

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

Meeting of

DRUG TESTING ADVISORY BOARD MEETING

Open Session

March 20, 2018

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Rockville, Maryland

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**P R O C E E D I N G S (10:00 a.m.)****Agenda Item: Call to Order**

CAPT BELOUIN: Good morning, everybody. I'd like to welcome you to the March quarterly DTAB meeting. I'm Captain Sean Belouin. I'm the designated federal official for the Drug Testing Advisory Board, and I officially call this meeting to order.

I'd like to take a moment to welcome everybody. First, the staff of the Division of Workplace Programs, our federal partners, contractors, invited guests, members of the public, and finally, our board members.

During today's open session, presentations will address updates on the mandatory guidelines for federal workplace drug testing programs. We will hear from federal partners, get early observations from the synthetic opioid testing implementation, review research data on a marijuana vaping study, and receive a brief update on the medical review officer guidance manual and the 2018 case studies.

The closed session today will discuss the proposed mandatory guidelines for federal workplace drug testing programs for oral fluid. If you are participating by web or teleconference, you are in listen-only mode. We do have a public comment section scheduled for approximately 12:45 in the afternoon. If anybody would like to register a comment, they'll be able to do so at

that time. Please make sure that if you are providing any commentary via the teleconference to mute any computer speakers and minimize your background noises during the comments.

All the information from today's meeting will be posted on the DTAB website. Stuff like the Federal Register notice and the agenda have already been posted. The open session meeting summary as well as the presentations being provided today will be posted, and any questions or public comments will also be posted. That information should be posted approximately four weeks from today.

The open session is scheduled to go from 10 a.m. to 1 p.m. this afternoon. We'll have a break at 11:15 a.m. for about 15 minutes, and start again at 11:30 a.m., and we'll go to 1 p.m.

After the public session closes at 1 p.m., we'll break for one hour and have a closed session that starts at 2 and ends at 3 p.m. We will also have a closed session tomorrow from 10 a.m. to 2 p.m.

I will say for all the presenters, the presentations are all in order. To scroll through the presentations, you can use the mouse and there's the two buttons on the screen. RTI is managing it through Adobe Connect, and I know there's a couple presenters that are

online, that are on the phone, that they'll be given the opportunity to actually control that from their computer.

Once again, thank everybody for attending, and now I'm turning it over to Ron Flegel, who is the chairman of the Drug Testing Advisory Board, and also the director of the Division of Workplace Programs, for his opening remarks.

**Agenda Item: Welcome and Introductory Remarks**

MR. FLEGEL: Thank you, Sean. I want to thank everybody that's here. I know the weather has been a challenge, if anybody's been watching that, I'm glad to see that there were some last-minute cancellations of both Drug Testing Advisory Board members making it here, as well as some just staying where they were instead of getting caught in the traffic and things being cancelled.

I will say, up front, logistically, it looks like there are a number of Drug Testing Advisory Board members that will be leaving probably later this afternoon, which I do not blame them at all. With what's predicted it does look like there's going to be quite a bit of snow here, or at least a little bit of snow, which usually shuts down Washington.

But currently, the items that Sean and I talked about is that if the government does shut down tomorrow, we're unsure if this office building will be open. We will

be doing closed session. We will try to shorten that a little bit to what we will be doing tomorrow, but we will still start at 10 o'clock tomorrow and then go from there. So I just wanted to say that up front.

I would like to thank the board members, ex officios, industry representatives that are here, and members of the public for taking time out of their schedule today to attend the Drug Testing Advisory Board. Again, I would like to update you on the progress of the implementation of the mandatory guidelines for urine, that was effective October 1, 2017, the proposed final oral fluid mandatory guidelines, and the progress DWP is making on the hair mandatory guidelines.

I would also like to update you on the program initiatives that are under way, programmatic information gained by the HHS certified laboratories, through our contractor RTI International, and also some of the federal agency updates, as well as other drug testing industries. I hope the public will find this informative and useful.

We have a number of presentations today from federal agencies, program updates on the available testing data, from the implementation of the urine mandatory guidelines, and presentations on studies that have been completed regarding marijuana. We continue to finish most of those up. As mandated by executive order public law,

the Division of Workplace Programs develops and revises the mandatory guidelines for federal workplace drug testing with the best available technology. The Drug Testing Advisory Board was created with the intention of utilizing experts in the drug testing fields of biochemistry, toxicology, laboratory operation, and alternative specimens, along with donor advocates, to advise the assistant secretary for mental health and substance use on the development and the revisions of the mandatory guidelines.

SAMHSA continues to seek to improve the quality of services for forensic workplace drug testing, regulated testing, and the private sector testing, by assessing the science and technology used in drug analysis and also by improving the quality of related laboratory services and systems for drug testing, and to set standards for laboratory certification for federal workplace drug testing programs, which helps to guide national policy in these areas.

The SAMHSA Drug Testing Advisory Board provides advice through recommendations 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.

Regarding the DWP status updates, I also have a presentation that I will give shortly, but I wanted to read through this introduction. The revised Mandatory Guidelines for Federal Workplace Drug Testing for urine had an effective date, again, as of October 1, 2017 for implementation. We have now been testing for approximately six months. The major changes in the urine mandatory guidelines were the inclusion of the semisynthetic opioids -- again, we have a presentation on some of that data -- which included oxycodone, oxymorphone, hydrocodone, and hydromorphone, and increasing the lower pH cutoff range for indicating adulteration. A presentation later today, again, will show some of this data in the federal testing program.

Additionally, DWP continues to streamline what's called the Annual Survey Report and has pushed back the reporting period for 2017 to early-mid 2018. Agencies have been apprised of this change.

The proposed oral fluid mandatory guidelines are under final review and will serve to enhance the federal programs' ability to use an alternative specimen. While the focus of the oral fluid mandatory guidelines was to develop federal standards for workplace drug testing using oral fluid, these guidelines will also serve to help set standards for laboratories, private employer testing, and

other public sectors as well as to set standards for state agencies or law enforcement to standardize their programs.

DWP staff and the MRO working group have updated the Medical Review Officer Guidance Manual, which Sean will give a presentation later today on that, and the review of workplace prescription drug testing, and the final revisions were posted on DWP's website this past October. Staff continue -- or have actually completed, I should say -- the review of both the revisions as well as the case studies surrounding opioid testing and they have further revised the MRO guidance manual. We anticipate both of these, both the case studies as well as the MRO manual, will be posted sometime in April.

We continue to work with HHS-certified laboratories that are implementing the current 2017 Federal Custody and Control Form, both paper copy and the electronic version. The 2014 CCF will expire on June 1, 2018. The use of these old forms should decrease to HHS-certified laboratories over the next several months and should be faded out going into June 1, 2018. The newly approved chain-of-custody form, which includes the semisynthetic opioids, is now in use by federal agencies and continues to move forward also in the federally-regulated sector.

DWP continues to focus on some special projects

to complete the extensive studies we have undertaken in conjunction with the National Laboratory Certification Program, the behavioral pharmacology research unit at Johns Hopkins University School of Medicine, and several of the subject matter experts in these field, notably Dr. Ed Cone and Dr. Ryan Vandrey. Some of the special project data will be presented later today.

And finally, I would like to mention DWP's Prevention of Prescription Drugs in the Workplace initiative that is developing a new toolkit. It is titled Substance Use and Emerging Issues in the Workplace. The toolkit will provide an engaging online federal and nonfederal prevention kit identifying and addressing opioid misuse and other emerging substance use issues. The new toolkit should be available sometime in September of 2018, so there's going to be two separate toolkits, one for the public, one for the private sector employees, as well nonregulated and regulated sectors.

Again, I would like to thank you again for attending the Drug Testing Advisory Board Meeting today. I hope you find the presentation I'm about to give informative.

In the presentation I would just like to give; it's hard to have everything behind you, but again, I just wanted to show the staff at the Division of Workplace

Programs. We do have one vacancy, toxicologist. I believe Brian Makela had announced that last time, so he is now back with DEA. Everyone else listed here.

Again, with regulation and policy, some of the things that we've included here, as, again, where the Drug Testing Advisory Board sits, where the medical review officers basically sat, on representing looking at the data, and then also the donor drug test results. Which have been, I would say, probably more challenging, especially since October 1 around the synthetic opioids, and as we go forward, and especially around the review of a valid prescription and what a valid prescription is.

Again, I think within the issues for the drugfree workplace program, there continue to be challenges specifically around state laws, federal laws. I know we're embarking, that will be shown a little bit later, on a CBD study. We continually get questions on CBD oil, if people can take them for the health benefit. So, again, we had a memorandum that was sent out, we re-sent that memorandum out. There's still a number of questions around that that we see.

DWP's objectives and goals -- I just put a present, future, and current goal. Again, present is the implementation of the revised urine mandatory guidelines, which was October 1, 2017, and we are in the process of the

final approval for oral fluid as an alternate specimen in the federal workplace drug testing program. I think to be an effective program, you have to have alternatives, especially in the sense that we've seen a number of invalid samples lately. So, I think you need, to have an effective program, you really do need a different tier of approaches with alternate matrices.

The future will be in the writing the proposed hair mandatory guidelines. I will go over that just a little bit more in detail on a later slide. Current goal is to continue to monitor the semisynthetic opioids testing in the regulated programs, specifically the four that are mentioned here.

Again, the Federal Register was published on January 23, 2017; we implemented October 1, which is now about approximately six months of data. So we have a good representation of the data. Some of the significant changes were we obviously added the semisynthetic opioids, we removed MDEA, we added MDA as an initial test analyte, and we also revised the lower pH cutoff level for adulteration from 3 to 4, which again, because of what we do know that's out there, it has helped in gaining some of those lower pHs that we've seen now as adulterated.

And there are many wording changes around the alternate specimens when authorized. That was specifically

in the urine, but also going forward in the oral fluid.

Again, HHS-certified labs met the October 1 date with the quality performance testing samples. Again, I want to personally thank the HHS-certified laboratories for making that date. I know there was a number of challenges, specifically around the IT issues, but now, essentially, both regulated as well as federally regulated samples, are split out, so I know that they've looked at it, so now we can see both individually, which is really helpful, I think, to the program, when you can look at that. And of course, NRC samples have always been split out a little bit differently than that, too, so now we can get a wide representation of all three.

DWP continues to follow up with the federal agency drug program coordinators that oversee the agencies' drugfree workplace programs. These are consistent with the requirements in the mandatory guidelines and testing for opioids. I'd say Ana and Sean have been busy going out and speaking with senior leadership at the division of -- at the different federal agencies, specifically regarding the opioids. We continue to look at to see how many federal agencies have implemented, as well how many federal agencies have not implemented the synthetic opioids at this time. So it is important we continue to follow up and work with the federal agencies.

Again, the HHS Secretary's priority has continued to be the opioid crisis, as everyone's aware in the news. The testing for the synthetic opioids again could help deter the illicit use of prescription opioids and provide treatment for employees in federal agencies specifically.

As mentioned earlier, the new CCF is effective for federal agencies. Use of the previous 2014 version chain-of-custody form has been extended to June 1. At that time, it will no longer be approved after this date.

The oral fluid mandatory guidelines. We continue and have almost finished all what we call the marijuana studies that we needed to look at, specifically around oral fluid. We have a number of technical and scientific peer-reviewed journal articles that are published. We have a list of those journal articles. We can put those on our website so everybody has those available. DWP continues to update this list continually as we publish articles.

And again, I want to thank specifically Dr. Ed Cone, and Dr. Ryan Vandrey for all the work that they have done specifically in doing these studies and the one that is still upcoming.

As far as what we've looked at, we're hoping, as a proposed FRN notice, that will be 2018, that's a question mark, as everything has to go through this last review process, through the federal agencies, OMB, HHS, et cetera.

So what we're hoping that it's a quick review, it gets through relatively quickly.

We have the inclusion of the testing oral fluid as the new matrix in the federal program. This will be hopefully, the first new matrix since actually, 1988 or 1986, when the program was implemented. Again, it will include everything that the urine includes, including the semisynthetic opioids, and they have been obviously added to the federally regulated drug testing panel.

I'll leave -- the MRO guidance manual has been updated. Sean's going to talk about that a little bit later.

The oral fluid mandatory guidelines, specifically, the final studies and data for marijuana analytes is under review. Again, just some of the reiterations from the last DTAB, because we haven't been able to come out with the final to the public, is again, we looked at -- there is no single immunoassay that detects both THC and THCA. There is a commercial THC assay, but it has significant cross-reactivity, so it would be positive either way.

Laboratories, again, as was in the proposed, they would be able to use an alternate method other than immunoassay for initial testing. That also goes out to urine, which I think is significant in order to move the

program forward. I think we need to let the technology lead us, not necessarily make it static in the mandatory guidelines, but to let the laboratories lead, and especially the new -- I think, some new and very great technology that's coming up that I've been looking at.

Testing for parent drug, again, THC is the psychoactive component of cannabis. It is very important for other uses including driving under the influence of drugs.

The hair mandatory guidelines. I know there's been a lot of attention paid to this, specifically as of late. DWP staff is drafting the proposed hair mandatory guidelines, I can say that. I wish I could say more as to the detail, but I can't initially say more than that. We have proposed research studies around unique metabolites. Last board meeting that was open to the public, we gave some presentations around some of those unique metabolites we have looked at.

DTAB's recommendation was to pursue hair testing as an alternate specimen, and again, as to be an effective program, I think you need alternate specimens in your program. There are some scientific technical issues that are being addressed or have been addressed, through literature or specific studies to address these specific issues.

To the proposed hair mandatory guidelines, DTAB's two recommendations were, in the recommendation to the -- at the time -- was the administrator, was around the decontamination of hair specimens and also hair color impact. Again, just notably, those were two of the things specifically spelled out in the recommendation. And I think in order to develop a scientifically sound mandatory guideline, they will require addressing these two specific scientific issues for the use of hair as a drug testing specimen.

And again, SAMHSA is continuing to develop the proposed hair mandatory guidelines for federal workplace drug testing. I specifically can't give you a timeline, but I'll show later in the presentation the timeline is not really static, as to how long it takes to get through the process.

Challenges. I think some of the challenges going forward will be implementing the oral fluid mandatory guidelines, the review of the technical and scientific studies to improve or support hair decontamination procedures and/or unique biomarkers and/or metabolites to rule out external contamination, and addressing the emerging issues, specifically around marijuana, the opioids, synthetic drugs, legislation, and state laws that are continually changing.

Opportunities, though, I feel, within the program, if we've implemented the revised urine mandatory guidelines, including the semisynthetic opioids, which was a very large issue to do that. The oversight and standardization of the semisynthetic opioids for drug testing, this helped develop the MRO guidance manual and the MRO case studies of how MRO should look at these. Specifically, again, I reiterate, in the federal program, to look at what they look at as far as a valid prescription, et cetera, around the semisynthetic opioids.

Again, hopefully this will deter illegal drug use, of drugs and prescription opioids, at least in the federal program. But as with all standards, as we roll it out, we hope it goes to the private employer and the laboratories that are doing the testing for the synthetic opioids to make it standard across the board.

Implement oral fluid drug testing as an alternate specimen, therefore decreasing the number of substituted and adulterated specimens, and again, I just mention that there has been -- we have looked at invalid specimens. There has been an increase of those. So again, I think that oral fluid is one of the alternative specimens specifically since you're actually in the collection process, looking at basically that specimen being collected. And this also allows federal agencies a non-

invasive alternative to urine testing.

Just real quick, everybody has seen the routing process. I just wanted to put this up here because, again, it is a pretty lengthy process. Again, the MRO guidance manual will -- Sean will give a presentation on that later. We're looking at the cannabidiol study that we hope to start in June of 2018, and again, the pharmacokinetics and pharmacodynamic studies around oral smoke and vaporized cannabis, have been so useful. I know, being on LinkedIn and other things, there are so many requests come across for those scientific papers that we published. And then gathering the opioid data under the revised mandatory guidelines, specifically looking at the pH changes, the invalid results, and also the substitution.

Marijuana continues to be an emerging issue. Again, just to reiterate, the passive inhalation we did, the cannabis brownie study we did, or edibles, very informative, not only to us, the federal agencies, but also to the public. And also the cannabis vaping studies, which it's really amazing in the vaping, is what you see out there, and how many people have converted over to vaping instead of smoking marijuana, which we should be aware of.

And again, DUID testing, we hope, as we roll out the standards for oral fluid, they will also be somewhat adopted as part of the standardization of both the devices

as well as the testing protocols within laboratories.

Emerging issues, just to mention we continue to see emerging issues. Specifically, the opioids have not gone away and they will not be going away for any length of time, I don't think. Again, the synthetic marijuana is sort of making a comeback, on some of the issues, as well as some of the other emerging drugs that we see.

With that I would like to thank you. I have probably spent more time up here than I should, and I'm going to turn it back over to Sean Belouin. But I'll ask specifically from the Drug Testing Advisory Board members, if there are any questions on any of the presentation at this time.

CAPT BELOUIN: Next up we have the agency summary of synthetic opioid testing implementation. This will be given by Paul Harris from the Nuclear Regulatory Commission.

**Agenda Item: Agency summary of synthetic opioid testing implementation**

MR. HARRIS: Thank you, Sean, and thank you, Ron, for the introduction, and in particular, I want to thank the Drug Testing Advisory Board for again inviting me, United States Nuclear Regulatory Commission to make a presentation to you on this important subject regarding opioids within the workplaces of our nation's commercial

nuclear power plants.

Before we get into the technical discussion, I'd like to introduce two other individuals from the Nuclear Regulatory Commission, one of which is Silas Kennedy here to my right. Silas is the new chief, my boss above me, and I'm going to let Silas say a few words, and after Silas is finished, I want to say a few words, and then Brian Zaleski, who is our fitness for duty expert in drug and alcohol testing and other elements of the 10 CFR part 26 Fitness for Duty Programs, he'll present a brief summary of performance within the nuclear industry.

So Silas, you want to make a few words?

MR. KENNEDY: Yes. Thank you, Paul, and additional thanks to the members of the Drug Testing Advisory Board. I am the newly appointed chief of the Fuel Cycle, and Transportation Security Branch. Within my group, we also provide regulatory oversight and policy development for the fitness for duty programs described in 10 CFR Part 26, which includes a drug and alcohol test in our nation's commercial nuclear power plants. As Paul said, Paul and Brian both work for me. I note that we have now been participating within the Drug Testing Advisory Board since 2009 and was recently accepted as ex officio member in about 2015.

Since that time, the Drug Testing Advisory Board

has contributed to a number of achievements. You have, one, incorporate four additional opioids into the testing panel. Two, you issued draft oral fluid guidelines. And three, you published a substantial revision to the MRO handbook. And you also continued to work hard to implement guidelines for the use of hair as a testing matrix.

We believe the use of hair would be a marked improvement in not only deterrence but in significantly increasing the window of the testing for Schedule I illegal drugs, which would significantly benefit pre-asset testing and random testing.

We personally commend HHS and the Drug Testing Advisory Board for all your work. I'd also like to say that you are the silent key roles behind the technical justifications used to support our 10 CFR Part 26 drug test requirements that are implemented at our nation's commercial nuclear power plants, and therefore your efforts do contribute to public health and safety and the common defense and security.

So we look forward to many more years coordinating with the Drug Testing Advisory Board and working with our federal partners, the Department of Defense, Department of Transportation, to help provide assurance of public health and safety. Thank you.

MR. HARRIS: For the new members of the Drug

Testing Advisory Board and members of the public, the NRC has about 3,000 staff located in Rockville, Maryland that provides regulatory oversight of the commercial nuclear industry. Drug testing is one of the significant elements that lead you to provide assurance that the workers at these facilities can accomplish their job safely and competently.

We use the Defense in Depth approach to assure that these workers can conduct their roles and responsibilities the way they are trained and authorized to and to provide the security of these facilities. And what you'll hear from Brian Zaleski in his presentation is this Defense in Depth approach. Because of rulemaking and the time it takes to implement rules and evaluations that need to be done, we're trying to get outside of the box to develop additional methods to provide a level of assurance that ensures that these facilities are operated safely.

So we call this the Defense in Depth approach, and drug testing is one element of that, coupled with behavioral observation that we do. So you're going to see that in Brian's presentation. You're going to see a sophisticated analysis of what we can do in the nuclear industry, and you're going to see possibly some of the results and outcomes from these data in which we can better implement our framework that is more performance-based and

more risk-informed, because, as we know, we can't go drug testing our way to safety and security. We need other approaches, like Ron said, to ensure that we conduct our activities safely. With that, I'd like to introduce Brian and have him do his slides.

MR. ZALESKI: Thank you, Paul. Good morning. My name is Brian Zaleski. I'm a fitness for duty program specialist at the U.S. NRC. This presentation is going to highlight our operating experience in 2017. We, however, have not implemented the 2017 HHS guidelines, so we did not expand the panel to test for semisynthetic opiates. I have highlighted some information in this presentation.

We do afford our licensees the opportunity to expand testing panels in certain circumstances, and I'll talk about that, I'll present the results that we have for those additional substances that we've identified since 2011. So I'll give you some sense of what we're seeing in our program.

This is extremely early for us to present results, so these, I would call them super draft results, because our reporting period just closed at the end of February, and so we have yet to perform the typical QA that we do prior to reporting on these. So there are fewer slides, but I think the information here is pretty close to being what we're going to report out when we finalize the

information.

So what we're going to speak about today, we're going to briefly highlight our program, the fitness for duty program. There are multiple elements of it. It's more than just drug and alcohol testing. I'm trying to articulate here why our program is a little bit more unique than some of the other testing programs, and as Paul said before, articulate what Defense in Depth means at the NRC.

So because we have multiple tiers of protections to improve our assurance that individuals are not going to be impaired inside a protected area, inside an area where they are subject to testing, we believe that we have a robust program. We monitor our industry very closely. We collect electronic reports on individual test results.

So since 2009 when this program started being voluntarily available, industry has begun to use it since 2014, we've had 100 percent use of this system. So we have uniform data collected from 2014 through today for every single individual that tested positive in our industry, which I think is pretty unique in terms of information that the public can be able to see about a federal testing program.

I'll also highlight some of the issues that we're seeing with the HHS-certified laboratories. Part of our regulatory framework requires our licensees to report to us

within 30 days of an event where there's an unsatisfactory report at a testing facility. We've had a handful of them this year, in the past year, that I'll make mention of.

So fitness for duty is more than, as I said, it's more than just drug and alcohol testing; it's this access authorization program. In prior years, I've talked about that. This is doing background investigations, psychological evaluations, this is doing credit reports.

So there's a multiple tiering of individuals prior to even getting a drug test that improves our screening on individuals who will be trustworthy and reliable and fit for duty in terms of not being impaired by substance use. So the access authorization piece works on the trustworthy and reliability element. So fitness for duty, for us, is more than just drug and alcohol testing.

Another element of this program is the fatigue management program. Since 2008, we have had worker fatigue provisions in place similar to what FAA has for their pilots and certain elements of their workforce.

Individuals are only able to work a certain number of hours to prevent chronic and cumulative effects of fatigue. That is not something we're going to talk about today, but it is another element of our program that was implemented recently.

And then finally, behavioral observation, that's

something that all of the individuals that are going to be working in our workforce are trained to identify impairment, to identify if there's credible information that they see, and they are required to report it to the program so that corrective action can be taken.

I'm not going to read this slide other than to articulate two of the points that I did previously. So what is the FFD program? Our FFD program is to provide reasonable assurance that individuals are trustworthy and reliable. So that is the access authorization piece of it. Plus, they are not under the influence of any substance, legal or illegal. So this is beyond just the substances that we can identify in our testing panel -- and then also the mentally and physically impaired from any cause. So it's a broader umbrella under which we regulate to ensure that our individuals are safely and competently performing their assigned duties.

In practical terms, we test for a certain number of drugs, so we're only able to articulate that, but we have aspects of our program that are called fitness determination, so if someone is impaired and they test negative, they're still going to get evaluated to ensure that if they're on some sort of impairing medicine, they're going to take appropriate actions to ensure that that individual can either return to the workforce or they're

going to disqualify that individual until such time that they are determined to be fit.

That photograph you see there is an armed security officer. So Paul talked about that -- primarily, these are power reactors, they're generating electricity for homes in the United States, businesses and homes. So the types of individuals that are subject to our testing are armed security officers, supervisors, maintenance employees, physicists and chemists that are working in the facilities, anyone that has unescorted access inside this protected area, which it's a protected access point where individuals are screened with metal detectors, bomb detectors, and controlled.

Here are seven elements that we wanted to highlight in terms of the Defense in Depth approach that NRC takes to provide reasonable assurance that individuals are trustworthy and reliable and not impaired. First is this access authorization piece. It's the biggest piece of the screening prior to us doing the testing.

We test under a variety of circumstances, which is similar to most federal agencies, pre-access, random, for-cause, post-event, and follow-up. I will say that I think we are unique in some ways in terms of how we do random testing, because we're doing a 50 percent random testing rate for drugs and alcohol both.

I know some federal agencies modulate that random testing rate based on positivity. We do not. The types of testing -- so NRC provides licensees with ability to customize their testing program, meaning they can lower their testing cutoff levels if they choose to do that. We require that licensees apply time-dependent cutoff level for alcohol testing. That came into being in 2008.

So if we have individuals onsite for a period of time and they're testing positive at 0.02 or 0.03, they may be in violation of our policy depending on how long they are at the power reactor site. We also permit all of our licensees to test to the limit of detection for confirmatory testing assay if the specimen is dilute.

This is one level of assurance that we have to identify drugs in individuals that are trying to avoid detection through diluting their specimens. It's not a common approach for individuals to dilute their specimens, although we do have some positives each year. I will show data later on in terms of subversion attempts or it seems like individuals are just replacing their specimen with something else to thwart the testing process.

And finally, we give our licensees the opportunity to test for additional substances. Some licensees, and I will present that information, a limited number of licensees systematically test for additional

drugs for all tests, but primarily where we're seeing this is under targeted circumstances.

Either it's an individual that reports a prior use problem in their follow-up testing program where the MRO is going to direct a particular type of test, say, an expanded semisynthetic opiate panel, but we are not seeing a large number of our licensees test for additional substances beyond what's in our testing panel.

Another very unique thing about our program, I think, in terms of the civilian testing world is that we have graduated sanctions. An individual who tests positive for drugs or alcohol the first time is denied a minimum of 14 days, much longer, because the treatment process would be at least 30 days from what I hear for someone who has tested positive at least once, but it can be a lot longer depending on the licensee.

These are minimum sanctions in our rule. Many times, a licensee will terminate an individual that's tested positive. Second time you test positive, it's a five-year denial, and the third time, it's a permanent denial from access to our facilities.

One other unique piece of our program is that we require annual refresher training on drug and alcohol fitness for duty program of employees to ensure that they understand what they are required to comply with and

they're not just seeing a big policy one time when they start working at a licensed facility.

The last piece, I mentioned it previously, is that we get some types of reportable events. We keep a closer eye on certain segments of our workforce. So licensed reactor operators who are controlling a reactor, supervisors, we'll get a report within 24 hours of them testing positive. A small number of individuals each year, I think last year was two, up to maybe seven, eight, nine, ten.

Typically, these individuals test positive for alcohol, but there's more widely used drugs in the supervisor population that we occasionally do see. So we're getting timely reporting for critical elements of our workforce, but we collect information on an annual basis at the conclusion of the calendar year, two months after the conclusion of the calendar year, and that's what we'll present here.

Not much has changed in comparison to 2016's test results, so in 2017, 148,357 individuals were drug and alcohol tested. The parenthetical notes identify the small number of changes. There's down by 3.6 percent. I think in large part that has to do with one of the two power reactor construction sites ceased their construction activities in the middle of 2017 because of Westinghouse

going bankrupt.

I don't know if people are aware of that, but anyway, that had dire consequences to the construction at that one site and because of that, we saw a little bit of a downtick in the testing. The number of positives is pretty comparable to last year, 1,143 positives.

If you break that down in terms of where we're identifying detection, roughly two thirds are coming at pre-access, which we like to see. We wish that we could see all of our detection at pre-access testing. That is before individuals are employed to work inside our power reactors. And 20 percent, up to 23 percent-ish, was under random. So random testing does have a strong detection component, not just a deterrent component in our program.

The overall industry positive rate for all tests conducted in 2017 was 0.77 percent. However, there are differences when you look at employment type, whether someone's a contractor/vendor, which is generally going to be a short-term employee that's supporting an activity at a site for a period of time, or a licensee employee, which is a fulltime permanent employee.

Drug and alcohol uses rates are much higher in the contractor/vendor population. This has always been the case. The last piece on this slide is that the industry positive random testing rate, 0.44 percent, so it's low.

It's much lower when you look at just licensee employees at 0.14 percent, and that rate varies very, very small. There's small variation in that rate.

And the contractor/vendor population has been pushing up over the years. This year is the highest that I've seen in our program at 0.84 percent. I also will say that when I mention construction sites, since about 2011, the construction site workforces have been so large that they have been pushing some of these rates up. So without construction workforces, these rates would be even lower.

One other note, all of the results you're seeing here are MRO-verified results in terms of drug tests and alcohol through evidential breath testing devices. These are not unverified results.

There are only a few things I want to highlight about this chart. It's very busy, we do it every year, but it gives you a good sense of, programmatically the differences in detection by the types of tests that we conduct. So the columns present results by licensee employees and contractor/vendors, and the rows represent the reason for testing.

There are only a few things I want to make note. You can look at these on your own time. But one is that there are big differences in the types of testing and the detection. For example, if you look at the pre-access

testing row, over 80,000 people were tested in 2017, and 71,000 of those were from contractor/vendors, and only 8,000 from licensee employees. So primarily, the people that we're introducing into our workforce are coming from the contractor/vendor population, and that also has an impact on where we're detecting use. Since we detect two-thirds of our use at pre-access testing, we're going to see a lot more detection in the contractor/vendor population on pre-access.

So the second table there breaks out where we're getting our detection of the positives. Contractor/vendor, as I said, 70 percent is pre-access. Licensee employees, most of it is coming from a random testing program, because the licensee side of the house, there's not a lot of hiring, it's a static workforce.

This chart presents trending of detection across time, 1990 through the present. It's only presenting the substances that are in our testing panel, and each year, the vertical column would add up to 100 percent. So we're doing a presentation of prevalence of detection of various drugs. You'll see that marijuana has always been the most prevalently detected drug; it's the top line in the chart. Alcohol has been the second most prevalently detected drug since 2008, and I think in large part that has to do with the fact that we lowered our cutoff levels. So when I

talked about time-dependent cutoff levels, we improved our detection of alcohol by 30 percent. We have 30 percent more positive results each year since that change.

From my perspective, we always want our cutoff levels to be as low as scientifically supportable, assuming that they're not substances that are medically acceptable, prescribed drugs. So illicit drugs, I'd like to see us be testing as low as we can to expand the window of detection.

One other item I wanted to point out in this chart is that you'll see the convergence; on the bottom right hand corner of the chart, you'll see two lines, one is opiates, the bluish color, and the other is cocaine, it's green. Cocaine use plummeted from around 2006 in terms of prevalence, and it flattened out around 2011.

And both amphetamines and cocaine are basically moving in tandem at this point. So that's something that we're mindful of. One thing this presentation doesn't talk about is our panel of drugs. We have not even yet aligned with the 2008 HHS guideline changes. So our cutoff levels are higher for cocaine, higher for amphetamines, they're higher for methamphetamines, and we do not test for ecstasy.

So we would assume, and the modeling we did in our proposed rule that's before commission to align with the 2008 HHS guidelines is that we would see roughly a 10

percent increase in detection for those substances. That's primarily modeling what we saw in other federal agencies and using our detection as the baseline.

Two notable items about these pie charts, they break out positive test results by employment category, licensee employees and contractor/vendors. The biggest difference is that licensee employees test positive more often for alcohol than they do for marijuana, although that's starting to trend downward.

It used to be much more alcohol. And conversely with contractor/vendors, it's much more marijuana than alcohol. Other than that, they're comparable trends with the exception of refusing to test. Contractor/vendors, I think they're more fungible in terms of the types of activities, so they're more willing to subvert or refuse a test.

If you subvert a test in the NRC-regulated workplace you are permanently denied access. You can never work in the industry again. So a licensee employee has a lot more on the line in doing that -- they are fulltime employees -- than, say, a pipefitter who is coming in to do work at a nuclear power plant on an outage. So the deterrence of that subversion policy is much different.

Okay, so, I'm trying to provide some insights in terms of our additional substance testing. There are two

provisions in our regulations that permit testing for additional substances. One is to provide licensees with the ability to monitor local drug use trends and adjust their testing panels accordingly. The other one provides more strategic individual-specific testing for any scheduled substance under three circumstances, follow-up, for-cause, and post-event tests.

If a licensee chooses to use an expanded panel or even to use lower cutoff levels, they need to get a forensic toxicologist to review the testing and validate that those tests and those cutoff levels are scientifically supported at the laboratories that are performing them.

In 2017, we had eight facilities, so we had roughly 70, 70, seven zero, facilities in 2017 that are subject to our rule, and the vast majority are power plants. There are a few facilities that are fuel cycle facilities; they prepare uranium for use by the Department of Defense. But primarily, we're talking about power reactor sites.

So eight facilities, so it's a small number of facilities, have expanded panels, and this is associated with two corporate programs. Two corporations in the United States have expanded their testing panels as follows. One test for barbiturates, benzodiazepines, methadone, and propoxyphene, and they have four facilities.

So it's one corporate program, they test all specimens regardless if it's pre-access, random. Very few positives. They've been doing this since the 90s.

The other program that I think implemented their expanded testing panel, the second sub-bullet under the first bullet, to expand their panel for follow-up, for-cause, and post-event testing. They did this, I think, in 2015. They have not recorded any positive results for these expanded panels, but the slide there mentions benzodiazepines. I failed to include, upon further review of their information, they're also expanding for hydrocodone, hydromorphone, and oxycodone.

As I said before, occasionally a licensee will expand their testing panel specific to an individual, and I think that would either relate to credible information they are receiving on illicit use or illegal action offsite, or some type of information that supports their use of the expanded panel. For-cause tests, for example, they may expand the panel because of obvious impairment that may warrant that type of testing.

MR. FLEGEL: Sorry, Brian. I just want to ask a quick question. This is Ron Flegel. Have you looked at, because the new guidelines have come out, have you supported any of the facilities changing to the expanded panel individually?

MR. ZALESKI: No. Paul and I have been working with them for years to try to support them implementing lower cutoff levels. Many times, what we hear is that because of the binding contracts they have with unions, they are unable to adjust their testing panels because they would have to renegotiate so many of their union contracts at the sites.

But that's not always the case. The one case here that, this second sub-bullet where they expanded for follow-up, for-cause, and post-event includes some additional substances, that was an extremely proactive fitness for duty manager at that corporation that worked very closely with their unions over a number of years to try to expand the panel.

But no, we're not seeing much traction in that regard. So while we do provide flexibility, and we've always provided that flexibility in our regulations, in practical terms, it's not being used, no.

So I went back and I queried all of our results since 2011 for any additional substances that were reported as being identified in individuals. So this chart presents the number of hits for each of these substances. This is not -- so the takeaway point here is that an individual may test positive for more than one of these. The next slide, I'll show you that.

So you'll see that there's a very, very small number of individuals that are testing positive, and I will give you just a little bit of context to understand that. We roughly test between 150- to 170- or 180,000 people a year. So in 2011, for instance, we tested 178,000 people. We had two positives for an additional substance. So it's extremely rare that we're seeing these tests identifying use and also being used. And that has not changed over time.

This one, while a little busier, hopefully the slide that I printed out is a little bit more legible to you, presents information at an individual specific level, and it's broken out by the types of tests.

There's a few takeaway messages here. I listed them in the green box at the bottom of the slide. One is that two-thirds of these individuals that are testing positive are testing positive on for-cause testing, and our for-cause testing is a little bit different than, say, I think the Department of Transportation's where it's limited to observed impairment.

So we have that in our program, but we also have the piece of credible information, so someone calls up the employer and anonymously leaves a message providing some reasonable information that they can follow up on an individual is illicitly using a substance, they will take

action and do some testing on that.

Twenty-five percent of the individuals in this analysis that we did over time tested positive for the expanded panel. So that's the only piece of this that I could present to you, is that, yes, we are seeing some use of the expanded panel of the semisynthetic opiates in our workforce, and 25 percent of the individuals, 6 of 24, tested positive for those semisynthetic opiates. In many cases, when they were being tested, it was because they had credible information of use. Either it was prescription-seeking behavior that was reported by a coworker or an arrest offsite for possession of an illegal substance.

One way that we look at this as policymakers is we say, well, we have an expanded panel; are individuals solely using one of those substances so we're missing them entirely, or would we capture them anyway because if you used, say, hydromorphone, you're also going to use amphetamines or you're going to use marijuana? So in this presentation here, 57 percent of the individuals that tested positive for an additional substance also tested positive for something that we identified in our minimum panel. So they tested positive for amphetamine, or methamphetamine, or cocaine, or marijuana.

That's just one thing that we're seeing. One, that these individuals are testing positive for multiple

substances, and two, we would still be able to identify some of them even if we weren't looking for these expanded panels. So, that's one level of assurance, even though we've yet to implement, that we'd still catch some of these individuals.

I like to highlight this because it's an important one, it's an important message to present to the Drug Testing Advisory Board. I'm not aware of this information being presented anywhere else. We are still seeing a huge number of our individuals attempt to subvert the testing process, and we're identifying them primarily with out-of-temperature specimens. This trend was first identifiable in around the 2012 timeframe, and it's been upticking since.

If you look at the percentages under the subversion attempt trends, you'll see that between 15 -- roughly 15 to 25 percent of our violations each year are associated with a subversion attempt. Now, it actually gets a little bit worse if you think about, well, subversion attempts are primarily on drug testing. It's not alcohol testing. If someone's going to refuse, they're going to refuse both, but in this case, the majority -- maybe one a year, where someone refuses an alcohol test it's drug testing.

So if you remove all the alcohol violations from

that denominator in terms of the number of violations each year, we're now talking about 20 to 30 percent of our positive results -- quote-unquote positives, I'm talking about a refusal as being a positive -- are subversion attempts. That is 298 individuals in 2017, 300 in 2016. We have very controlled workplaces. Primarily these subversion attempts are occurring on pre-access testing. So it's the predictable testing event, and this is a serious concern.

We know that some individuals are beating the testing program because they self-admit. They get caught subsequent to a negative result, and they say, yup, I cheated previously. And the high number of attempts suggests to us that there are successful products on the market that we are not identifying at the laboratories.

Our highest and best method of assurance in this regard, in terms of identifying subversions, again, is temperature. It's temperature.

MR. HARRIS: Brian, this is Paul Harris at the NRC. Before you move on, can you please explain how, to the audience, these high number affects the overall drug testing results?

MR. ZALESKI: Yeah, I'm sorry. I have a note on one of the earlier slides and I'll push this back a bit. Folks might be thinking, well, you know, marijuana is more

legally available now in states, why isn't marijuana increasing in this prevalence chart? And arguably, it's bouncing around a bit. So, the fact is that 60 percent of the time that someone subverts a test, we don't collect the specimen because they outright refused. So we don't know what's in their body. We don't capture that information in our summary results. So, these charts here are impacted by that. So that the outcome of us collecting every specimen from every individual testing, it would probably adjust these results a little bit. How much, don't know.

Okay. Then we're going to conclude with a summary of the five reports that we received in 2017, and we provide these to Ron when we get them to make sure that you can follow up in the NLCP program if it supports that. But what's interesting is that we've seen over the years, we're seeing more human performance errors at the laboratory, and fewer formulation issues with our blind specimens.

I think there's two reasons for that. One, we really only have one blind performance test sample supplier in the industry right now, and it's an HHS-certified laboratory that also creates those specimens. So the specimen quality has improved such that we're not getting errors at the laboratories from poor formulation. These five results are unique in that they are from a variety of

types of issues.

The first one is that specimen validity tests were not performed on two donor samples. So, these are donor samples, so that's a bigger deal. It was caught when the MRO reviewed the test results, and it turns out that the laboratory didn't enter the correct testing profile for those specimens.

The second bulleted item, there were two specimens. These were blind specimens that returned as negative instead of substituted. The laboratories investigated, determined that manual pipetting of those specimens resulted in those outcomes, those incorrect outcomes, when generally they're using an automated process to aliquot.

The third bullet, there was a marijuana blind performance test sample that was formulated to test positive for marijuana. However, it was negative. The laboratory investigation identified that a bad reagent was used in the testing. So, the supervisor notified staff to discard the reagent, but it was not. So that specimen tested negative for that.

The fourth bulleted item, a marijuana negative, again, blind performance test sample. In this one, the individual that was evaluating the test result incorrectly interpreted the result, there was a bunch of interference

in the chromatograph, and correct procedure was not followed, and therefore a negative was reported.

And then the final one was, again, it was a data entry issue. A blind specimen should have tested positive for amphetamine and methamphetamine. It only tested positive for amphetamine. And the scientist who conducted the testing failed to enter the data into the necessary computer in the correct field, so methamphetamine was negative in that case.

So, when we're looking at these, clearly these were human performance errors. These were not machine malfunctioning. And it's something that we're seeing an uptick on.

The concluding slide provides some resources in terms of where this information came from for the public. The annual reporting requirement for drug and alcohol testing is under 26.417(b)(2) -- that's for construction sites -- and 26.717, that's for everybody else. Again, we collect this electronic reporting information which provides us with the ability to do more robust trending across time. Previously we couldn't do that. And drill right down to individual specific data elements. I would encourage folks to consult with our reports that are published on our website. That's the third bullet.

This is the summary reports that we present to

the public on our testing program. The latest one that's up there right now is from 2015. Last year we published two reports for 2014 and 2015, and we'll have our next two reports out by this summer, I estimate, and we'll be back up and honest and current with everybody.

And finally, those are the two images there are just screengrabs of what these forms look like. They're publicly available. Anybody can download them and look at them. They're PDF files. We occasionally update them to improve the uniformity of data that we collect. A couple of years ago we added a field to collect information on which laboratory's licensees were using, which has been helpful, because if we see a 30-day event report, we might be able to more strategically target those licensees and say, hey, take a look at this.

And that's the summary, the really high-level summary. We had a small amount of information that we could provide on additional substance testing. Ron, as I said before, most licensees are not deploying that, or at least in a quick manner. There's not the procedural way they can do it without significant burden in terms of cost. However, I will note that many of the sites do have their own type of workplace testing, corporate workplace testing programs, where they do use expanded panels, but it's independent of the NRC.

And we will have more detailed information after we validate these, and we can present that at subsequent DTABs, if appropriate.

CAPT BELOUIN: Okay, Brian, this is Sean. We've got a few questions from the board members on the line. Jim Ferguson, he has the first question is, do you anticipate aligning with the new guidelines any time soon? And then he also says, does NRC allow buprenorphine and methadone?

MR. ZALESKI: Good questions. Paul Harris and Brian Zaleski, we speak as individuals, not as NRC. We would love to have our panels aligned at the same time that everyone else does, but we don't have that in our regulatory framework to be able to do that right now, and Paul has been working very, very diligently to try to explore options to do that.

We -- and I've spoken about this in prior Drug Testing Advisory Board meetings -- we have additional levels of review to demonstrate that we should implement drug testing panel changes. We need to demonstrate improvement and effectiveness in our program. So without information to support an increase of protecting the public health and safety, and for that to be a costly measure to implement, we have to be much more conservative in our approach.

So, I do not, as we currently stand, anticipate that we're going to quickly implement these, no. The proposed rule that we had before commission has been there for a year, this February, that just aligned with the 2008 HHS guidelines. So, no.

And secondly, methadone and buprenorphine, they're impairing. Some licenses, I think, will automatically disqualify and in other circumstances they may, depending on the worker, they may evaluate what they're doing. But we don't know that. We don't collect information at that level, but we do not, as an agency, have a list of medicines that you can take that would disqualify you outright.

CAPT BELOUIN: Okay. Thank you. This is Sean again. I have one other question from Michael Schaffer, another board member. Says, do you think urine screen for benzos cross-react sufficiently to be adequate for identifying these analytes? And what do you think the reason for subversion in your program, that is, what drugs?

MR. ZALESKI: I can't really answer the question on benzodiazepines. I don't have any information that -- I don't look at the testing that they're doing enough to offer an opinion on that.

In terms of the subversions, we've looked at that a lot. And I think there's a few reasons why we have such

a high rate. One, we have very good optics to collect information uniformly on it, and we've modified our data collection process over time, once we identified that there was a problem, to just be able to more effectively characterize it. So, we updated our electronic reporting forms to collect this information, we educated the industry on these events, and we got a better picture of it. So that's one.

Two, we have highly trained collectors that are onsite at our licensee sites. So it's a small number of collectors that are trained to collect specimens from that workforce at that location, and they catch people. So an example, one example, of the additional level of assurance that many of the licensees are using for temperature specimens, is they have infrared temperature guns and they'll check the temperature on the specimen and they'll know that the specimen's 80 degrees or it's 120 degrees, and they have sufficient information at the time to stop a collection from proceeding further.

So there's additional measures they put in place to identify these individuals subverting. And then I think also there's a piece of this where nuclear power plants need to get maintenance on a scheduled basis. They have to change out the reactor cores. There are outages. And when they take that power plant offline, that power plant, I

believe, each reactor's offline for days, losing a million dollars in revenue. So they pack a lot of maintenance activities into those periods of time.

So they screen an inordinate amount of people in a short period of time to do maintenance activities, and those individuals are there for a short period of time, and we're drawing from a workforce that is not generally subject to testing. So, I think the incentive for them to cheat is high, because they're only going to do this for a short period of time. They don't have a career in the nuclear industry, per se. So the consequence of being caught is low, versus the licensee employees, where it's rare to see a subversion attempt, because that individual knows that that fulltime job is gone, and they will not be able to transfer to another site. So that's one of the differentials, I think, in why we see it. Ninety-eight percent of the subversions are from contractor vendors. And that's every year that we've looked so far.

MR. HARRIS: Sean, this is Paul Harris, NRC. What I'd like to add upon what Brian said, what is important for the Drug Testing Advisory Board to understand on the subversion is that -- Brian just said it -- 98 percent of all the subversions are by contractor vendors. These individuals are members of the general public that are coming to the power plant to do work.

So, they're representative of the general public, so that gives an indication that the members of the general public have a high ability to subvert drug tests. In the preponderance of the identifications that we're doing in the nuclear industry, is not because of a laboratory test result for an adulterated substituted specimen, but because the collectors are vigilant in identifying the individuals like Brian said, under temperature.

So, when we take a look at lowering the lower cutoff of the adulterated pH level to help identify adulterated products, we think that's a significant contribution to safety, because of the subversions that we are seeing and potentially those we are missing.

MR. ZALESKI: And many of the subversion attempts that -- so, when we collect two specimens, it's not just that one's negative and one's positive. Many times they are negative, in fact, or some of the time they're negative in both of them. But pH is so different, the creatine levels are so different, that they can conclusively make a determination of a subversion.

One other point I want to talk about in terms of the contractor/vendor, and our reports have this, we break it out by labor categories, whether someone's a reactor operator or maintenance employee. There, I think, it was 80 percent of the subversions were committed by maintenance

workers. So, if that gives you any sense of that, of who we're talking about. Because of this information, the hope is that we can be more strategic and target the types of risk, and then improve our program through better information to our licensees, better information to our inspectors. Each of these fitness-for-duty programs are inspected every three years by an NRC inspection team.

Any other questions?

DR. COLLINS: Jennifer Collins. Do you track the number of positives that you get from the additional testing performed on dilute samples with an elevated immunoassay result? Are those numbers tracked separately?

MR. ZALESKI: Yes. There's two things. We do get the cutoff levels, and we do get if they do this special analysis testing that's in our rule determined. So, yes, we do get that. And it's anywhere from maybe 3 to 10 or 12 tests a year that we're seeing positive results from a limit of detection test that performed, and I've seen it from several types of substances. Mostly it's marijuana, but a couple of cocaine results, and we've seen that across test pipes, pre-access, some random, some follow-ups.

So we do see some detection gains there, but specimen dilution doesn't seem like it's a preferred choice. We optionally provide licensees with the ability to let us know how many dilute specimens they actually have

at their site each year, but we're not requiring them to present that. We are requiring them to present information on how many special analysis tests they do. So, it's a small number. And I'm assuming that if we're doing a special analysis test that we're going to get a positive result, but I don't have the laboratory -- you guys have that laboratory data, I don't have that.

And we do present some of the LOD test result data. There was a slide, I think, in the last presentation, where we had the last five years' worth of results -- the drugs, the type of test that detected it, and we'll update that again at the next DTAB.

CAPT BELOIN: Thank you, Brian.

Given that we're wanting to get back on schedule, it's a quarter after 11, so what we're going to do is we're going to take a five-minute break, a ten-minute break -- okay, ten minutes, so we're going to start back up here again, Operator, at 11:25.

(Brief recess.)

**Agenda Item: Agency summary of synthetic opioid testing implementation (DoD)**

CAPT BELOIN: Again, this is Sean, the DFO, because we're a little bit behind, we're going to just keep on running, and we will probably going to run over until we finish, and obviously we'll extend the open session a

little bit, and then we'll have a short public comment period, if there are any public comments, we'll take them at that time.

All right, Tom, if you're ready, go ahead.

COL MARTIN: Thanks, Sean. Good morning, everyone. This is Tom Martin. I work with the Department of Defense Drug Testing and Program Policy Office, and I'm going to kind of give you just a short rundown of our synthetic opioid testing for our military program.

Okay, so just in general, in the Department of Defense, our drug demand reduction program, we talk about our mission; it's to maintain operational readiness and safety and security for the total force. That's active duty, National Guard, Reserve, as well as our civilian workforce.

The scope of our mission is all military as well as our Department of Defense civilians in those testing designated positions, and of course we have policies and instructions that guide what we do.

Some of you have probably seen this slide or something similar. So our driving factors, we recruit the majority of our military servicemembers from the 18- to 25-year-old male population, and this is the population that's anywhere estimated up to almost 20 percent of drug abuse in the general population, and we are recruiting them. So we

need to be vigilant on who we recruit, how we recruit, and then when they're in, how we test them to deter their drug use.

As far as a little bit of history, and I'll touch on it a little bit more later, the DoD instituted drug testing in the Vietnam era. There was estimates of about 5 percent of our servicemembers were returning addicted to heroin at that time. And at that point, it was a treatment rehabilitation program, identifying service members who have an addiction and treat them, as best we could. Everything changed in 1981, when the aircraft carrier Nimitz aviation mishap. Many servicemembers were killed and injured. Seven aircraft were destroyed and damaged. Over \$150 million in damages in 1981 dollars.

What was interesting to note and what changed the perspective within the Department of Defense is that of the deceased, six of them had detectable levels of marijuana as well as almost up to 50 percent of the servicemen on the Nimitz itself had detectable levels of marijuana. There was no definitive association with marijuana use for the crash. However, from that point forward, changes were made to our program where it became more punitive in nature. If you tested positive, significant penalties would happen.

Some of the other driving factors over the past 10 or 15 years, there has been a notable increase in use,

increase of abuse or misuse of prescription pain medications, and abuse of the drugs -- you know, they endanger the safety and readiness of our force.

As far as our program, we have really four pillars that we go by. The majority of the program is focused on testing at our laboratories. We also obviously have to collect the specimens and all the services do that. We have a prevention, education, and outreach program, and then we capitalize on what we call joint service, maximize the buying power of our dollars for instrumentation as well as we run the recruit testing program, and then we have a special testing and surveillance program out at the Armed Forces Medical Examiner System at Dover Air Force Base.

So as far as our drug testing laboratories, up until February 1, 2017, there were six, and then the Navy laboratory at San Diego officially closed on that date. Their workload was distributed amongst the Navy, Army, and Air Force laboratories. You can see them here depicted on the map.

So the two Army labs, one in Hawaii, one in Fort Meade, Maryland; the ones for the Navy are in Great Lakes, Illinois, just north of Chicago; one in Jacksonville; and the Air Force laboratory which is in San Antonio, Texas.

So just to focus -- the focus on this is on opiate or opioid testing within our population and our

program. So in this slide, we looked at -- we are sharing with you our cutoff concentration, both from our initial screen which is by immunoassay, and then our confirmation. You can see for a variety of our drugs, for the codeine, morphine, hydrocodone, hydromorphone, we start with the 300 nanogram per milliliter cutoff concentration, and then for those specimens that are presumptively positive there, we will reflex and then either test again using a cutoff of 2,000 for codeine and morphine.

Then we move onto the definitive confirmation analysis, and you can see our cutoffs on the slide.

So a little bit more on the history, especially on the opiates. I mentioned the drug addiction to heroin in Vietnam and the aircraft carrier incident, and then in 1981, that changed the way our program was run, and now punitive measures could occur, such as court martials, military separations, dishonorable discharge, things of that nature. The formal instruction or directive that codified our program was issued in 1984, and then as far as for federal civilians, that happened in 1986.

For synthetic opioids, within the military program, we have been doing this for a long time. We started with oxycodone and oxymorphone in 2006, and at that time, we did what we called pulse tested. So about a quarter of the specimens submitted to the laboratories were

tested for oxycodone and oxymorphone. Starting in FY2010, the Chairman of the Joint Chiefs of Staff directed us to expand our prescription testing program for additional synthetic opioids and benzodiazepines.

Took us a couple years to get that up and running. So in FY2012, we added hydrocodone and hydromorphone, and it was an incremental process. So in the fiscal year 2012, about 40 percent of the specimens were tested for those two drugs. Then in FY13, we issued 100 percent testing. So all specimens tested for all the different opioids on our test panel.

So some of our observations from synthetic opioid testing, and some of these probably are not unique -- I know are not unique to our population. It's just a potentially huge increase in confirmation workload. A significant number of our servicemen and women are on prescriptions for these opioid medications. So when they collect their urine, they test positive. In the past, they would go to confirmation, and the medical review process would take over.

We have been able to mitigate this somewhat through what we call our electronic review or automated MRO process. So within our DoD system and our medical system, those servicemembers using that system, all their prescription medications are tracked in a database, and we

are able to link or sync up on laboratory testing data with that database in an almost real-time fashion. If the servicemember has a valid prescription that would cause or likely cause a positive for that specific drug during a test, the would be what we call washed or electronically washed or considered authorized use.

So we implemented this May 1, 2012, a significant reduction workload, and you can see in this slide, we have FY14 data, and it's remained just about the same since then. So for oxycodone alone, almost 80 percent of the specimens that test positive for oxycodone or screen positive for oxycodone, are washed. So that's almost 12,500 specimens a year don't go to confirmation. And you can see the other drugs listed here on the slide.

To get a general feel of our distribution of positives, in FY16, the number one drug not surprisingly in use by our servicemembers who are testing positive is marijuana, almost 75 percent. And then you can see a breakdown of the positives. What you can note there is almost 12 percent were the opiates, and then you can see benzodiazepine and some other prescription medication.

So when we initially started the program, if we go back to 2012, starting with that date and move forward, we had a high positive rate; a significant number of our members were testing positive, and they did not have an

authorized prescription. But over time, over the last five years, those numbers have trended in the proper direction for us. We have seen a significant decrease in positives.

And we attribute that to several reasons. Of course, drug testing and deterrence is one reason, but really what we feel is the most significant deterrent or significant factor that drove those numbers down or has driven those numbers down is from our medical side and the prescription, how prescriptions are handed out or distributed to our servicemembers. Several policies and procedures were put in place to provide oversight to ensure that no doctor shopping or things of that nature can occur. If a servicemember has more than two opioid prescription medications, his record is flagged and another review is performed when he goes to pick up this prescription at the pharmacy.

Now we talk about heroin. Heroin peaked for us in 2013 and then has slowly gone down, and you can see 2017 we had approximately 88 servicemembers test positive. We are still waiting on that data. So it's gone down from high and it's trending in the correct direction.

And then when you look, if you take this and you look at our other opioid medication or other opioid positives numbers, it doesn't appear to us that our servicemembers have been using heroin as -- abusing

prescription medications, have moved on to using heroin. But we are still monitoring that to see if these numbers, the heroin numbers, are going to go in the opposite direction.

Another observation, since we have been doing the opioid testing is the MRO review is much more complicated. MROs need to be aware of a variety of different metabolic pathways and ratios. One thing we noted initially is that some of our MROs, if someone tested positive for an opioid, if they prescribed any opioid that would be considered an authorized use. Additional education was performed, and all of our medical reviews are actually, once they are submitted, they are reviewed by the appropriate specific service representatives before a final result is considered authorized or unauthorized.

So any instances where the wrong MRO review or MRO call was made, those are returned with clarification to that physician for another review. What we have also found is we saw a significant number of claims of what we call innocent ingestion or accidental ingestion. Inadvertently took my spouse's oxycodone or Percocet or inadvertently in the middle of the night, I grabbed the wrong pill. Things of that nature.

We have also seen from our military commanders who make the ultimate decision on the adjudication of a

positive result is there's more empathy for those who -- when they are adjudicating a result, if someone shared a medication for pain, they have a little bit more leniency compared to whether they used a different drug of abuse.

But our number one concern, the number one issue that we have within our program, and I know it's not unique to us is what is the definition of an illicit or unauthorized use? We just, some reasons listed here, is if you use a medication that prescribed for one -- use a medication prescribed for one condition and then you use it for another, is that unauthorized use? You use a different dose. If you use someone else's prescription or you use it after the expiration date, and which expiration date is that? Or is there even truly an expiration date for a prescription?

As far as we know, there is no federal law on expiration date, that a prescription doesn't -- in almost all cases -- does not expire on a specific date, and what we found within the military and the legal community is that in all likelihood, one prescription can essentially last a lifetime for authorized use. So if I had a prescription for Percocet six years ago and then I used it again today, they consider that authorized use at this time.

Many attempts. We have made many attempts to

implement expiration date within the DoD, and we have been very unsuccessful. The Army in particular tried to make it policy where 180 days from the day it was dispensed was considered that was the expiration date. Again, that was not able to be enforced. So right now, essentially what is happening within our program is really only enforcing one finding for illegal or unauthorized use of an opioid medication, and that's really using another person's prescription.

So I know that was quick, a quick presentation, on our part. Some conclusions are that we found that random urinalysis appears to be an effective deterrent of opioid use along with medical and education and outreach programs. The prevalence of opioid use can result in large increases in workload, which the majority at least in our population is legitimate use.

MROs are more complicated, requires additional training and oversight, and really the big -- legal limits on possession and use of prescription drug is truly needed.

CAPT BELOUIN: Tom, this is Sean. There's one question from Jim Ferguson. Which benzos do you test for?

COL MARTIN: We test for five different benzodiazepines. Off the top of my head. Easier, once I get off, I can type the answer in, if that works for Jim.

CAPT BELOUIN: Yeah, that's fine, thank you.

Do any other board members have any questions?

MR. HARRIS: I have a question. This is Paul Harris with the Nuclear Regulatory Commission. Just a really quick question, and not to spend a lot of time on it, but when your MRO washes out a prescription, is he only washing out DoD prescriptions, or is he doing public prescriptions like from CVS?

COL MARTIN: That is a great question. So any prescription that a servicemember gets, whether within a military treatment facility or out at CVS if they are using our insurance or Tricare, that data is captured. If I go out and I'm not using Tricare, then that data is not there in our database, or for a lot of our National Guard and Reserve, they have separate insurance. We don't capture that either.

MR. HARRIS: And a follow-on to that is when it gets washed out, does the MRO do a job-specific fitness determination to ensure that the opioid use does not impact the performance of their job?

COL MARTIN: The answer truly to that is no. We have been pushing for that, you know, notifying commanders about that, but right now, the answer is no, and we have gotten a lot of pushback to make that happen.

MR. HARRIS: Thank you, Tom.

DR. PAUL: This is Buddha Paul. Do you have wash

for amphetamine?

COL MARTIN: The wash for amphetamine we do after confirmation. I don't have that data here. So it does go to confirmation, and then we will do that electronic wash at that point.

What we see is for those folks on a like amphetamine-only prescription, we wash somewhere between 40 to 50 percent. At that point, they have amphetamine only on confirmation and the data supports, the results support someone using amphetamine.

DR. PAUL: Thank you.

CAPT BELOUIN: If there are no other questions, we'll thank you, Tom.

COL MARTIN: Thank you.

CAPT BELOUIN: And we'll move onto the next presentation by RTI and Marquita Brogdon.

**Agenda Item: Opioids and pH**

MS. BROGDON: Good morning, everyone. I'm Marquita Brogdon, and as Sean just stated, I'm from RTI, and I will be presenting data on opioids and pH changes.

I know Mr. Flegel already went over this a little bit. So please bear with me, because I'll be going over the same thing again. On January 23, 2017, the Department of Health and Human Services published the mandatory guidelines for federal workplace drug testing programs

using urine, also known as the urine mandatory guidelines. The guidelines and the revisions therein became effective October 1, 2017.

The revised mandatory guidelines allow federal executive branch agencies to test for additional Schedule II drugs of the Controlled Substances Act. That is, oxycodone, oxymorphone, hydrocodone, and hydromorphone, in federal drugfree workplace programs.

The revised mandatory guidelines allow federal executive agencies to -- the guidelines also removed MDEA from the drug testing profile, added MDEA as an initial test analyte, and raised the lower pH cutoff from 3 to 4 for identifying specimens as adulterated. Furthermore, revisions include requiring MRO requalification training and reexamination at least every five years after initial MRO certification.

So, jump to October 1, 2017, implementation involved a revised pH cutoff for federal agencies and for DOT regulated specimens. It discontinued testing federal agency specimens for MDEA while testing DOT-regulated specimens continued. Also, testing of federal agency specimens for the added opioids was delayed until further notice by the individual federal agencies while the additional analytes of the testing panel for DOT was delayed indefinitely.

Ultimately, some federal agencies were not prepared to add the additional analytes to their testing programs by the October 1 effective date. Agencies were instructed by SAMHSA to notify their service provider of the date they will begin testing their workplace specimens for these drugs. To date, it is possible that all federal agencies still have not implemented testing for the added opioids.

DOT, however, did revise their part 40 on November 13 and implemented testing for the semisynthetic opioids effective January 1 of this year, as well as removed MDEA from the testing panel.

Let's take a look at the number of nonnegative results. Those are results reporting drug positives, adulterated specimens, and/or invalid, that we have seen since 2014. More specifically, let's look at the pattern for which those nonnegative results have been reported by month. I do want to stop and take a second here. This is data from our HHS-certified laboratories. It is not MRO certified.

As you can see, the number of nonnegative results has remained pretty much consistent by month over the past few years. I do want to point out, however, though, the noticeable gap between the fourth quarter of 2017 and all other years represented here. You can see how beginning in

October 2017 and then becoming more pronounced in November and December, the red line representing 2017 deviates from what is typical of past years. This has been due in part to the addition of the semisynthetic opioids.

Even more pronounced is the gap that we have been seeing the first couple of months of this year, represented by the green lines here, January and February. As compared to previous years, you see that the gap is pretty wide. Again, the difference is due in part to the addition of the semisynthetic opioids as well as it does coincide with the January 1 implementation of the added analytes by DOT.

Then we'll move on to discussing the added opioids a little bit further. Here we have drug positivity rate by drug class since the October 1 implementation date of the revised guidelines to present. As you can see, hydrocodone and hydromorphone and oxycodone and oxymorphone have positivity rates at levels only behind THCA and amphetamines. Please note that a portion of this period was not representative of the entire federally regulated testing pool for, as I stated, some federal agencies were not ready to implement on October 1 and the Department of Transportation didn't add the analytes until the 1st of this year.

What we have seen so far is that as a percent of those specimens tested for the added opioids, hydrocodone/

hydromorphone and oxycodone/oxymorphone, have about a .57 and .52 positivity rate respectively. Looking at the monthly breakdown between hydrocodone/hydromorphone and oxycodone/oxymorphone from October 1 to present, it appears that we have seen more specimens reported positive by the laboratories for hydrocodone and hydromorphone as compared to the oxy counterparts.

I will also note that the February 2018 data is missing data from two of our smaller HHS-certified labs. So although we don't have it, I don't believe that it would skew these numbers greatly, because they are two of our smaller labs.

So now let's change gears for a second, and I'll talk about how the guidelines, the revised pH cutoff in particular, have affected laboratory and MRO reports of adulterated specimens. Prior to October 1, specimens with a pH between 3 and 4 were in the invalid range. Those revised guidelines did raise the lower pH cutoff for specimens reported adulterated due to pH.

So what we want to know or what we are trying to see is how has this revision impacted the number of specimens reported adulterated? We have seen about 20 additional specimens per month with a pH between 3 and 4 that have been reported adulterated since October 1 as represented by the red numbers in the chart here. This

represents an approximately 25.5 percent average percent increase in adulterated reports per month.

Without revisions to the guidelines regarding the lower pH cutoff, in October and November for example, you would have only had 82 and 96 specimens adulterated due to pH as opposed to the 106 and 119 that were actually reported --r actually that's 102 and 108 that were reported due to pH.

On the other hand, had the lower pH cutoff of 4 been in effect in, let's say, August and September, there would have been 128 adulterated reports due to pH and 144 adulterated due to pH, taking into account those specimens that were reported with a pH in the range of greater than or equal to 3 and less than 4. At the time, though, however, these specimens were reported as invalid.

So essentially, with those specimens in the range of 3 to 4, since they're no longer being reported invalid, but rather adulterated, and for specimens reported adulterated, if there's no legitimate medical explanation, the MRO now reports a refusal to test to the federal agency, which may have adverse consequences for the donor.

I will also point out here in this chart that I believe the months of September and December to be slightly skewed with regard to the actual number of specimens that were reported. This is my belief, that it is due to

quarterly submissions of blind samples to the laboratories.

MR. HARRIS: May I ask a question before you move on? Paul Harris at the NRC. Will you go back one slide? So when you say the invalids became adulterated because of the pH change, did you actually see a change in the invalid numbers or not?

MS. BROGDON: Yes, we did see a difference or a change in invalid numbers, though that difference is due in large part to what the labs are reporting as immunoassay interference, which is not in the adulterated range, but as you see, these numbers are relatively small as compared to the whole universe that we are getting, and it's kind of hard to differentiate between whether, okay, it's coming from the change to the pH cutoff or, like I said, we did see an increase in invalids. But the piece of that further is due in large part to immunoassay interference, and possibly the belief of a substitution product being used.

I also want to point out the difference between those adulterated specimens due to a low pH that prior to October 1 would have been less than 3, and post-October 1 less than 4, and those that are due to adulterated, due to a high pH or a pH greater than 11. The black line here represents the percent of total tested that were recorded adulterated due to high pH, while the red line are those that are adulterated due to low pH.

The shaded red line here that begins in October, the October 1 effective date, that represents the percent of total tested that had we not changed the pH cutoff from 3 to 4 would have been adulterated due to pH under the old guidelines. I just kind of wanted to highlight that here so that you guys could see, and then as I also mentioned, you'll notice that the peaks that are more pronounced coincide with those quarterly submissions of blind samples to the laboratories.

Then you also see that from the black line that though small in number, we are still seeing specimens reported adulterated due to pH on the high end, and that's greater than 11.

So to recap, the revised mandatory guidelines when into effect October 1. The revisions added hydrocodone/hydromorphone, oxycodone/oxymorphone to the federal regulated drug testing panel, raised the lower pH cutoff, and removed MDEA and revised MRO requalification requirements. Although it's very early, but we only have data from October 1, we feel that the revision to the pH cutoff has helped to detect more donors trying to subvert the drug test, while the effects of adding the addition of the semisynthetic opioids is still to be determined.

One thing that is for sure, though, is that with opioid epidemic that is plaguing the nation, prevention of

prescription drug abuse is paramount, and we will continue to monitor this going forward.

CAPT BELOUIN: Does anybody else have any other questions?

DR. COLLINS: Just to clarify, it's hard to separate it out just because you're assuming that the peaks are due to -- blind already. But it really doesn't look like it's very significant. So the difference, the impact does not look like it's that significant. Is that -- am I wrong?

MR. FLEGEL: If I could address that, Jennifer, because I think it is important. It also points out what NRC was showing with substitutions. As you have synthetic urine manufacturers running samples through the lab, they can very quickly, I would assume, change the pH based on our guidelines. So I think it's interesting that you have a huge peak in December of low pHs less than 4, but all of a sudden there's a huge significant decrease, almost below of where they ever have been.

So again, I think it's overcompensation on what's being entered into the program, which is important, and I think substitution adulteration products in general are one of those things we have to look at much, much closer in all programs. Did that answer your -- so I think you're correct in saying that. It looks like it's insignificant,

but I think it's a significant correction on what is happening.

DR. COLLINS: I think that obviously we need to look at more data, because really if it is a synthetic product, I would be surprised if they had products that were between 3 and 4. That doesn't make any sense, but I think more data is needed. It's hard to tell from the difference in number.

DR. GREEN: A quick question regarding the populations that are being tested, and I vaguely recall looking at the -- subjectively looking at the data when only HHS samples were being tested for the opiates, it seemed like the positivity rate was exceedingly low. Now that we have started testing the DOT private employees, government, or DOT, it's much higher. That's pretty much what we are seeing.

MS. BROGDON: Yes.

DR. GREEN: The other part, I'm wondering if we are getting any information back from the MROs regarding -- I'll just use Tom's term, the wash procedure. Are they getting overturned most of them, or do we know?

MS. BROGDON: Well, the NLCP does not get any information from the MRO. So I would have no idea.

MR. FLEGEL: And just to address again, this data we were looking at from October 1 to really December 30 of

the federal samples, I don't know; maybe Marquita can answer this in that data -- I do not believe there was any necessarily federally regulated samples within the January data. That didn't start until obviously DOT started testing on January 1. So just to clarify, the data that we looked at for the opioids was from federally regulated testing the first three months. Correct, okay.

DR. PAUL: I have a question. I see that one of your graphs from October to -- and in two months now, recently, that the synthetic opioid is quite high comparing the others, but is trying to use that in 80 percent wash, wash calculation, that it significantly comes down. Does that make sense?

MS. BROGDON: Yes, that makes absolute sense. Like I said, the NLCP, we only get the data from the labs. So we don't have data from the MRO and how they're reporting what they're seeing.

DR. PAUL: Thank you.

MR. FLEGEL: And I will clarify what Dr. Ferguson had said, and just to open it up, the board members should have a passcode that allows them to talk directly, unmute them. I apologize if you don't. But that's why we're reading the questions from the board is the board members seem to be muted.

But Jim Ferguson does say: in my practice, most

opioids are overturned, often reported with safety concerns. So even though you're looking at a -- what was termed from Department of Defense as a washed opiate, you still may have the safety concern in the regulated sectors.

CAPT BELOUIN: All right, we're going to move on to the next presentation with Ed Cone, the vaping study, and Ryan Vandrey will finish the second half of the presentation.

**Agenda Item: Disposition of and whole blood after vaporized and smoked cannabis in oral fluids**

DR. CONE: Good afternoon. Thank you for allowing me this opportunity. This is a study that we have anticipated needing to be done for quite some time.

I know we are a little short on time, but we'll spend a little bit of time on what vaping is. I'm sure most of you know. The study goals for this particular study and I'll present pharmacokinetic portion of what we observed, and then Dr. Ryan Vandrey of Johns Hopkins will present the pharmacodynamics.

Vaping has really come along the last decade. It's been around for a little bit longer than that, but the technology of vaping has advanced to the point we're in the fourth generation of the technology. And it's quite effective. In this particular instance, vaping has been around of nicotine for quite some time, but the technology

was quickly adopted by cannabis users.

I'd like to reflect on this a little bit.

There's a lot of information on the internet from cannabis users, and they are actually very health-conscious and they have realized over the years that the scientific data fully support vaping as a much safer alternative than combustion or smoking. There's a number of articles cited in literature that looked at the toxin level from combustion compared to vaping, and vaping eliminates at least 95 percent of the toxins.

So it has become quite popular. I saw one quote that somewhere on the order of approximately 40 percent of the cannabis users in Colorado are now vaping exclusively. So it's looked upon very conscientiously as a safe alternative.

And there are literally, as I said, thousands of devices now based on the different technologies. The devices can be portable, as you have seen people vaping nicotine, that they can -- cannabis as the plant material or a concentrate. So there are a variety of devices are adapted to delivery of vapor from different types of cannabis use. And finally, there are a few reports of people using vaping devices in public surreptitiously, and they seem to be able to get away with it with some ease. So there's concern there.

Now the technology, at least the scientific literature, is primarily based on the smoked route, and we saw the need to look at vaping as a potential way of delivery and would it be the same as combustion? Would it be better? Would it be worse? These are some of just a few of the many thousand devices, and on the lower righthand corner -- I think it's righthand, yes. This is the tabletop that's quite popular for use at home. It's called the Volcano. You can put either plant material or the concentrates in it. It fills a bag. You can inhale directly from the bag, and this is the technology we adopted in this particular study.

As I said, our real goal was to find out how efficient vaping was. We wanted to profile the distribution of the different cannabinoids after vaporization compared to smoked. So this was a crossover study. We used an infrequent user population so that we didn't have a background of cannabinoids that we had to see what the effect was.

These people were former drug users who came in drugfree. Healthy adults. We had almost an equal distribution of male and female participants, 11 Caucasians, three African Americans, and three listed other. Moderate age in the range of 26, 27 years old, and a mean bodyweight of 26.

The design of the study was six eight-hour sessions. It was a crossover study. The subject inhaled vapor from 0, 10, and 25 milligrams equivalent of plant material that was vaped, or they smoked the same amount as a cigarette. It was clustered in three consecutive sessions with random dose order within each route. We collected blood, oral fluid, urine, and a whole host of pharmacodynamic measures that Ryan will get into.

It was NIDA-supplied material. Not very potent by today's standards, but it was the most potent that NIDA could produce at the time, 13 percent THC, .1 percent CBD, and .8 percent CBN. We collected whole blood, oral fluid, and urine, post dosing. The specimens were analyzed by LC/MS, quantitated levels at .5 in blood and 1 nanogram per ml in oral fluid and .02 nanograms for carboxy acid.

Here is the distribution in blood after smoking and vaping, and the red arrows indicate blood levels after vaping, and you can see almost perfectly orderly dose response curve, and you might also notice that vaping as compared to smoking was very efficient. In fact, smoking the same dose, they achieved approximately 50 percent higher blood levels.

Now in the legend, you'll see L/L, and I want to give you a brief explanation. We actually had the opportunity via Christine Moore in the analysis to do these

assays in two ways. We did a liquid/liquid -- or she did -- and a solid phase extraction. And I'm presenting the liquid/liquid assay, because it had the advantage that she could recover both free carboxy acid and the glucuronide and we could differentiate the distribution.

Now Ryan's data is slightly different, because he'll show you a blood curve or two that's slightly higher from the solid phase for THC. It seemed like the solid phase was just a little bit more efficient for THC. So his data is slightly different but these data that I'm presenting come from the liquid/liquid assay, and they allow us to see not only the distribution of THC in blood but metabolites, and if you look at the red line, vaped on one side, smoked on the other, the red line is the free carboxy that's produced and it's produced quite rapidly in the body.

And the light blue line with the squares is the gradual formation of the carboxy acid glucuronide. I thought that was really interesting how fast carboxy acid is produced and then its further metabolism to the glucuronide, and there's a little bit of 11-hydroxy that you'll see at the bottom of the screen. Now again, the vaped versus smoked again show the same pattern. The vaped was much more efficient, but generally similar in pattern.

Here's oral fluid, and based on blood, you might

think you'd see some differences, but from oral fluid, we saw very similar THC, which makes sense. Vapor is going through the mouth, and we think most of this is coming from THC being laid down in the oral cavity and ultimately either being absorbed or leached out.

And carboxy acid. It was there a few times but not very often. It was very erratic. I think 11 of 18 subjects produced no detectable carboxy acid, and when they did, it was very erratic. So it would be there in one specimen, but rarely in the next specimen. I think we only had a very few positives above .05 nanogram cutoff level, if that were the cutoff you were using.

So carboxy was virtually rarely there at adequate levels. We did see CBN at -- there's a couple of studies now with CBD that shows vaping is very efficient for both of these compounds. CBN, because of its higher content and starting material, was there at fairly decent levels, upwards of 40, 50 nanograms, for the higher dose. And CBD, it was in much lower concentration, but it was certainly there.

So we were a little bit surprised at how efficient vaping was. It looks like a good way to go for a user to deliver a relatively pure stream of vaporized THC without the additional toxins. Oral fluid concentrations were pretty much equivalent between smoking and vaping, and

the carboxy acid in oral fluid was, as I said, very erratic and rarely present at reportable levels.

So with that, I hope we have Ryan on to present this next part. I'll turn it over to you, Ryan.

DR. VANDREY: Okay, so the pharmacodynamic measures, we collected a number. The first was subjective drug effects. We asked a series of adjectives that commonly describe cannabis effects. Those are rated on a 0 to 100 visual analogue scale. We collected vitals at the seated resting position, heart rate and blood pressure, and we had a battery of three cognitive performance tasks.

The picture on the lower left with the numbers illustrates a serial addition task, and so in this task, participants had 90 trials in which they had to add single integers that were presented on the screen in that central square at a fairly rapid pace, and add the number that they saw to the one that they previously saw, and then use the mouse button to click on the sum of those two integers, and it went at a pretty rapid clip, about one integer every half a second or so.

In the upper right, you can see the screenshot of the digit symbol substitution task. That's a measure of psychomotor performance with a little bit of a working memory component to it there. In this one, participants had 90 seconds to type as many patterns as they can, being

as accurate but as fast as possible.

They look at the number at the bottom, and then they type the pattern listed in black that corresponds with that number, using the numeric keypad on the computer. In the lower rate, we have a divided attention task. This takes up the entire screen on a computer laptop, and the participants have to do two things at the same time here.

One is they use the mouse to track the square that goes back and forth across the center of the screen, and it changes direction at random. While they're doing that, they have to monitor the numbers in each corner of the screen and each time one of those numbers matches the target number, which is in green at the bottom middle of the screen, they click the mouse button. They are doing that all while continuing to track the central stimulus back and forth across the screen.

So we have divided attention, psychomotor performance, working memory, and executive function being measured in these tasks.

So on this slide here, we are showing our subjective drug effect ratings by participants. This is mean data, and the left-hand panel shows drug effect data after the 10-milligram THC dose and on the right panel the 25-milligram THC dose, and what we can see here is that both smoked and vaporized cannabis at both doses

significantly increased ratings of drug effects from baseline and compared to placebo, and when similar to what Ed showed in the pharmacokinetic data, we see that vaporization is associated with a higher magnitude of drug effect compared with smoking at the same dose, and we see dose orderly increases, although at the 25-milligram dose, we are kind of getting close to a ceiling effect. So not really dose orderly where we see twice as high as a drug effect with vaporization that's pretty high to begin with.

As far as a time course here, you can see the peak effects occur immediately, and then gradually return to baseline, returning to baseline by the end of the study session at 8 hours.

Cardiovascular effects, I'll similarly show a greater magnitude of drug effects with vaporization versus smoking. We see a dose orderly effect with smoking, but again, we're kind of maxing out our drug effect even at the lower dose vaporization. In this case, both doses and both routes are significantly different from --

MR. FLEGEL: Ryan, it sounds like we lost the connection with you.

DR. VANDREY: -- but we are seeing a return to baseline one to two hours after drug administration.

This slide here shows our first cognitive performance data. This is the serial addition task which

is tapping into working memory and executive functioning performance. We saw no change compared to placebo at the 10-milligram dose with either route of administration, but you can see at the 25-milligram dose, we see very robust impairment in performance on this task. It was statistically significant for the vaporization, but not for smoking, but I can say that that's a clinically significant reduction in performance.

So this is a reduction of baseline performance at peak for vaporization of 23 items correct out of 90, and recall again this is just a simple addition task, say, for example, adding 2 plus 3 equals 5. Now it does happen rapidly. So people have to pay attention. And at the smoked, the peak change is about 16 fewer correct compared to baseline.

The time course here on cognitive performance when you're looking at the right panel looks much more like what we saw with the subjective drug effect ratings, where the peak effect occurs pretty much immediately. Maybe a little bit of a delay with the smoking; the peak effect is a one-hour time point, but then a gradual return to baseline by the end of the session.

For the digit symbol substitution task, we had statistically significant differences from placebo in both doses for vaporization. We really saw no change at the 10-

milligram dose for smoking, and this is a reduction in the number of correct responses in 90 seconds; on average people got about 50 or so correct on this task.

So again, going from 50 and at the 25-milligram dose following vaporization, having about 15 fewer at the peak level of impairment is substantial. Time course was comparable to what we saw for the serial addition task. So peak drug effects occurring with peak impairment half hour to one hour after drug administration, with a gradual return to baseline levels of functioning by the end of the session.

And then this slide here shows performance on the divided attention task. The y-axis here shows the distance that the cursor was from the central target stimulus that they were tracking back and forth. You can see again here vaporization is showing a significant difference compared with placebo, and a more robust level of impairment compared with smoking. Smoking was not different from placebo at either dose.

Now, again, in the 25-milligram dose we are seeing impairment in terms of a greater distance from the target stimulus with smoking. But we also had a stronger placebo effect with the smoked session versus the vaporization session. So where we are seeing some level of impairment, it's not statistically significantly different

from placebo, because we did have a stronger placebo response with smoking. But even with that, we're seeing a stronger effect with vaporization versus smoking in this task as well as the others.

So what does this all mean and how do we relate these pharmacodynamic assessments back to the blood levels or pharmacokinetic assessments? Here's a side-to-side showing blood THC levels. This is with the solid phase extraction, as Ed noted earlier. Blood THC on the left-hand panel, and then subjective drug effect ratings in the righthand panel. This is at the 25-milligram dose.

So you can see that we get comparable separation between the smoked and vaporization, but a much different time course of drug effect. So again, with blood THC levels returning back to zero, three to four hours after administration, but subjective drug effects and, as we saw earlier, cognitive performance impairment persisting well beyond that timepoint.

And then to throw a historical data point on here, recall we did an oral cannabis administration study. If we overlap the curves from that study onto this, we can see on the righthand panel, we get comparable peak drug effects, different time course of drug effects, with oral versus smoking slightly less than vaporization, but the THC values are far different. We don't get THC levels anywhere

near what we saw with inhalation.

When we look at correlations between blood cannabinoids and oral fluid THC and our pharmacodynamic measures, following smoking, as you can see, subjective drug effect levels were significantly correlated with blood cannabinoid levels, but this is moderate in terms of correlation at about .5, and the highest correlation was with the non-psychoactive carboxy metabolite.

We saw no significant correlations between blood or oral fluid, cannabinoids, and cognitive performance following smoked route of administration. Now the bottom panel here with vaporization, we see comparable correlations between subjective drug effects and blood cannabinoids. We see a significant but modest correlation between oral fluid THC and subjective drug effects, but none of those would be of a magnitude that we would argue would be predictive in a roadside, workplace, or law enforcement setting.

In addition, with vaporization with our more robust impairment levels, on our cognitive performance tasks, we are starting to see some significant correlations between blood cannabinoids and performance on these tasks. Again, I think that these are modest at best in terms of predictive validity, but they are inverse correlations. So higher blood cannabinoid concentrations are associated with

worse performance on these tasks.

So in addition to these things, we did see higher ratings of adverse side effects, such as paranoia, dry mouth, red or irritated eyes following vaporization, versus smoking. We had two instances of vomiting in this study, one at each route of administration at 25-milligram dose. So that highlights that this is not an inconsequential dose. People got very intoxicated at the 25-milligram dose.

We also had one instance of hallucinatory effects at the 25-milligram dose following vaporization in a single participant. Now these resolved within a couple of hours of onset and didn't require any medical attention. But again, just highlighting that these are substantial doses in nontolerant individual.

The limitations that we do want to mention with respect to the study is that we only evaluated these effects in infrequent cannabis users. They all had negative urine, blood, and oral fluid specimens at baseline for each study. So we had a one-week washout in between sessions to ensure that.

We only studied one type of cannabis in a fairly limited range of doses. I think we reached the higher end of doses that we would want to see, but I'd like to expand this in future studies to look at some lower doses to see

where we start to see, and possibly some intermediate doses to really find at what dose do we see impairment onset.

And then additionally, we need to look at other types of cannabis. So if we keep the THC dose equivalent, what happens when we add higher concentrations of cannabidiol, which has been purported to mitigate some of the adverse effects of THC, and we need to also evaluate other routes of administration and other cannabis types such as oils, concentrate, extracts.

So with that, I think we can summarize that vaporization appears to be a more efficient method of delivery. It's associated with greater blood THC level, as well as subjective drug effects and cognitive performance impairment. We do see differences in the time course across assessments where when we look at blood THC and cardiovascular effects, the time course is much shorter than what we see with subjective drug effects and cognitive performance effects. I think that probably translates to the fact that THC and other cannabinoids are highly lipophilic. So these substances are imbedded in tissue, are still active, but not necessarily systemically available in free blood.

The correlations between our pharmacokinetic and pharmacodynamic assessments were modest at best. I would say that they would be predictive in areas where we would look

at forensic interpretation and that THC in the blood and oral fluid exposure returned to zero within about four hours of exposure.

I think that's the last slide.

MR. FLEGEL: Ryan, this is Ron. Either for you or Ed, if you could just expand on it, two things that I think you slightly touched on it, is we -- you guys had done a 25-milligram dose, and with the oils or the concentrations of the oils, I think those could be significantly more potent than what we looked at or the potency of that. So if you could just expand on that.

The second part of the question is it is my understanding when you're vaping the oils, there's very little smell if any that you could detect that is actually is marijuana they're using.

DR. VANDREY: To your first question, the THC levels that we see in concentrates, like shatter and wax and things that are used in dabs, the THC concentrations in the product get very high. It's not uncommon to see 60, 70, even 80 percent THC in those products. But the user tends to use much smaller amounts than they use raw plant material.

So while the concentrations are much higher, they tend to use less of it at a given time. I think the higher concentrations are more difficult for users to titrate

dose, but we really need controlled studies to evaluate how effective they are in doing those.

The other part of that that I think is important that is often missed is that when you increase the amount of THC in those products, through a process of extraction, it's unclear what else is being extracted. So what else from the raw plant material is being removed? How -- this is a complex chemical product endpoint. It's unclear whether there are important chemical differences outside of THC in those extracts versus whole plant material that would lead to either pharmacokinetic or pharmacodynamic differences. So in metabolism or drug effects, those are all important questions that I think need to be addressed.

To your latter point, as many of you know, I was recently in Colorado for a snowboard trip. John Mitchell says I was doing research, and as a good researcher, I was paying attention. I can't recall a day that I did not see somebody using what I was certain to be a cannabis vaporization device out in the open, and a vapor, a visible vapor, does come out of these things. In some cases, there was a noticeable smell that I could say, yup, that's probably cannabis. In some cases, it's not so much. If you're outside or in a well-ventilated area, it may not be obvious.

CAPT BELOUIN: Do any of the board members have

additional questions for Ed and Ryan?

(No response.)

If not, then we'll move on to the last presentation, mine.

**Agenda Item: MRO Guidance Manual and 2018 MRO**

**Case Study Update**

CAPT BELOUIN: I'll try to make this pretty fast so we'll be right on schedule.

Ron was already alluding to -- he actually gave a little bit of a brief for the medical review officer, some of the updates, and, I'll try to get through this fairly quickly. As you're all aware, the final mandatory guidelines for urine, they were issued on January 23, 2017, and they were implemented as of October 1. So as Ron said, there's about six months that we have actually been working under the revised guidelines.

The MRO manual, guidance manual, is based on subpart M, medical review officer section 13.1 of the guidelines, and part of what we have done, as Ron alluded to this, I've always considered -- we have always considered the MRO guidance manual as a dynamic document. So as issues come up, we address those issues and so we have some clarifications that are coming out here in the month of April. We're very close to having this published up online. We're just going through 508 compliance, and

there's a couple key provisions here in section 4.53, prescriptions, and 6.3, which is occupational and public safety, and I'll just briefly touch upon those right at the end of the slides.

So again, the anticipated posting of the guidance manual will be April, we'll have it uploaded onto our website here. Here's the website address.

Again, as everybody is aware, as part of the revised mandatory guidelines, we're now testing for four new prescription drugs, oxycodone, oxymorphone, hydrocodone, and hydromorphone. Hydrocodone combination products, they were, for quite a long time they were Schedule III by the DEA, and as of October 6, 2014, they were actually effectively rescheduled to Schedule II, and there's the website there. If anybody is interested, you can read more about that.

I put up a couple slides for what we call in pharmacy brand generics, because a lot of times, depending upon where you are in the country, you will see a lot of brand generic medications for hydrocodone. Here's a whole list of them that as MROs you might actually see. There's only a couple for hydromorphone. As you'll also see here for oxycodone, there's a whole slew of those as well. It's quite extensive. Again, depending upon where you are in the country and what's distributed out there, you might see

different types of brand generics in addition to just seeing the actual generic name hydrocodone.

Again, touched upon before, there's the cutoffs, initial cutoffs for hydrocodone, hydromorphone, oxycodone, and oxymorphone, and then for MDMA and MDEA. As Ron pointed out, MDEA was dropped from testing. Again, here is another slide. You can go into it more. It shows all the screening cutoffs as well as the confirmation cutoffs.

In terms of the negative and positive test results, obviously for having a negative test result, you know, all the immunoassay results, they have to be below the initial test cutoff, or the actual confirmatory test cutoff would have to be below -- the test results would have to be below the confirmatory test cutoff, and obviously the specimen validity results have to be in acceptable range.

For a positive drug test, the specimen's immunoassay results have to be at or above the initial test cutoff for that particular drug class and with a separate aliquot, the specimen's confirmatory drug test result has to be at or above the confirmatory test cutoff.

It was also alluded to previously, when it comes to adulterated specimens for specimen validity testing, previously the pH was less than 3. It's now been updated to where pH is less than 4, and you can see the rest of

them, that remain unchanged. In terms of invalids, previously the pH values were greater than/equal to 3 but less than 4.5, and now that's been changed to pH is greater than or equal to 4 but less than 4.5.

I see a question there from Michael Schaffer. We'll address that after I finish this presentation. We'll make sure we cover that.

With the addition of the opioids to this federal panel, we're obviously now expecting to see much more in terms of a potential increase in positive federally-regulated tests, and this is also going to sort of bring about the issue of this issue around safety, especially as it relates to not so much because of the way that our federal program is set up, but especially towards the DOT and NRC programs, because those primarily fitness; they have a fitness for duty component, where we as the HHS program, we're a deterrent program. We don't have that fitness for duty component.

So, a couple of things here we've done with the MRO guidance manual is section 4.5.3, prescriptions. What I did is, these updated slides actually reflect some of the clarifications that we've provided that will come out in April, and so that in any of these clarifications, the MRO guidance manual now provides greater guidance in determining whether there's a legitimate medical

explanation for a positive drug test, and one of the key issues -- and you guys can always go back and read this -- one of the key issues, what is clarified is if the MRO should consider whether a medication was used during the time period for which it was legitimately prescribed, if such a time period is specified.

If a donor possesses a valid prescription with no limitations on the drug's use, even if the dispensed prescription is past its expiration date, the donor specimen should be reported as negative. Also, the donor does not possess a valid prescription, or other medical authorization that would supply a legitimate medical explanation for the positive drug test result, the specimen should be reported as positive.

One of the key issues when an MRO is looking at determining a legitimate medical explanation, there will be times when you'll actually have a donor and they won't have a prescription that they can refer to, but say, for example, they may have had a hospital procedure where they were there for two days, they were given oxycodone, and then when they were released, the very next day they show back up at work, they're given a drug test, and they come up positive. In that particular instance, what the MRO can do is they can actually reach out to not just the prescribing physician, but they would have that

documentation at the hospital.

Another key area is around section 6.3, occupational and public safety. One of the things we really would like to address in this is if an MRO is given information that indicates that a donor's use of a legitimately prescribed medication creates a safety risk, the MRO may be faced with the decision about what to do with that information. So the mandatory guidelines actually do not address this situation, and they actually do not require the MROs to determine whether a valid prescription medication can be used safely while performing the donor's function.

So before an MRO decides to discuss safety information related to a donor's valid prescription, which, again, we would consider legal drug use, and having that conversation with a donor's agency, the MRO should consult the terms of any service agreement that they may have with that particular federal agency, and any agency policies or rules that govern such circumstances.

Just briefly touching upon the case studies. We finally have completed these. We have a total of 32. They cover a whole range of issues, and I personally am very grateful for all of the individuals that have contributed to this. Again, the case studies, I want to emphasize, they're there to supplement the HHS MRO guidance manual.

The MRO guidance manual and the case studies, they do not apply to DOT procedures, as well as NRC's. Again, ours is a deterrent program, it is not a fit -- we do not have a fitness for duty component to our drug testing program.

We anticipate both the MRO guidance manual and the case studies, we're, like I said, we're very close to having those completed. We should have them posted here in the month of April, and they'll be posted on our website.

If you do have any questions, I'm always welcome to respond by email as well as phone, especially around these issues of what's a valid prescription, and then addressing these issues around safety. So, if nobody has any specific questions for me, I would like to go back and we can address Michael Schaffer's question.

Ron, could you read that?

MR. FLEGEL: Michael Schaffer asked, how does this population -- this is around cannabis user population -- how does this population compare to the population that vapes regularly, almost daily? And since the latter may be more prevalent than the former, can you extrapolate your data from the study to the potentially greater population that is abusing vaping or vaporizing regularly, and since the THC -- there's like three, four, five questions in this. Hopefully, Ryan, you're still online.

Since the carboxy levels in the study were

erratic and rarely present in this user population, do you consider this finding significant in situations where multiple doses are administered over large periods of time, and which population is more clinically significant in determining the true drug user population, especially in a fitness for duty situation where impairment may be more relevant?

And I would add, I would also add to that, DUID situations at the roadside, or testing at the roadside. So I will ask Ed, or Ryan, if they can address the questions one by one.

DR. CONE: Let me take the first shot, hopefully Ryan can fill in. I think we did have, in very general terms, two populations. There's a lot of chronic frequent users, but I don't think that population is most representative in the federal workplace program. I think it would be more likely the weekend user.

If you're subject to drug testing, and you're a chronic daily user, almost any of these tests you do, urine test, oral fluid test, they're going to come up positive. The accumulation of carboxy acid is going to be there for a long time in urine, and even once a chronic user stops, it may be there for up to maybe thirty days, and it builds up. And it's also found in oral fluid in chronic users. I don't think you can extrapolate the data. The occasional

user will have THC in oral fluid for a short period of time after use, approximately during the time they're impaired, and certainly urine, the urine concentrations will be there, and they will be typically that of a smoker, positive for 24 hours, possible a little longer.

There is some suggestion in the literature that the occasional user doesn't have the tolerance, of course, that chronic users do, and may become a little bit more impaired than the chronic user would be observed in a laboratory setting. I'll let Ryan, if he's online, add anything else.

DR. VANDREY: Ed, I think you're absolutely right that within the context of federal employees in drug testing, the infrequent user is certainly the most relevant, and that's why we selected this population here. And, you know, the drug testing is important in frequent users, so it's important to keep that under consideration. I don't think that our data really speaks to that, either from the PK or the PD standpoint. Daily users, when we give comparable doses, tend to have a shorter time course of drug effects, and much less impairment on these cognitive tasks.

But that being said, I think it's important that we highlight that there are complicating factors from a regulatory standpoint, because you can't have separate drug

testing cutoffs based on the frequency of use. It's a continuum. And while people tend to kind of lean towards one of two profiles of use, there's a lot in between. So interpretation is very, very challenging, especially when we're talking about interpretation of indications of impairment, versus indications of use. So it's challenging.

In terms of fitness for duty situations, I think at this point all we can say is that the most appropriate approach right now is to require a clean test, no matter what matrix you're using. And in the absence of a clean test, the only method of determining fitness for duty is through behavioral testing, and that would require establishing a baseline level of performance for the individual. So, these are all really challenging situations in an era where legalization for both medical and nonmedicinal use of cannibal is expanding rapidly.

CAPT BELOUIN: Are there any additional questions from the board members?

If not, we'll open it up for public comment. We're not aware that there are any public comments, but Operator, please see if anyone is interested in giving a public comment at this time.

**Agenda Item: Public Comment**

OPERATOR: Thank you. There will now begin the

public comment session. If you would like to make a public comment, please press star-1, unmute your phone, and record your name clearly. Your name is required to introduce your comment. If you need to withdraw your comment, please press star-2. Again, to ask, make a comment, please press star-1. It will take a few moments for the comments to come through. Please stand by.

You have a comment coming through. One moment please.

The next individual's line is open. Their name is not recorded. Would the individual who pressed star-1, can you ask the question? Your line is open.

Your line is open. Please ask your question.

MS. NAPOLEON(?): Hi, this is Danielle Napoleon with the IRS. My question was are these slides available for download anyplace? Could you make them available? Thank you.

CAPT BELOUIN: Yes, this is Sean Belouin, the DFO. All the slides will be made available in approximately four weeks. They'll be up on our website, and they'll be available for download at that time.

OPERATOR: The question did clear. Again, if you would like to ask a question or make a comment, please press star-1 on your phone. One moment.

We show no further comments at this time.

CAPT BELOUIN: All right, if there's no other further comments, public comments, at this time, Ron, do you have any other comments or questions?

MR. FLEGEL: I just want to thank everyone for making the trip here, especially in the weather that we have. I also want to thank our federal partners, everybody that gave individual presentations. I think there's a lot of good information that we're showing, and hopefully everybody found that informative and enjoyable.

We're looking -- and Sean can go over the logistics -- we're looking to open it back up for closed session at 1:45, since we know some of the board members have to leave probably a little early, so we'll take that into account, too, so we can open up a little bit earlier, I think, than 2 o'clock, and start back up again.

With that I just want to thank everybody for being here.

CAPT BELOUIN: All right, with that said, I'll officially bring the open session to a close, and we will begin the closed session at 1:45 p.m.

(Whereupon, the open session was adjourned.)