the house had a greater than 1 percent positive rate. So you're seeing not only higher levels of positive rates for the contractor populations, but more sites reporting that as well.

So all the data that we've said in the past, contractor/vendors are using more drugs, they are using more drugs and they're using more drugs across the board at these sites. It's not a regional issue in this case because of these distributions.

This exhibit presents the detection of the standard panel drugs since 1990 when drug testing began. This is the relative percentage of positives that are identified in the year. So the top line is marijuana, and testing is identified between 43 and 53 percent of the positives each year has been marijuana. There's been some bouncing around of the proportion of marijuana positives in the last three or four years.

I'll talk a bit more about that. As a society, we're starting to use more marijuana or we're seeing a lot of data to support that, and yet our positive rate or proportion of positives is starting to drop from marijuana. I think it's pretty convincing and I'll show you this. I think it's the subversions are starting to affect our positive rates. The reason I say that is because 60 percent of the individuals that are identified as attempting to cheat on a drug test do not provide a specimen for testing.

So we're having a large number of individuals that are being sanctioned but we're not identifying that use. We're not identifying what's in there. So that part of the pool is not even in there. So for instance, in 2016, we had about 20 percent of the drug-testing violations, there was no test result. So that has a lot to

do with the proportionality of some of these positive rates. So I'd say that some of these rates are low.

Why is this important? These rates are important because as a regulator, when we want to propose a new regulation, we need to evaluate the effectiveness of rule changes. So if you're looking at positive rates and you're modeling detection improvements based on changes, this can affect how much you think you're going to get in improved benefit.

This chart, I should also say that in 2008, we had a rule change and you'll see the increase in detection in marijuana and also in alcohol. Those lines start bumping up in 2008. We lowered the cutoff levels for alcohol. They're time-dependent, so there's two additional cutoff levels beyond federal programs. So it's 0.2 and 0.3 cutoff levels that are applied. We get about 30 percent improved detection each year since that change has been in place for alcohol detection. As a regulator, it's very important for us to be able to measure if we're getting bang for the buck, so to speak.

Likewise, marijuana cutoff levels were dropped in 2008 and our detection improvements were there. We do not yet have the 2008 HHS guidelines that have been in effect since October of 2010. In place, we have a rulemaking package before our commission since February to vote on

that. The regulatory analysis that we completed, we believe based on the federal data that we received, and Patrice was kind enough to provide us with very good information from DOT that we used as part of our regulatory basis, we think we'll get 10 to 12 percent increase in detection for the substances that we're lowering our cutoff levels. So we'd be lowering cocaine cutoff level, the amphetamines levels, and expanding the testing panel to include ecstasy and a few of the other ecstasy-type drugs.

One final note here, as you'll notice, is that amphetamines have been ticking up pretty consistently since 2008. I think the increase in use is consistent with other testing data that we see, the drug testing index data as well as the DOT's data.

Their data are laboratory data. Our data are verified data. So that's a good way of comparing those two trends and saying they're real and in our case, this is illicit use that we're identifying. So this stimulant has been increasing in use since around 2007, 2008, and we're seeing the cocaine rates drop considerably in the same period of time.

We didn't see an uptick in cocaine as much as you did this year, Patrice, but it's starting to move a little bit, but it's been fairly flat since 2008, 2009. If we had

lower cutoff levels, we'd of course believe that would go up.

These two pie charts highlight the difference in detection of substances by licensee employee and contractor/vendor. They convey relative percentages of results. They don't convey the magnitude so the magnitude is conveyed in the text underneath the titles. So the licensee employees, there's 106 positives in 2016, compared to contractor/vendors is 1,000. So the pie chart on the right should be ten times as large as the pie chart on the left. The contractor/vendor population is two times larger so that's another indication that contractor/vendors use a lot more drugs, or at least we're identifying drug use in those individuals in much higher percentages.

I also looked at the proportion of marijuana positives over the last three years to see if that's shifting because of societal use and recreational use. We're not seeing that in our data. The proportions are fairly consistent for both licensee employee and contractor/vendor populations over time. We're not seeing that increase yet.

However, we did see a decrease in detection in marijuana in 2016 for contractor/vendors and I believe that's in large part due to the subversions that we're seeing. I'll show you that in a minute.

I'm sorry, one more thing. We do have a number of individuals that test positive for more than one drug. So if you're starting up numbers here, you'll notice at the top of the left pie chart, licensee employees, it says 106 individuals positive, and the n for that pie chart at the bottom is 108. That indicates that there were 2 individuals that tested positive for more than one substance. The contractor/vendor population, we had 86 individuals that tested positive for more than one substance. That's from one to four substances.

We actually changed our data collection forms this past year to ensure that we're capturing all the substances. I haven't seen anything beyond four, but we have seen up to four.

This is a new chart that I think is going to start giving us a new level of precision in measuring risk by labor category.

This chart gives you the relative percentage of substances identified by labor categories. So the left to right is 0 to 100 percent. So it gives you the relative percentage. It doesn't give you the magnitude. The problem with horizontal bar charts where you have magnitude is you have two that skew the data so far to the right, you can't see with any precision the small number of positives for many of the labor categories. In this chart, you get 0

to 100 percent of the positives for each line item. For the magnitude, you just need to look at the numbers inside of those segments.

The top four lines account for 80 percent of the positive results, and they're all related to maintenance-type activities. That's important, again, to us because understanding what kind of job activities those individuals have and where they are inside of our sites can give us some perhaps better tools to mitigate that risk.

This is a new comparison that we've been doing. We've only been able to collect labor data since 2009 and really, we've only had complete data since 2014. One thing that we did do a year or two ago is we tried to improve the categorization of the labor categories, so you'll see the second category is other. That's really not very helpful to anybody, but the other category, just to give you an example of what those are: administrative clerk, cafeteria worker, carpenter, data technician, intern, contract laborer, elevator technician. So you're talking about non-safety or security related individuals.

We want to be able to bin those categories better. It's far better for a cafeteria worker to be using drugs in my mind than a reactor operator. So what we are seeing is that maintenance is the large number of individuals that are using.

Subversion attempt trends, this is something that I don't see anywhere else and I think it's primarily because of the way we collect the data and the fact that we are a regulated industry with very good trained collectors, we collect precise information on each of the events, and because we also have a very severe sanction in place. This was put in place after 9/11. Trustworthy and reliability is a significant part of protecting our power reactor facilities and if an individual is willfully choosing to disregard required procedure under our rule, they are permanently denied access.

So ensuring that we're collecting information on how these individuals are doing these types of activities gives us the ability to strengthen our regulation and to ensure that we report back information to the industry so the collectors know the types of techniques that are being used to subvert or attempt to subvert.

Seventy-three percent of subversions are identified on pre-access testing. That's not a surprise. It's a predictable testing event. Ninety-eight percent of the subversions are committed by contractor/vendors, also, in my mind, not a surprise. Contractor/vendors may have many different employment opportunities, one of which may be supporting a short-term outage, versus a licensee

employee which would be a full-time employee that wants that job.

What's alarming in my mind, and I know Paul's as well, is the number. The magnitude of subversion attempts has been high, and as long as we've been able to collect this information. So beginning back in 2012 we had 177 subversion attempts. That was 15.8 percent of the violations in that year. But another way to look at it is these are drug-testing subversion attempts, not alcohol. So if you take out the alcohol component of there, we're talking anywhere between 20 and 30 percent of our drug testing violations each year are subversion attempts. Twenty to 30 percent.

That's an inordinate amount of individuals attempting to beat the drug-testing program through subversion. And the data on the next page will show you that the majority of those individuals are being identified through collection procedure. Not actual testing technology, although the test results confirm what we identify at the laboratory.

So it's temperature. It's usually a temperature type of situation. Sometimes it's paraphernalia that's identified, but primarily it's temperature. Collectors, I think it's 70 to 80 percent of the subversions are initially identified by the collector, with temperature.

We have many of our sites are also using infrared temperature measurement devices to confirm temperature, gives them an additional level of assurance, that not only the strip is working, but more precisely, if the specimen is 116 degrees you know that human being didn't produce that. They can stop the collection process at that time.

Characteristics of the subversion attempts. We presented this data for the first time last year. This is the 2016 version of it. So 38 percent of the individuals that subvert do provide a specimen. These are individuals that are primarily providing an initial specimen that's out of temperature, or it's demonstrating characteristics inconsistent with a normal urine specimen, such as odor, color, perhaps it's bubbling; but primarily it's temperature.

The individual submits a second specimen under direct observation, and these are the results. The subversion determination is made by the MRO based on the fact that the initial specimen provided was out of temperature, the second specimen provided was in temperature, and the first specimen is negative and the second specimen is positive. So that's definitive evidence of a subversion attempt.

What you notice, took in this is that there are a number of multi-substance users that are being identified.

Of these results, about 19 percent are individuals that are using more than one substance. People do not choose to cheat on drug tests unless they are using drugs, and subverters are using drugs at a more frequent rate than individuals that are subject to testing but not choosing to subvert. So they have a reason to cheat.

The bottom line is one of the compelling ones, in my mind. Only two of these subversion attempts were identified as substituted specimens. Haven't seen an adulterated specimen -- I think maybe one. I'm not sure if a lot of these are falling out as invalids. But we do capture, I don't know, a handful of initial specimens that are invalid, no medical explanation to provide evidence for that, so we bring them back in under direct observation and they test positive, or they refuse. But it's only a handful.

So the laboratory's identifying the majority of subverters by test results on two specimens collected. That's how we identify the majority of our drug users.

I wanted to provide some information about testing errors that we've received. There's been a bit of an uptick in the last couple years in terms of human performance errors that we're seeing at the HHS-certified laboratories. We use blind performance test samples to challenge the laboratories and ensure that a low-incident

event as a positive is still being treated the same as a negative.

Three of these events -- these are all publicly available reports. That's one thing I should also say, is all the information that's presented here is publicly available. All the licensee reports can be pulled out of our docketing system called ADAMS. These 30-day event reports that I'm referencing here are also publicly available. Paul and I do provide HHS with these results if we think that's something that would be beneficial in terms of the NLCP review.

These three cases demonstrate that human performance resulted in an unexpected test result. The initial one was a dilute negative that was reported by the laboratory as negative. It came down to manual aliquoting of the specimen, resulting in an inaccurate test result. The laboratory typically used an automatic process, but in that case they did a manual process. They didn't say why in the report, but that was the result of the negative, that inconsistent aliquoting.

The second one was an adulterated specimen that was reported back as invalid. This was an interesting one where the laboratory aliquoted the specimen for confirmatory testing, but a separate technician, the nitrite technician was already gone for the day. They left

the specimen out at room temperature, the next morning they come in and test the specimen, and it comes out as invalid.

It turns out that through the laboratory's own testing of the specimens, the licensee's MRO asked the laboratory to do this. They demonstrated that within 24 hours of a specimen being at room temperature, the nitrite's concentration decreased by 25 percent. So the laboratory changed their SOP to ensure that a specimen would be refrigerated before it was confirmatory tested.

This is really useful information. This is blind testing. It's working through standard operating procedure issues that are not typical. We see these, one, maybe two every year or so. In the past we've seen issues where a highly concentrated specimen was diluted, reported out as a negative, and it's because the certifying scientist didn't multiply back by the dilution factor on the result.

So when we see human beings making determinations in this, that's where we're seeing some of the issues. Previously, it used to be the blind specimen providers would incorrectly formulate the specimens, they'd degrade in transit, and you'd get negative results. That doesn't happen so much, primarily because there's really only one blind performance test sample supplier left in the industry that's doing this. The others lost their business because of it.

The final 30-day event report that I wanted to highlight, was there was a false positive for a morphine result. This was an actual donor specimen, a false positive. This example demonstrates the donor protections that are in place in our rules as well as in the DOT's and the federal testing program, where an individual can request the test of their specimen at another laboratory. So based on the MRO's review of information provided by the donor, they did testing at a second laboratory and the result was negative, and this was caused by the initial laboratory analyst pipetting the same specimen twice for confirmatory testing.

So again, when human beings are doing this, we need to make sure that we are applying vigilance, and the blind testing program in NRC's experiences over the past few years is demonstrating that that's the case.

I'd like to conclude with 2017. We've already seen a couple human performance issues from the laboratories as well. They were false negatives for marijuana positives, and I just wanted to present a little bit of information about what those were all about. One was an incorrect reading by the certifying scientist on the GC/MS peak, and this was a blind specimen. And the second one, also blind specimens, there was a false negative on

the results and it related to improperly preparing of testing reagents on the screening testing.

So these are two additional results related to human performance issues, and I know that NLCP does the inspections and we will make sure that Ron has these results and you guys can close the loop on that.

Thank you.

MR. MAKELA: Thank you very much, Brian, and thank you, Paul. It's 11:35 right now. We're going to go on a 15-minute break. So we'll reconvene at about 11:50.

(Brief recess.)

MR. MAKELA: I'd like to introduce Colonel Tom Martin. He's no longer Lieutenant Colonel. He's the Deputy Director of Drug Testing and Program Policy in the office of the Undersecretary of Defense for Personnel and Readiness.

So I'm going to turn it over to Colonel Martin.

**Agenda Item: Department of Defense Drug Testing Update**

**COL Tom Martin, Ph.D., Deputy Director, Drug Testing and Program Policy**

**Office of the Undersecretary of Defense For Personnel and Readiness**

**Operational Readiness and Safety**

**Department of Defense**

COL MARTIN: Thanks. I appreciate the opportunity to talk about the Department of Defense Drug Demand Reduction Program, and some of our data from FY16, as well as other initiatives over the past year or year and a half.

So I'll just look at -- that should be we do have a mission, and again, it's to deter illicit and prescription drug abuse by military servicemembers, as well as our Department of Defense civilian personnel in testing designated positions. So both military and civilian drug testing policy falls under the oversight from my office. In addition to the testing piece, we do provide drug abuse prevention, education, outreach services to our military personnel and their families in those communities.

Some of our regulatory guidance is found both in Department of Defense Instructions, which I have there, as well as from the executive order for a drugfree federal workplace.

So the Drug Demand Reduction Program, or DDRP, we have four larger efforts or four major functions. The majority, probably half of what we do, is in the testing part of our program, by collection. So collections for military as well as our recruits falls under the Drug Demand Reduction Program, and for those that are not aware,

all of our collections on the military side are observed. So we do not do any validity testing.

Second function is prevention and outreach functions, we look at antidrug awareness programs and training as well as other programs that fall under our purview. Then our program, even though each of the services manages their own separate drug testing and prevention pieces, in order to capitalize on efficiencies as well as purchasing power, we have some joint service programs where essentially for equipment purchases for our laboratories, and then all military recruits that go to the military entrance processing stations, all that falls under our program.

And then we have a separate arm that manages our quality assurance piece in terms of special testing, and that's at the Armed Forces Medical Examiner System Division of Forensic Toxicology in the bottom righthand portion of the slide.

So real quickly, a wire diagram of where we fall within the Department of Defense. See actually the Secretary of Defense at the top and he has a variety of different undersecretaries. Our office, or my office, falls under the Office of the Undersecretary of Defense for Personnel and Readiness, and then within that Personnel and Readiness piece, we're under the Assistant Secretary of

Defense for Readiness. So we do policy advice and guidance for the department, and then the execution goes to the different services, secretaries of the Army, Navy, and the Air Force.

I think this is the last wire diagram for my presentation. So again, I talk about policy is at my level or department level, and then the execution is at the service level, and any recommendations to the Drug Testing -- as far as both the collection side, falls under the Biochemical Testing Advisory Board or BTAB, and it's similar to -- the functions are very similar to what the DTAB does.

So each of the services in the testing side has a program manager who is a voting member for the BTAB, and then it's run by the chair and that is the chief of the Division of Forensic Toxicology, Armed Forces Medical Examiner System.

So I just talk about how it's organized. Again, there are two separate divisions of the BTAB. So you have the technical or drug testing piece and then you have a personnel policy, on the collection side of the program.

So some of the functions of the BTAB. Identifying the methodologies and new technologies for testing, administering or managing our external proficiency program, any of our quality assurance procedures. Make

recommendations for certification as well as decertification of our laboratory through Armed Forces Medical Examiner System.

We look at adding and deleting drugs, and I'll talk about that -- from our panel -- I'll talk about it in a few moments. We look at what policy changes, what are we -- what can we do better, and then of course we'll talk about the prevalence testing, and I'll talk about the most recent prevalence testing when we looked at that within our military servicemember population.

Then the process is always data driven. We always emphasize that we can minimize the bureaucratic paperwork and the red tape. So we can go from collecting data on drug prevalence, identifying need for testing, implementing and certifying the testing procedures at the laboratory, notifying our servicemembers, and then adding it to our panels in as short as six months, if needed. So there's no public comment or anything like that. Servicemembers are told this is your panel; this is what you'll be tested for.

So again, it's a rapid response. Again, we'll talk about prevalence testing in a second. Some recent examples regarding using the BTAB process to add drugs to the panel. We looked at synthetic cannabinoids or spice. I'll present data on that. Those were added and they are

part of our panel. We have looked at that. Our data indicated that there did not appear to be an abuse issue, that there was no recommendation to add synthetic cathinones, bath salts to the panel.

So as we add drugs to the panel, we also look at prevalence in drugs currently on the panel, whether there's a recommendation to remove those from the panel and just monitor them over time. Some of the recent deletions from our panel were LSD, MDEA, and barbiturates.

So as far as fentanyl, fentanyl has been in the news and continues to be in the news, and of course, my leadership highly concerned whether we have a fentanyl or does there appear to be a fentanyl abuse problem in the military population. So in FY16, we implemented a prevalence study, looked a random sampling of approximately a little over 6,000 random urinalysis specimens from our -- at that time, we had six drug testing laboratories.

We screened all of it at a cutoff of 1 nanogram per milliliter, and then you could see the results of our screening test. At that cutoff, 127 specimens screened positive, but we also identified any specimens that showed any possible drug presence, and that was an absorbance that was greater than the low-quality control in that analysis.

So there are a total 856 specimens. Of those, ten of them confirmed positive. So that would be a .03

positive rate. Five of those ten would have been below the administrative cutoff. So the positive rate would be about half. Then we were also able to capitalize on looking at our prescription or medical records of these individuals. Of those ten, eight of those indicated that they had a legitimate medical explanation for their positive fentanyl result.

So in the end, what we have is a positive rate, .006 percent, and the recommendation to the BTAB does not appear to be a significant fentanyl abuse within our population; we don't recommend adding it to our panel at this time. But we will continue to monitor and perform future prevalence tests.

I talked about -- I alluded to in the prevalence study, up until February 2017, there were six Department of Defense drug testing laboratories. There are two Army, one in Hawaii, one in Fort Meade, Maryland. Up until February, there were three Navy, Great Lakes, Illinois, Jacksonville Florida, and then the Navy Laboratory of San Diego, California. That one closed on February 1, and the distribution of their workload, the majority went to the two other Navy laboratories. However, all of the -- the two Army as well as the Air Force laboratory in San Antonio did absorb some of the work as well.

Here's the list of current panel of tested -- what we test for. In addition, you can see the synthetic opioids have been on our panel for a while, as well as we look at benzodiazepines and synthetic cannabinoids. Those are all part of the standard panel. Anything outside that panel, we call it a special request. We can send that to the Division of Forensic Toxicology at Armed Forces Medical Examiner System for analysis.

So here's the cutoffs of the screening and the confirmation cutoff, just for your information. I won't read all those. You can look at those later.

The next two slides are kind of busy. I left the data. So from FY2011 to FY2016, the most important thing to note in this data, this is unique positive servicemembers. That means an individual who has tested positive for any of the drugs, and if an individual tested positive three or four times during the course of the fiscal year, they're only counted once.

The second thing to note is all of this data is post-MRO review. So all of the data here is illegal use or unauthorized use, depending on how the different services call different things. So these are post-MRO data.

So you can see in FY16, it has been, since the implementation of program, marijuana is the number one drug, and now you can see that cocaine is number two. I've

highlighted a few things on this slide. We have seen an uptick since 2013 for cocaine positives. We are monitoring that. We are also seeing an uptick in ecstasy. While the numbers are very low, again, the trend is in the wrong direction for us.

Now highlighted in green a little bit further down the slide, opiates as well as opioids, synthetic opioids, and starting at FY2013, prior to that only a random sampling or a portion of the specimens that came to the laboratories were tested for those drugs. Starting in 2013, all drugs are tested for those drugs, and if you look at the data, you can see a significant decline or decrease in the number of enlisted use of those prescription medications by our servicemembers.

While this is great, it's almost 70 percent, I wish I could attribute all of that decrease to our testing program and our deterrence. I think that's part of it, but in all likelihood, it's also better oversight from our medical providers, better prescription prescribing practices, and things of that nature. But again, we are trending in the right direction and it's continuing to decline. So that's a good news story for us.

Here are other confirmation metabolites or drugs that we confirm for. You see those there. At the bottom part of our slide is our synthetic cannabinoid panel, and

again, you can see the numbers are going down significantly in either, a, some of those members were not using those drugs or they are using synthetic cannabinoids that are not part of the testing panel.

So overall, our military drug positive rate within our military population is very low. FY2016, it was 0.85, and you can see it's fluctuated slightly below 1 percent since 1990. The high number there at the beginning, around 3.5 in 1987, it was at that time that the program changed from a rehabilitative program to a punitive program where servicemembers could be disciplined, punished, and removed from service if they tested positive in our drug testing program.

So the next few slides, I'll show you some data broken down by the different services and different components, active duty, national guard, and reserve. So if we look at components, our active duty population have the lowest drug positive rate, whereas our national guard, both the Army and the Air Guard are combined here, and they have the highest positive rate.

So to look at active duty positive rate, we looked at the different services. You can see the Air Force and the Navy have the lowest positive rate and the Army has the highest. But again, the Army is trending in the right direction and, again, it's below 1 percent.

If we look at our reserve population, similar type trends, and again, the Army has the highest, unfortunately for me since I'm part of the Army. Then the National Guard again. So the trend continues in each of the components, with the Army having the highest and the Air and Navy having the lowest.

So interestingly, when we look at a distribution of our drug-positive personnel on this slide, what I'm looking at here is what we call our high-risk personnel or non-high risk. We define high risk population as 18-25-year-old males. What you can see is about one third of our military is composed of our high-risk population, but on the right side, you can see they account for about two thirds of our positive results.

So if we just look at overall at all our positive servicemember distributions, taking that slide I showed earlier, again marijuana is about 70 percent of our overall positives, but cocaine, you can see a breakdown here on this slide.

Now if we compare the distribution based on high risk and non-high risk, you can see there's a little bit different. I apologize for the largest blue portion of each of the pie charts. That is marijuana. I'm not quite sure what happened there. Again, what you could see on the left side is the non-high-risk personnel, they have a

higher use rate of cocaine and prescription medications, and the opiates, whereas on the high risk, they tend to use marijuana; it's close to 75 percent of their positives are marijuana.

Also mentioned at the beginning of the presentation, we're responsible for civilian testing within the Department of Defense different agencies. You can see in the data here overall the positive rate amongst our individuals who are tested hovers right around a little less than .4 percent, and it's broken out here by both those in the random pool as well as applicants, and it stays relatively steady over those past five years.

So the last portion of my talk, kind of switch gears here and look at what we call surveillance testing. What we are trying to do, what we are able to do, is take a random sampling of our submitted urine specimens and send them to the Division of Forensic Toxicology to do a largescale review to see if our servicemembers are using, or what they are using, and if there appears to be a problem that we need to investigate further.

You can see the mission there. We want to proactively monitor and identify any novel emerging drug use by servicemembers.

This is just kind of how the protocol works. So each of our laboratories -- what happens at each of our

drug testing laboratories. They segregate specimens that initially screen positive, but then confirm negative or confirm a no drug presence. They segregate those. When they reach a certain number, they send them to AFMES, Armed Forces Medical Examiner System toxicology labs, and then the laboratories have several different protocols that they follow, looking to see what's there, what testing is given. This is just kind of a quick cartoon or wire diagram how they go about their testing.

So within our surveillance program, for every 2,000 specimens received at the Division of Forensic Toxicology that they run their testing protocol, and you can see all the data present here includes the Laboratory of San Diego, because it was still operating the last time we received the report.

So of the specimens that screened positive from our laboratories confirmed negative, you can see the largest majority not surprisingly comes from our amphetamine screen, followed by benzodiazepines and then a small handful from our other drugs.

Overall in our surveillance report, so what you see here is from left to right, the blue is the first 2,000 specimens, and then followed by the next 2,000 and so on for each of the drugs we're seeing. I'll break it down further in the next few slides, but overall you can see

D2PM was the -- of those specimens sent to the toxicology lab, that had the most number of positives.

This is kind of a breakdown of those. This is all the different drugs on what they call the emerging drug compound panel, and you can see the different prevalence of those drugs in the course of those specimens sent to the laboratory.

We also looked at spice and synthetic cannabinoids, and you can see over time in the last 2,000, so versus around 8,000, in the panel that they looked at, where they were looking at, they did not see any synthetic cannabinoids.

Here's just the numbers from the previous slide. So the other thing that I field many phone calls, many email messages in this regard, dietary supplements, ingredients in dietary supplements, and whether the Department of Defense has a banned list or allowed list.

First of all, we do not have a banned list. You can see what we consider banned, anything on the DEA's controlled substance list, any use of a prescription drug that is not written specifically for you, and then you can see the other things there. Through the Human Performance Research Center, that's where this paper is received.

So looking at what we call dietary supplements, and you can see in those submitted to the laboratory we

still see a significant number of DMAA and DMBA in each of those cohorts of samples that have been sent for surveillance testing. Here is just a breakdown from the bar chart on the previous slide. See DMAA, DMBA on there.

So what does the future hold? At the toxicology lab for their surveillance program, they continually need to update what they call their designer panel, reevaluate their methods, reevaluate what drugs to look for and update panel with any novel or emerging drugs that they have become aware of they can test for, and see there, again, it's all the different panels, continually monitoring, updating, to provide a more comprehensive picture for DoD leadership.

So just to end, the bottom line goals of the Drug Demand Reduction Program is to provide a safe, secure, and mission ready total force. We want to effectively deter drug abuse, and part of that deterrence mission is we need to be able to detect drug abuse and we do that through frequent random testing, and we want to raise the perceived risk of detection above, over the desire to use drugs.

The penalty for using drugs, being caught using drugs, is significant. Our goal is to deter, to make sure that that risk that service members are not willing to take that risk.

In addition, we always educate our servicemembers on the adverse consequences of their drug use, both from a health perspective and from a career perspective. We separate military members found guilty of drug abuse, and again, we want a drugfree workplace and a family environment, and of course, funding is always an issue. We need to maintain a significant, enough funding to perform the mission that we're required to do.

At this point, that concludes my presentation for this afternoon.

MR. MAKELA: Thank you, Col. Martin.

Okay, let's keep moving. Up next is Lieutenant Commander Eugene Hayes. He is the division's representative with the National Laboratory Certification program. He is going to provide an update on that program's activities. So here is Lt. Cmdr. Hayes.

**Agenda Item: Federal Workplace Drug Testing Programs**

**National Laboratory Certification Program (NLCP)**

**Eugene Hayes, Ph.D., MBA**

**LCDR United States Public Health Service**

**DWP, CSAP, SAMHSA**

LCDR HAYES: Good afternoon, everybody. Thank you, Brian.

I'll just start by saying that this is the second or third year in a row that I have been the person right before lunch. So I'm getting used to this particular position in the lineup. Unfortunately, you can see how many slides I have. So I can't really tell the joke that I have 100 slides and make you sit through 15 minutes of my discussion.

So let's get started. As of June 1, 2017, there are 29 certified laboratories. The largest group is category 1 with eight. There are two category 0 labs, eight category 1 labs, which include one IITF. There are seven category 2 laboratories. There are currently two category 3 laboratories, three category 4 laboratories, and seven category 5 laboratories. Two labs this year have withdrawn from the program, and these are due to what I would call business process choices, being mergers and just a specific choice to withdraw from the program.

So the number of specimens tested in 2007 was right around 7.99 million, and then dropped significantly the next couple of years, with a 10-year low of 5.47 million in 2009. Testing began to recover. However, we can see from the chart here that we are down somewhat significantly to 5.7 million, and this is for regulated specimens. This is for federal agency specimens added with

DOT specimens. The number of specimens tested in 2016 decreased by approximately 13 percent from 2015.

The total number of specimens reported as drug positive, adulterated, invalid, or substituted non-negative increased from 112,000 in 2012 to 126,000 in 2016. Those are approximate. I have the actual numbers, but I like to talk in approximates sometimes.

A difference of about 14,000, coinciding with a decrease in total specimens, testing, and the number of specimens reported on the non-negative decreased by right around 4.6 percent as compared to the previous year. The largest difference that we have seen so far was from 2012 to 2013, an increase of 11,449, and the smallest difference was 2013 to 2014, an increase of 1,705.

Distributions, specimens reported. This is basically the slide will go through all the drugs that we have and the distributions. The important piece will be for us to discuss or maybe just to take in will be on the next slide, and that's the total 2006 number of invalid results. Overall, the number of specimens reported as invalid increased from 7,320 in 2015 to 7,832 in 2016.

In 2016, as in the previous year, there was a decrease in all categories except for invalid due to pH, which increased by about 47 percent, going from 2,900 in 2015 to 4,200 in 2016. We have to note that the number of

specimens invalid due to pH rises in the warmer months and is lower in the cooler months. This is a trend that has been going on since I've been here, and many years before that as well, that we have been able to recognize.

As shown by this chart, the percentage of specimens reported as invalid due to pH remains higher than the other invalid categories. pH invalids demonstrated a seasonal increase May through August, and decreased September through December. That's really illuminating the fact that the summer months have an increased invalid due to pH.

Other invalid categories are abnormal physical characteristics, abnormal creatinine, specific gravity levels, GC/MS or immunoassay interference, and oxidant activity. All varied from month to month, but overall remained at the 2015 levels.

The percentage of invalids due to a low pH, have remained steady at or around about 10 percent. Over the past few years, we haven't consistently seen those levels as was seen in late 2011 and early 2012. That was a result of a substitution product with a pH lower than that normally found in urine.

However, beginning in 2015 and continuing throughout 2016, the percent of invalids due to pH rose well above the levels normal. The increase was primarily

due to the number of specimens with high pH greater than or equal to 9 but less than 11.

Of the specimens reported as invalid due to immunoassay interference, the majority occurred with the 6AM and THC immunoassay. Notwithstanding the number of invalid specimens due to 6AM immunoassay interference decreased by more than 50 percent from 2015.

The same is true of those specimens invalid due to amphetamine immunoassay interference. This is because most certified laboratories use one 6AM assay, CEDIA, and there is a substitution product on the market that is used with this reagent. Interferencefrom that product is also seen with CEDIA amphetamines and cocaine metabolite assays.

So when we are asked to do some of the specimen validity that Bohdan asked for, we are doing it.

This slide demonstrates the decrease in specimens reported invalid due to immunoassay interference since a high in 2013. We can see a steady -- or not a steady, but almost a dramatic decrease. Specimens reported due to immunoassay interference by AMP and cocaine.

Okay, here's the slide I wanted to get to. Positivity rates 2016, or 2012 to 2016. As we can see, our rates hovered right around the 2 percent range for a combined rate. Drug, we were at 1.69, as you can see at 2012. In 2016, we were right at 2.03. I think that that

is one of the critical and most important parts of our program is that we need this number to stay low in all of our programs, in DOT, NRC, and the military, because that means our program is working.

I think when this program first started, the numbers of percentage of drug positives was 100 times that number, at a minimum.

Now here we get to talk about the fun stuff. Program projects. You heard from Ron earlier about urine and oral fluid mandatory guidelines. The eCCF applications and approvals. We have 11 current approved labs that use the eCCF. We have one lab that's approved to use two different eCCF systems, and then we have three labs that are currently pending eCCF approvals.

The oral fluid pilot proficiency testing, those have went on, but due to certain budget restrictions that have come forth over the last year, we are going to be reducing the number of activities that we have in that area. Laboratory investigations, they continue, and we continue to find and try to improve upon laboratory processes as we find basic items of discrepancy with our particular checklists.

Ron talked about the marijuana as smoked and vaporized study. We also have, and had been working on, a marijuana SmartBook. We were going to publish the

SmartBook -- I think it was 2016 -- however, because of certain restrictions within our agency, we're going to keep that book currently inside, or in-house, and we're going to use it for the director, Mr. Flegel, his consumption, and for his use in discussions with our federal partners and the like, up the chain of command.

This book actually details kind of a history of marijuana, where the country's at with marijuana, some of the current case law with marijuana across the country. So it really is a good resource, and we'd like to get it out there, it's just we have to get it through our communications division, I guess you'd call it.

There are -- not listed on this slide -- but there are some problem areas that we've identified within the NLCP, not specifically the program but within the area. And one of those is diminished junior toxicologist knowledge of the federal program.

So, many of you have been to SOFT, I went last year and I went the year previous, but when I talk about where I'm from or what I do, a lot of the junior toxicologists didn't actually know who our program was. The older, the more seasoned toxicologists, knew who we were, knew what we did. And I just found that to be a problem, because we are an aging population. Our profession at the drug-testing world is aging, and we need

to revitalize that blood as we age out and begin to want to retire. I know that nobody in here will ever retire, but we need to think -- in forward-thinking terms we just need to be prepared for the inevitable. If Ron Flegel decides to retire in, you know, 20, or 30, 40, or 50 years.

One of the things that we've done, is we've revitalized our online training and we've put it out there, so that the online training for what NLCP is can be out there for not only the junior toxicologists but for anybody who wants to consume that information. We are going to be looking at other things that we can do to tackle that problem as well for the NLCP purposes, but it's really a problem that's not specific to the NLCP. It's kind of generic to the field.

The second problem that we identified at the beginning -- or at the end of 2016 -- was uniform inspector education, transfer of knowledge, and the application of inspection criteria. Now for this particular piece we are looking at changing the format of our NLCP workshop, and changing that format from what it is currently, which is kind of an update meeting, to more of a training session, so that all of our inspectors, all of our lab directors, understand what's on our minds, what's on the top of the inspection list, what we really want to get out there that

everybody knows at the same time, and can then apply in the inspection process.

The second thing, and I heard Col. Martin talk about this, is that we have in the federal program a non-agile drug testing panel. And he talked about having an agile drug testing panel. I wish. So, we don't really have a way that we can tackle that through regulation because we have to go through public comment. We have to get several rounds of federal agency and sister agency feedback.

But what we can do, and what we've looked at doing, is looking at the -- it's a report called the NFLIS report -- it's the National Forensic Laboratory Information System, to identify trends across the country that we can then either publish with our new Drug Testing Matters Newsletter, or that we can somehow get out. What trends are currently going on in different areas of the country as far as drug use is concerned? That way, if that particular set of symptoms or drug is found, an employer, federal agency, regulated industry, could actually test for that under reasonable suspicion or the like. That way it's not a secret, it's not information that we're holding, waiting for, you know, five years of regulation. We're getting it out there because this is important for the safety of the entire country.

In summary, the number of regulated specimens tested in 2012 through 2016 decreased by 6.1 percent. The yearly increases between 2012 and 2015 were outweighed by the significant 12.9 percent decrease in testing in 2016 as compared to the previous years. The number of regulated specimens reported as positive, adulterated, invalid, and/or substituted in 2012 through 2016, has increased by approximately 13 percent.

Specimens reported as invalid due to low pH decreased from the levels seen in 2011-2012, and while slightly elevated in 2014 and 2015 remained under 10 percent of reported invalids throughout 2016. Specimens reported as invalid due to high pH increased significantly in 2016. Specimens reported as invalid due to immunoassay interference continue to decrease from highs experienced in 2013.

And that's all, folks.

MR. MAKELA: Thank you, Lieutenant Commander. While you're still up there, we'll open it to any questions or comments you have for Lt. Cmdr. Hayes, first for the people in the room, and then the people on the phone. Anyone in the room?

Operator, can you find out if any board members on the phone have any questions or comments?

OPERATOR: We do have a question or comment from Christine Moore; your line is open.

DR. MOORE: Thanks. Thank you, Gene. Good presentation. Can you just clarify that the oral fluid proficiency program testing has been canceled for this year? I know we got a note about that. And if you really think it's three times a year, or four?

LCDR HAYES: Hi, Christine. How are you? The note that you got about the oral fluid proficiency testing program is simply because we had to take a look at what our budget was going to allow for this particular year, and your question was, are we going to open it up for three sessions, or four sessions? Is that correct?

DR. MOORE: Yes, next year. There was an earlier presentation that said January 2018 it would start again.

LCDR HAYES: We are looking at three sessions.

OPERATOR: Thank you, and I'm currently showing no further questions or comments from the phone.

MR. MAKELA: While we are waiting, I'm going to ask Charles LoDico, he's a senior chemist in the division workplace programs, if you had anything extra about the CCF form, any additional information, from something that was asked earlier.

MR. LODICO: Good afternoon, everyone. Can you hear me? I wanted to reiterate what Ron said earlier about

the federal custody and control form. We have gone through the normal channels of submitting the package to OMB with the minor changes to the document. The document had been received, and is awaiting OMB's decision at the OMB site. So Jennifer, you asked the question concerning the status of the CCF. It is our understanding from OMB that the package that's already submitted, which was submitted back in April, has a 60-day window, so there is de facto continuation of the expired form.

Every day I go in and I look for the approvals, but as of today it still has not been reviewed and approved. So the only answer I can give you or provide, is that the program has submitted all the applicable information and the requested changes to the custody and control form, and now it's up to the OMB agency to approve it. Does that answer your question?

I'll end with that. Thank you.

MR. FLEGEL: Thanks, Charlie.

MR. MAKELA: And if there were no other questions or comments about Lt. Cmdr. Hayes' presentation, since we were running on limited time between NRC and DoD, I'd like to open it up for any questions or comments about their presentations, from board members first in the room.

And I'm going to start off. There was a question in chat about the surveillance testing; if you see the

slide, there was clarification about what those numbers -- the 2000 through 4000 -- meant, asked by Christine Moore, and Col. Martin clarified that these tests are performed as the number -- the 2000 or 4000 -- as those number of specimens are received by the AFMES lab. They're analyzed, and then the statistics are drawn on the chart. So those 2000, 4000 numbers represent testing as that number of specimens are received by their laboratory and then they perform that surveillance testing.

So if there's any other questions in the room, regarding Nuclear Regulatory Commission or DoD presentations?

MS. KELLY: I am Patrice Kelly. I have a question regarding -- for Col. Martin -- regarding his data. Specifically, do you have the number of service members who were subject to testing in 2016, and then the actual number of tests conducted in 2016?

COL MARTIN: I know the actual number of tests was about 4.4 million, and then the actual -- the unique number of individuals tested overall was about 85 percent of our servicemembers. I don't have that exact data right in front of me. Some services are a little bit higher, closer to 95 percent. Some are a little bit lower. About 85 percent of servicemembers got tested at least once in fiscal year.

MS. KELLY: And 85 percent of about what size of a pool? In other words, what's the total pool of servicemembers --

COL MARTIN: You are talking about 1.2 million servicemembers. So that's active duty, reserve, National Guard -- and then as servicemembers come and go during the year, so they're counted as well.

MS. KELLY: Thank you very much.

MR. ZALESKI: Tom, this is Brian Zaleski, NRC. I had a question for you about the prevalence testing. So you said that that you take up to 2,000 specimens, and when you get to 2,000 specimens total for specimens that screen positive, and then confirm negative you test, is that correct?

COL MARTIN: Yes, each of the labs will essentially put those aside, and then they'll ship them, send them off to AFMES, and when AFMES gets 2,000 of those then they run their tests. Each of the labs are shipping monthly whatever they have. And I don't have it here, but I have a separate breakdown by laboratory, which is a good geographical distribution, for the most part, of where their sample workload comes from. But again, it's just 2,000, the lab gets it, and they run their tests. So that's what that's looking at.

MR. ZALESKI: So the screens are picking up some activity but they're not confirming the precise analyte that's in the panel. So you're evaluating around those screens, is that right? So you're not testing for substances that are not in that specimen on the screen, that you're seeing any activity --

COL MARTIN: That's right. We had to make some sort of filter to start the surveillance program, not just a random sampling, and we felt that was the most appropriate at the time. You're right. If there's no drug activity, whether below cutoff on confirmation, or -- if this cutoff is not included in this, it has to be flat negative.

MR. ZALESKI: Thank you, that's really helpful.

MR. MAKELA: Operator, is anybody on the phone, any members on the phone?

OPERATOR: Yes, we do have a question or comment from Jennifer Collins. Please, go ahead.

DR. COLLINS: Hi, this question is for Brian Zaleski. I think you mentioned in your presentation that there's currently a rulemaking package under consideration for the NRC. I was just wondering if you could comment further on the content and whether it's intended to align with the current HHS guidelines, and perhaps where that is in the overall process for approval.

MR. ZALESKI: Sure. Yes. The materials are actually available, publicly available on the website, the NRC website. I can provide Brian with the link for that, so he can distribute that. The proposed rulemaking language is in there -- or the proposed rule language is in there, and other documents, regulatory analysis, et cetera. It's with our commission. They are going to act on it in their own timeframe. Right now, it's been there since the end of February. It's to align with the guidelines that were effective in October 2010. So it wouldn't help for any of the new guidelines changes.

One difference in NRC that I should have mentioned previously. The criteria that we use to make rule changes is a little bit different than some of the other programs. It's not a mandatory change for us, so we need to evaluate the effectiveness of those panel changes. And we also have what's called a backfit rule. No other federal agency in the country has this, which basically means that if you're going to make our licensees change their existing behavior, you need to get a significant improvement in public health and safety, which is a subjective measure. It's not clearly defined in our rules what that means.

So our hurdle is a bit different, and that's why our access to other federal partner data is so important

and why Patrice's information is very important in being able to evaluate the effectiveness improvements of lowering cutoff levels for amphetamines and methamphetamines, et cetera.

In terms of when they may decide on if we move forward with that proposed rule, I don't have any information on that, but the commissioners will vote on it and they will then give us direction either to proceed or not.

DR. COLLINS: Okay, thank you.

MR. MAKELA: Any other questions, Operator?

OPERATOR: No further questions or comments.

MR. MAKELA: All right, I'll say there's no further questions or comments for board members, and with no registered public comments, I'm going to officially adjourn this meeting of the Drug Testing Advisory Board.

Thank you all for your attendance, and we'll see you in September.

(Whereupon, the meeting was adjourned.)