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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING TO DISCUSS THE PROPOSED RULE

ASSOCIATED WITH THE FITNESS FOR DUTY DRUG TESTING

REQUIREMENTS RULEMAKING

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THURSDAY,

NOVEMBER 7, 2019

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ROCKVILLE, MARYLAND

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The Public Meeting convened at the Nuclear Regulatory Commission, Room T8-D02, Two White Flint North, 11555 Rockville Pike, at 9:00 a.m., Stewart Schneider, NMSS/REFS/RRPB, presiding.

NRC STAFF PRESENT:

STEWART SCHNEIDER, NMSS/REFS/RRPB

HOWARD BENOWITZ, OGC/GCRPS/RMR

ANTHONY BOWERS, NSIR/DPCP/RSB

THERESA CLARK, NMSS/REFS

NICOLE FIELDS, R-III/DNMS/MCID

PAUL HARRIS, NSIR/DPCP/RSB

GLENNA LAPPERT, NMSS/REFS/RRPB

FRED SCHOFER, NMSS/REFS/RASB

SOLY SOTO LUGO, NMSS/REFS/RRPB

BRIAN ZALESKI, NSIR/DPCP/RSB

ALSO PRESENT:

NICK DIPIETRO, FirstEnergy

RON FLEGEL, HHS

KEN GREER, NFS

LISA HOGG, NEI

RICHARD MOGAVERO, NEI

CHEREE MONTGOMERY, Southern Nuclear

MIKE McNALLY, Luminant

TEDDY REED, Duke Energy

HYDEN SHEN, HHS

MARY FRAN YERKES, Exelon

P R O C E E D I N G S

(9:00 a.m.)

MR. SCHNEIDER: Welcome to today's meeting. Good morning. I'd like to thank all of you for your interest in today's public meeting. My name is Stewart Schneider, and I'm the project manager for the Part 26 Fitness for Duty Drug Testing Requirements Rulemaking.

I'll also be acting as today's facilitator at this public meeting. My role today is to make this

meeting productive for everyone involved. At today's meeting, the NRC staff will discuss the proposed rule to revise the drug testing requirements of Part 26.

This meeting will also provide an opportunity for the NRC staff to address your questions and solicit feedback on this rulemaking activity. This feedback will help to support the NRC's development of the final rule.

Before we begin, I'd like to cover the meeting logistics, first to let you know today's meeting is being transcribed. For those participating via the bridge line or WebEx, there will be designated points during the meeting where you'll be asked to provide questions and provide feedback.

Information on accessing the bridge line and WebEx can be found on the announcement slide. We have a number of people participating by phone and WebEx today, and everyone will have an opportunity to participate in this meeting.

At this time, I ask those participating here in the room to please turn off or silence their electronic devices. For those of you on the bridge line, the operator will keep you in listen-only mode until I request that the operator take your comments.

During the discussion and question

section, I will first take feedback from those in the room and then from those on the phone, which includes those on the bridge line or WebEx.

Because today's meeting is being transcribed, I'm going to ask speakers both here in the room as well as those on the phone to identify themselves and any group they are with when they speak so everyone knows who's talking.

I'd like to remind the visitors in the room that you must be escorted at all times because we're above the first floor of this building. If you need to leave for any reason, please let one of the NRC staff members in the room know.

However, if you can wait until one of the scheduled breaks during today's meeting that would be appreciated. Also, should there be a need to evacuate the building, please follow the NRC staff to the elevators and then to the outside of the building.

The meeting is scheduled to last from 9:00 a.m. until 4:00 p.m. today. Once the logistics and introductions are complete, the NRC will discuss the proposed rule to revise Part 26 of the Fitness for Duty Drug Testing Requirements.

Mr. Brian Zaleski is the technical lead for the rulemaking activity, and he will be providing

the technical part of the discussion. Today's meeting is a Category 3 public meeting. Public participation is actively sought at this type of meeting, and the public may provide feedback and ask questions throughout the meeting.

During the staff's presentation, the public will be given several opportunities to ask questions and also provide feedback as we've already identified in today's meeting agenda.

The meeting slides from today's meeting are currently posted on regulations.gov. Also the meeting summary and transcript will be posted on regulations.gov within 30 days after this meeting. If you search for docket NRC-2009-0225 on regulations.gov, you'll be able to find these and other documents related to this rulemaking.

For those attending in person, please sign the attendance sheet before you leave today. The list of attendees and phone and WebEx participants will become part of the meeting summary that will be prepared for today's meeting and eventually made public.

Copies of the NRC staff presentation can also be found in the back of the room. Additionally, there are copies of the NRC public feedback form in

the back of the room. Please be sure to fill one out. You can leave it with one of the NRC staff here or drop it in the mail. The postage is free. Your opinion on how this meeting went will help us to improve our future meetings.

For those on the phone or participating via the WebEx, please send an email to me, Stewart.Schneider@nrc.gov to confirm your attendance and provide your feedback. You can also use the meeting form on the NRC public website. Simply log on, locate this meeting under the public meeting schedule and you will find the feedback form.

And finally, I'd like those in the room to speak loud enough to ensure that everyone on the phone can hear you. Those on the phone, if at any point you cannot hear the meeting, please let the operator know. Now let's begin with the introductions with those present in the room and then with those on the phone, if you could please provide your name and your NRC office or organization.

So I'm Stewart Schneider. I'm the rulemaking project manager. I'm in NMSS, REFS, the branch that does rulemaking for reactors.

MS. LAPPERT: Glenna Lappert. I'm a regulations specialist and your driver today.

MS. CLARK: I'm Theresa Clark. I'm the deputy director of the newly reorganized Division of Rulemaking, Environmental and Financial Support.

MS. MONTGOMERY: I'm Cheree Montgomery. I'm the medical services manager of Fitness for Duty program manager for Southern Nuclear.

MS. YERKES: Mary Fran Yerkes, Access Authorization, Fitness for Duty for Exelon Generation.

MR. DIPIETRO: Nick DiPietro with First Energy Solutions, Access Authorization, Fitness for Duty, Health Services, Safety, Human Performance and manager for the fleet.

MS. HOGG: Lisa Hogg for NEI, project manager.

MR. REED: Teddy Reed, manager of Access Services and Fitness for Duty for Duke Energy.

MR. HARRIS: I'm Paul Harris, senior program manager, Office of Nuclear Security and Incident Response, targeting drug and alcohol testing.

MR. ZALESKI: Brian Zaleski, Fitness for Duty specialist also in Nuclear Security and Incident Response, Paul and I are colleagues on Fitness for Duty.

MR. GREER: Ken Greer, Nuclear Fuel Services, BWXT. I'm the emergency services manager as

well as the Fitness for Duty coordinator.

MR. BOWERS: Anthony Bowers. I'm the Reactor Security Branch Chief within the Office of Nuclear Security and Incident Response, Fitness for Duty programs for federal reactors falls under my area of responsibility.

MR. BENOWITZ: Howard Benowitz, the NRC's Office of the General Counsel, supporting this rulemaking.

MS. SOTO LUGO: Soly Soto, Acting Chief of the Reactor Rulemaking Management Branch here at NSS.

MS. FIELDS: I'm Nicole Fields. I'm doing a rotation in the Reactor Rulemaking Branch.

MR. MCNALLY: Mike McNally, manager, Nuclear Security Improvement, Luminant.

MR. SCHOFER: Fred Schofer, reg analysis team lead supporting this.

MR. SCHNEIDER: Okay. Now that everyone in the room has identified themselves, can the operator please open the lines so we can find out who is calling in today?

OPERATOR: All lines are now open.

MR. SCHNEIDER: Can each individual please identify themselves and their organization?

MS. BOND: Tammy Bond, supervisor for

Access and FFD at Cook Nuclear Plant.

MS. LONDON: Lisa London, Office of Commissioner Baran, NRC.

MR. VIDAL: Ozzie Vidal, Certrec Corporation, project manager.

MS. ODOM: Dawn Odom, Access, Fitness for Duty supervisor, NextEra Energy and FPL.

MR. BONTHRON: David Bonthron, Florida Power and Light, Access Authorization, Fitness for Duty program manager.

MS. FINDLEY: Amy Findley, supervisor at Access Authorization, Fitness for Duty, Callaway Energy Center.

MR. PUCKETT: Steve Puckett, Fitness for Duty coordinator, BWX Technologies, Lynchburg, Virginia.

MS. DUMAIS: Stella Dumais, Senior Access and Fitness for Duty coordinator, NextEra Energy Seabrook Station.

MS. THORBAHN: Brenda Thorbahn, Davis-Besse, Access Authorization, Fitness for Duty supervisor.

MR. TOWNSEND: Don Townsend, Access Authorization, Fitness for Duty supervisor, Pacific Gas and Electric, Diablo Canyon.

MR. FULTON: Walter Fulton, licensing, South Texas Project.

MS. LUDWIG: Sarah Ludwig, Access Authorization and Fitness for Duty, South Texas Project.

MR. POPP: Don Popp, Access FFD, NextEra Energy, Point Beach.

MR. KERBY: Jeff Kerby, PSEG, Access Authorization, Fitness for Duty coordinator.

MS. BOMYEA: Cynthia Bomyea, DTE, Fitness for Duty Access Authorization supervisor.

MR. HAGLUND: Mike Haglund, Fitness for Duty coordinator, Callaway Energy Center.

MS. GEPLER: Lindsey Gepler, Fitness for Duty nurse, Callaway Energy Center.

MR. NIELSEN: John Nielsen, Fitness for Duty, Nuclear Access manager, INPO. Also have Tim Chapin. He is the associate program manager at INPO.

MR. WOODS: Jerry Woods, Access Authorization, Fitness for Duty supervisor at Arkansas Nuclear One with Entergy.

MR. PLUMLEE: G.L. Plumlee, consultant for NuScale Power.

MR. SUMMERS: Scott Summers, Access Authorization, Fitness for Duty supervisor, Entergy

Nuclear, Palisades.

MR. PRESLEY: Jason Presley, NRC Security Compliance manager, BWX Technologies in Lynchburg, Virginia.

MR. SCHNEIDER: Has anyone not had an opportunity to identify themselves?

MR. DENTON: Yes, Jim Denton, Access Authorization, Fitness for Duty coordinator, FPL, Turkey Point.

DR. SCHECODNIC: Gary Schecodnic, medical review officer with Florida Power Light and NextEra Energy.

MR. DEIGNAN: Matthew Deignan, Access Authorization, Fitness for Duty supervisor, Entergy, River Bend Station.

MS. CHENIER: Kelsie Chenier, Entergy, Waterford 3, Access, Fitness for Duty coordinator.

DR. YORGASON: Andy Yorgason, MRO and NSAE at Palo Verde.

MR. SCHNEIDER: Anyone left, or are we complete now? Okay. So again, thanks for attending today's meeting, and at this point in the meeting, I'd like to introduce Theresa Clark.

Theresa is the deputy director of the Division of Rulemaking, Environmental and Financial

Support in the Office of Nuclear Material Safety and Safeguards. Theresa will now provide the opening remarks for today's meeting.

MS. CLARK: Hi everybody. So I have the, I guess, responsibility of giving opening remarks and then bolting for another meeting, so please don't be offended when I leave. But I was really pleased to see all of you here in person and hear you on the phone.

It's important that we get a good cross section of the regulated community to understand what we're trying to do in the proposed rule as well as to give us feedback formally through the public comments and we'll certainly listen to what we hear today as well.

These guys will talk in great detail about the technical elements of this. We certainly have an interest in aligning across the government on testing standards that are in place. I'm looking at the best practices that other agencies are using and using them to the extent possible. So that's what you'll see in our attempt to incorporate the 2008 guidelines.

Certainly we're aware that there are 2017 guidelines as well, and at the time that we were putting this rule together, there wasn't a lot of run

time with those guidelines and so that's one of the things that we're keeping in the back of our minds as we continue this rulemaking. I'm sure you'll hear more about that later.

Another piece that's really important, and why it's great that we have so much participation of the users of this rule is that one of the things that we look at very closely when we put forward any new requirement for the industry is the cost and benefits of the rulemaking.

So we have our impressions of how many additional individuals would be detected by imposing these requirements. We think that that's a good thing, to detect people and not have them at the controls per se.

But we've also estimated what the cost would be to do this sort of activity, and so it's important for us to feedback on whether our very carefully conducted cost estimates by Fred and his team are in the right ballpark because they're an important piece of our decisionmaking. So I hope that as you go through the day's discussion that that'll be in the back of your minds as well.

So thanks for being here. When I split, don't be sad, and I look forward to hearing about this

productive discussion.

MR. SCHNEIDER: Thank you. So we have a morning agenda and an afternoon agenda, and we have several breaks in here as well as several points for discussion after each main topic. There's also a period in here for lunch.

So the purpose of today's meeting is to provide an opportunity for the NRC and the public to exchange information on the proposed rule, which is of course the drug and alcohol testing requirements in Part 26, Fitness for Duty.

Specifically, the four main topics we're going to discuss today are the proposed rule changes, the specific requests for comments which were in the Federal Register notice for the proposed rule, draft regulatory guidance and the draft regulatory analysis.

Additionally, I need to note that the NRC will not provide written responses to any comments made at this meeting. The NRC will though consider, to the extent possible, feedback from today's meeting in developing the final rule, regulatory guidance and regulatory analysis.

The comment period for the proposed rule is open until December 2nd, so you can provide comments through that vehicle and the information on

how to provide that is in the Federal Register notice. We'll talk more about that a little later.

So let's talk about the background. I start with March 31, 2008, and that's when the NRC published the revised Fitness for Duty program requirements that aligned with the 2004 HHS Guidelines.

Subsequently, shortly thereafter, HHS published a revision to those guidelines, which were the 2008 HHS Guidelines. On July 1st of 2013, the NRC published the regulatory basis, which recommended the development of a proposed rule to align the NRC's regulations with the specific HHS Guidelines of 2008.

On February 22nd of 2017, the staff submitted a paper to the Commission to obtain approval to publish the proposed rule, which then aligned the NRC's drug testing requirements with the 2008 HHS Guidelines.

And as Theresa was saying, because the 2017 were not established at that time, we did not provide that as part of the proposed rule, but we'll talk again about that a little bit more.

On June 3, 2019, the Commission issued SRM SECY-17-0027, which approved publishing the proposed rule and the draft regulatory guide. Additionally, it

needs to be noted that the SRM also directed the staff to include the 2017 HHS Guidelines updates for testing of ecstasy drugs.

And this is something that Brian will discuss further in upcoming slides as well as the specific request for comment on this topic in the Federal Register notice.

And finally, on September 16th of this year, we did publish the proposed rule and draft guide, and that's what we're here today to talk about. With respect to the rulemaking schedule, December 2nd, as I noted, is the date that the proposed rule comment period closes.

The other two dates, February 26, 2021, which is the final rule to the Commission and the May 26, 2021, which is the final rule publication date, these are dates which are available on our public website for rulemaking.

And as you see at the bottom, it says these dates are subject to change. Regulations.gov gives you information on the status of this rulemaking, and I'll talk more about that again later as well as if you go to the public website for the NRC, that's kept up to date as far as any schedule changes.

But currently, these are the dates that are up on that website for this rulemaking. So with that introductory information, I'm going to turn it over to Brian.

MR. DIPIETRO: I have a question on the --

MR. SCHNEIDER: Yes.

MR. DIPIETRO: -- dates, subject to change. Would they move forward, or is there a possibility of them moving up, or would they move possibly back?

MR. SCHNEIDER: Typically, due to our process, which this includes our internal process, this is a reasonable estimate. The February 26, 2021 date is based on the closure of the comment period December 2nd and then our internal process to get it completed and back up to the Commission.

The final rule to the Commission, that's a ticketed date internally, so that's a metric we have to meet right now. I don't expect that to have to change because we've worked in enough time into that to be able to address any concerns and comments that we receive.

The final rule publication date, which is several months after, that'll depend on how long the Commission takes to review it and then issue the SRM on the final rule, which directs the staff how to

proceed with the issuance of that final rule. So, if anything, the May 26th date might change.

MR. DIPIETRO: Thank you.

MR. SCHNEIDER: So now I'll turn it over to Brian.

MR. ZALESKI: Thank you very much. I'm Brian Zaleski, Fitness for Duty specialist, and I'll be taking you through the proposed rule changes. This presentation is meant to highlight the key elements off the proposed rule changes. It's not going to detail every proposed change.

The best way to understand the proposed rule is to actually read the proposed rule document. Of course, as Stew said, if you have any questions, feel free to stop me during the presentation. If we get caught up in something for a long period of time, we may table it and come back to it at a later point.

But this is hopefully the opportunity for the public, our stakeholders to provide us feedback, to ask questions about what we're proposing to do. It's infrequent that we have the opportunity to propose a rule or change a rule, and so this is a good opportunity right now to provide feedback.

The goal of this presentation today is to ensure that you understand what's in this proposed

rule, and hopefully we'll be able to do that. Okay. Next slide, please.

Before I go through the individual changes, I want to remind everybody why we're here. So the Fitness for Duty program is based on a general performance objective.

The Fitness for Duty Program first started in 1989, and the performance objective is to provide reasonable assurance the nuclear power plant personnel are reliable, trustworthy and not under the influence of any substance, legal or illegal or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties. So it's a very broad, broad objective.

The 1989 final rule also stated that FFD program developed under the requirements of this rule is intended to create an environment, which is free of drugs and the effects of those substances. So in essence, this is why we're here. This is what the FFD program is based on.

The rule changes that were proposed in the current rule are focused on the drug testing elements. They don't address alcohol. They don't address worker fatigue. They're specific to drug testing and

a subset of those, in fact.

One last piece I want to point out about the general performance objective is how we operationalize that. So in Part 26, 26.33(d) has a statement on this performance objective, and it states that FFD programs are to provide reasonable assurance that the workplaces are free from the presence and effects of illegal drugs. So we should keep that in mind.

Another thing I want to talk about briefly before we get into the slides is what are the HHS Guidelines. So the executive order back in 1986 established testing federal employees. As part of that, the executive order mandated that Health and Human Services establish procedures and in this case guidelines to dictate how testing was to occur on federal workplace employees.

The NRC has always relied upon HHS and the HHS Guidelines to form the technical basis for testing. However, we have deviated in certain circumstances. One most notable is that for a long period of time licensees could conduct initial testing at their sites, licensee testing facilities. Most licensees no longer do that, but that was a distinct piece of testing under NRC that was not a part of the

HHS Guidelines.

HHS typically updates these guidelines when drug use trends change and additional substances are prevalently used that are addictive and impairing and will be potentially appearing in the workplace subject to testing. They also change guidelines as science advances.

Do we improve our testing capabilities to identify drugs in different ways? Lowering cutoffs, for example, are something that is part of this, or in our case, are people cheating? Are methods in the marketplace being developed that can subvert our testing process and undermine the testing program.

Okay. Next slide please. Oh no, I'm sorry, first slide, drug testing changes. So this is the crux of a lot of the benefit that we anticipate from this proposed rule, which is lowering cutoff levels for a number of substances.

So we're going to be lowering initial cutoff levels, and this would apply to testing performed by licensee testing facilities as well as HHS-certified laboratories and then updating confirmatory drug testing cutoff levels for HHS-certified laboratories.

For any drug test to be valid in the NRC

for a positive, you need two tests to be conducted, an initial and a confirmatory test. The third element of the drug testing changes is that the panel is being updated. Either we're updating the drugs or drug metabolites that are going to be tested for in a urine specimen. Next slide, please.

I should note that we just have representatives -- not to single you guys out -- we have representatives from HHS that could answer questions about the guidelines. Thank you so much.

MR. FLEGEL: Sorry we're late.

MR. ZALESKI: No, we just started. Okay. Drug testing cutoff changes. So when you lower the cutoff level for any of these drug tests, what you effectively do is increase the opportunity to identify a substance in an individual's body after use, so it increases the window of detection.

So the testing cutoff level changes that were implemented under the 2008 HHS Guidelines were broad based. The affected changes in testing for amphetamines, methamphetamine and cocaine metabolite, and reductions in these cutoff levels are anticipated to greatly increase our detection capabilities.

Most of the cutoff levels have been decreased by 50 percent, which is quite noticeable for

amphetamines and methamphetamine and cocaine. There's some variability in terms of the cutoff level changes. The initial cutoff for cocaine was reduced by 50 percent and the confirmatory by one-third from 150 to 100 nanograms per milliliter. Next slide, please.

As I said before, one of the issues that HHS grapples with is are there drug use trends that are impacting potential workers in the federal employee workforce or safety sensitive and security sensitive positions in the United States.

These two substances, methylenedioxymethamphetamine, MDMA, and methylenedioxyamphetamine, MDA, were added to the drug testing panel. The 2008 HHS Guidelines also added a third. We call them ecstasy drugs. There's three of them, MDEA.

Now Stew just spoke briefly about the Commission directing the staff to remove one of the substances from the testing panel because of the 2017 HHS Guidelines. So what occurred in that instance is they removed one of the three drugs, and so the Commission believed it was appropriate to remove that from our proposed panel changes as well.

I'll talk more about that later, but the point of this is that we're proposing to move forward

with testing for two additional amphetamine-based drugs, MDMA and MDA. Next slide.

Okay. This is an example of the science changing and clinical information supporting the need to change how we test for a substance. So drug testing for the heroin metabolite, 6-Acetylmorphine there was information that demonstrated the individuals could metabolize heroin and not have morphine in their urine specimen.

So currently, the way it works is if an individual tests positive for morphine, we only then will look for 6-Acetylmorphine. And the reason we do that is because that metabolite is only present in somebody who is using the illicit drug heroin. And if that's the case, that's definitive proof, and it's a case-closed determination on that. There's no legitimate explanation for that substance to be in that individual's body.

However, the information that was gleaned from testing over many years is that some individuals don't have the presence of morphine in their urine, but they do have 6-Acetylmorphine. And so what HHS did was remove the requirement to only test for 6-Acetylmorphine after a morphine positive. Now we'll test for 6-Acetylmorphine initially and under

confirmation.

And I know that the HHS-certified laboratories were supportive of this change as well because this delayed their ability to turn around test results within five days because of how this testing is conducted and how they grouped these tests together.

Most people are aware that there's been an opioid abuse epidemic in the United States for many years and improving our ability to detect heroin use in individuals in our program is an important element of this rulemaking. Next slide.

Validity testing for adulterants. There was a minor change in the 2008 HHS Guidelines in terms of adulterant testing. So adulterants are tested for in each urine specimen. It's oxidizing adulterants, and what an adulterant basically does is it interferes with the initial drug test and it basically will not allow that test to work correctly.

We test for these adulterants and make sure that someone's not subverting the testing process. That said, it is extremely rare that anyone attempts to beat a drug test under the NRC's FFD program by adulterating their specimens.

We get maybe one adulterated specimen

every four or five years. So it's a very rare circumstance. We'll talk more about this, the preferred subversion methods and strengthening of those requirements in our rule. The validity testing in itself, while very, very important, ensures that people are not substituting their specimen and adulterating it.

This is not, in itself, a significant change in terms of our detection improvement capabilities. It strengthens our ability to detect this, but it's not often used. And the only change that's being proposed is change the limit of detection to the limit of quantitation. And I'll go into that in a little more detail because it comes into play in a little bit when we talk about special analyses testing.

So the limit of detection is just a cutoff level, so in the previous slides you saw there was a 200 nanograms per milliliter cutoff level. Well, in this case the limit of detection is the lowest limit that you can identify a substance in a specimen and its valid.

And each assay that HHS certifies through the certification process has a limit of detection and a limit of quantitation associated with it in addition

to whatever cutoff level the agency may be using. So in this case, the LOD is the lowest level you can identify a substance.

The LOQ is the lowest level that you can identify and quantify. So you're both identifying the presence of it, but then you're also putting a quantified number to it. Okay. Next slide.

Subversion attempt detection. So one of the things that really was a game changer for us is with the last major rule as Stew spoke about earlier, the 2008 FFD final rule.

We incorporated alongside that an electronic reporting system that collected much more precise information about how people were violating, testing positive. We got individual specific information, and once we started collecting information, we started to realize that many more people were subverting the testing process and being identified as such.

This was not a known -- the prevalence was not known at the time of the final rule in 2008. Although, the 2008 rule did bolster the provisions in Part 26 to address subversion. Subversion is a willful act to thwart the rules of the NRC and the sanction for an individual identified in subverting a

test or the testing process is a permanent denial of unescorted access. It's the most severe type of sanction that's imposed by the NRC on an individual.

What we've encountered over the years since say the 2011 timeframe is the percentage of individuals identified that have been subverting tests has continued to increase up to the point of this year where it was about 30 percent of the drug testing violations were subversion attempts identified, which is a significant number.

The proposed rule would improve testing methods associated with the subversion attempt detections. So this is a lessons learned type of situation. HHS Guidelines do not include the methodologies that we use for subversions.

That's just not something that HHS is involved in, and so this is unique to NRC and it's something that we have operationalized because subversion -- because the trustworthy and reliability of individuals is paramount to us ensuring the safe and secure operations of our power plants and other facilities. Next page.

Okay. So let's briefly go over what the special analyses testing is. So in 26.163(a)(2), this is the provision in Part 26 that permits licensees to

do special analyses testing. An individual can attempt to thwart the drug testing process by hydrating, significantly hydrating prior to a drug test, and in doing so, they would drop the concentration of a drug or drug metabolite in their urine below the cutoff level that the laboratory is using.

And if they were successful in doing that, they would get a negative result and thwart the testing process. Performing validity testing, one form of validity testing is to look at the creatinine and specific gravity in an individual's specimen. And that results in a dilute result.

A dilute result basically means the concentrations of these -- the creatinine is below what is normally expected. It's still humanly possible to produce it, but it's lower than normal, and it's an indicator of a potential subversion attempt.

So in this case, the NRC gave all licensees and other entities the option in the 2008 rule to test the specimen at a much lower cutoff level. So the approach is to look at the initial testing assay and look at the concentration of the drugs.

So say the cutoff level for the initial drug is 100. Our rule says that if the concentration is within 50 or higher, you can continue to test and you can go to confirmation at the limit of detection, which I was describing before is the lowest level that's scientifically supported to identify a substance. So it's a much more -- it's a much lower cutoff level than would occur under a normal testing situation. So that's special analysis testing.

The majority of licensees and other entities have adopted special analyses testing over the years up to the present time. As of 2018 we have 66 of 71 sites that have adopted this optional testing policy. Let me describe what I mean by sites because it comes up a little bit and when we talk about the regulatory analysis.

So a site basically means a reactor. So if there's one or more reactors at a location, that's a site. It's not if there's three reactors at a location, there's three sites. It's one site that has three reactors. So when we speak about that, we're talking about a nuclear power plant site. We're also talking about a fuel cycle facility, there's two of those as well. Next slide, please.

Okay. So there's two -- and I will say

that the special analyses testing, and we reported out on these results in a variety of settings. We've briefed the Drug Testing Advisory Board under HHS. That's the advisory board that informs or assists HHS in evaluating the effectiveness of the HHS Guidelines.

We briefed them on our special analysis testing program. We've also published these results in summary data and presented at industry conferences and elsewhere. We have detected individuals using these methodologies for all types of testing, from pre-access to random, to for-cause, to followup and post-event, so it's been effective in that way.

And we have had detection across years, and I think that we've had between two and 19 or 21 individuals testing positive with dilute specimens each year. Diluting a specimen is not the most preferred method. The most preferred method that we've identified is that an individual use a substance that's not -- a specimen that's not their own, a synthetic specimen.

So what we're proposing here is to modify the special analyses testing in a few ways. First, we're going to require licensees to conduct this testing and not provide the option any longer, which is as I said before, most licensees already do this

testing.

The second one is we're going to lower the concentration of that initial testing assay where the drug metabolite is or drug or drug metabolite is to move forward to confirmatory testing. So before, it was 50 percent of the cutoff level, so if the cutoff level is 100 and the drug was at least 50, you would move forward.

But now, it would be if the drug was at 40, you would move forward in that same 100 cutoff level. So what that means is we're lowering the cutoff level and improving our ability to detect that drug to move forward with testing and confirmation.

The second piece is we're changing the limit of detection to the limit of quantitation for that confirmation test. So for some laboratories, the limit of detection and the limit of quantitation is actually the same number. It depends on how they're doing it. In other laboratories, the limit of detection might be a little bit lower than the limit of quantitation.

But the staff's position is that because this may result in a subversion determination, using the quantitated value of that specimen is an important donor protection. It's something that we again, the

HHS changed the validity testing measurement, too, so we propose to move forward with the LOQ testing here as well.

This is another lessons learned. All the special analyses changes are lessons learned. One, because we've seen the prevalence and, two, we've collected unbelievably accurate information from our licensees and other entities in terms of how people are attempting to cheat.

Primarily the way we identify people who cheat is that their specimen that they provide at the collection site is out of temperature range. And so when we identify that, our rule currently requires an observed second collection.

So one way we believe that special analysis testing would be -- would bolster our capabilities to identify individuals subverting is if their specimen is collected under direct observation conditions, we would also apply the special analyses testing process.

So what does that effectively do? That effectively lowers the cutoff levels that you're applying to specimens that are provided under direct observation. And that improves our ability to detect drug use for longer periods of time.

The direct observation conditions that we're proposing to apply special analyses testing to would be the individual had provided at a prior specimen collection a substituted, adulterated, or invalid test result. I mean we see invalid test results, and we bring someone back in.

The reason that you would want to do this under special analyses is because days are occurring between the processing that initial specimen and bringing back someone in under the second collection. So reducing the cutoff level gives you a longer period of time to identify use in that individual.

The second would be, as I said, the temperature of the individual's specimen is out of range at the time they provide a specimen. So you would immediately collect the second specimen under direct observation.

And many times, individuals just outright refuse and don't provide. And if they don't provide the specimen, that's conclusive evidence of the subversion attempt, and they're denied access at that point.

But in this case, if they provide a specimen, we would also apply the special analyses testing standard and process.

Collectors, our collectors are vigilant. They look at the specimen. They evaluate if the color, the odor, the individual's behavior, if there's any kind of product on them, if they're demonstrating any type of aberrant behavior that might indicate that a subversion attempt is underway, for instance, noises inside the collection facility where you're not being observed would be an indication of a subversion attempt and a likely collection under direct observation. Those specimens also would be collected and tested to special analyses.

Finally, we would propose to do special analyses testing on an individual that had to provide a second specimen if the initial specimen they provided was positive, adulterated or substituted, but challenged that result.

So it was a verified result, they challenged the result, and that specimen wasn't available for retesting. So say for instance the split specimen got sent to a second lab. The box got lost in transit.

Right now, that individual's positive result is canceled. And so they would have to be recollected. But what we want to do is to apply special analyses testing, which again, lowers the

cutoff levels that you're applying to that individual. And in this case again, days are transpiring from the point of the initial test to the point where you can collect the second specimen.

Any questions on this? I know there's a lot associated with special analyses testing.

MR. DIPIETRO: This is Nick DiPietro with First Energy. Some utilities, if the first test was out of temperature or whatever, then the MRO could just declare it a subversion and it's done.

MR. ZALESKI: Right.

MR. DIPIETRO: And we don't do a second collection.

MR. ZALESKI: Right.

MR. DIPIETRO: Okay.

MR. ZALESKI: And this wouldn't change that at all. If there's definitive proof, for instance, if the specimen collected is 108 degrees, the person would be dead. They would not be able to function with that kind of a temperature. You can stop the collection process at that time.

I know a lot of times what happens is you get a specimen. It's out of range. You talk to the individual. They admit they subverted, or during the directly observed collection process you observe

paraphernalia on them, and you stop the process and don't collect the second specimen.

So these processes would not change the ability of your MRO to declare a subversion attempt if sufficient information was obtained at the time of the initial collection.

MR. DIPIETRO: We had one that was 107.

MR. ZALESKI: Right.

MR. DIPIETRO: He was nearly dead.

MR. ZALESKI: Right. Exactly. On the phone, does anybody have a question about the special analysis testing provisions that we're proposing?

MR. SCHNEIDER: Operator, can you ask the participants via the phone?

OPERATOR: If you have a question, please press star 1.

MR. SCHNEIDER: Nobody has a question to ask or comment?

OPERATOR: No questions at this time.

MR. SCHNEIDER: Thank you. We'll proceed.

MR. ZALESKI: And we can circle back to this again later on because we'll have more to say about it. Okay. Next slide. So one of the housekeeping measures that we did, and I should've mentioned at the start of this on the background,

we've conducted four public meetings on this proposed -- well, before it was a proposed rule process, we had conducted a number of public meetings, two of which were to evaluate the 2008 HHS Guidelines with industry and evaluate the applicability of them in areas where we might consider rulemaking on.

If you've read the proposed rule already, you'll see that feedback that was obtained during those public meetings did shape some of the proposals in this rule, such as several of the proposals associated with changes in the definitions.

So what we did was we looked at the definitions that were in the HHS Guidelines. We also looked at provisions in Part 26 and lessons learned in terms of questions we would receive from licensees, and we are proposing to update a number of definitions.

I'm not going to go through each of them because some of them are just clarifying revisions and you can read for yourself. A couple of them I will go through, and I think they're important. And some of them relate to unusual testing circumstances where a specimen is canceled -- the test is canceled or the specimen is rejected for testing.

We're going to talk a little bit about the

HHS-certified laboratory definition that we updated, and we're also going to talk about the federal custody and control form, and again an invalid. So many of these are associated around subversion attempts and dispositioning of those. Next slide, please.

Okay. So this canceled testing provision that we added, it's aligning fairly closely with the HHS Guidelines definition in 2008 where it basically lays out what the MRO would be canceling a result based on. And so there was some confusion in terms of -- this was occurring, but there was some confusion amongst members at these meetings and in discussions subsequent to what is the process, and how does that lay out.

So to tighten the loop around that one, we're proposing to include definitions for clarity. So an instance where an individual result was canceled by the MRO would be the MRO receives an invalid test result from the laboratory, interviews the individual as required, and there's no legitimate medical explanation.

The MRO would cancel that test because it's not a valid result. They could not get it -- they could not confirm -- do the drug testing, the validity testing and a second specimen will be

collected. So in this case, that first specimen, the testing would be canceled.

Another instance where this would occur is the licensee testing facility or the HHS-certified lab received the specimen, but they outright rejected it. They couldn't test it at all. Either there was insufficient quantity, or they believe it would damage their instrument or other reasons.

Another reason would be that the number, the tamper-evident seal on a specimen bottle was different than what was on the chain of custody form, which would indicate the chain of custody was invalid. And that's a donor protection.

And then the last one would be if the donor tests positive, they challenge the result. As a donor protection they have the ability to send that specimen to a second laboratory, and if the testing at the second laboratory fails to reconfirm the result, in that case, that test also would be canceled.

The final piece of the definition, which is not a part of the HHS Guidelines, HHS doesn't address alcohol testing. The Department of Transportation tests for alcohol and NRC tests for alcohol, so our testing provisions are fairly similar with the Department of Transportation's testing

provisions in this way.

But a canceled test for alcohol would be if the equipment was not working correctly, and we have quality assurance provisions in place to make sure that if someone tests positive that you're validating the equipment, and you're adhering to the quality assurance protocols.

Next slide, please. Federal custody and control form. So we created a generic term for the form. We're not using a specific form name that HHS publishes in the Federal Register, but the federal custody and control form is the form that you're using to collect specimens under the NRC's Part 26 requirements.

There are endless numbers of references in Part 26 to the custody and control form, and there was only one reference to actually use the federal custody and control form. So we made an aligning change to make sure that that terminology is consistent throughout the rule.

The other piece that we wanted to make sure is that you're using a non-expired form. Every three years these forms go through review. They're required to go through review under OMB because you're collecting information, and they can't expire.

And so not using expired forms is important because sometimes the forms are updated to include other specimens and will soon be updated to account for additional changes HHS has underway. So that's one change that we've made.

Rejected for testing, this is a straightforward definition, but again, there was some confusion in terms of canceled tests. Rejected for testing means that the result reported by the MRO -- reported to the MRO by the licensee testing facility or HHS lab when no tests can be performed on a specimen. Okay. Next slide.

MS. YERKES: Brian, can I ask a question?

MR. ZALESKI: Yeah.

MS. YERKES: This is Mary from Exelon. When you refer to federal chain of custody control form, many licensee use their own chain of custody form. Are we saying that's no longer allowed?

MR. ZALESKI: No, the provision in 26.153(g) allows you to use a non-federal form assuming that you have all the required elements of it. So you would still continue to be able to use that form.

You'd have to provide your laboratory with a memorandum to demonstrate that you were complying

with that requirement. But we're not proposing to change that. We're clarifying terminology throughout the rule as is.

MS. YERKES: Thank you.

MR. SCHNEIDER: Operator, does anybody on the phone line like to ask a question or provide a comment?

OPERATOR: As a reminder, if you would like to ask a question, please press star 1. At this time, I'm showing no questions.

MR. SCHNEIDER: Thank you. We'll continue.

MR. ZALESKI: Next slide, please. Okay. So this is a revised definition, and we have the proposed rule changes in redline and strikeout here. This is an example of where we're trying to build flexibility into our rule so that we don't have to update our rule requirements if things change outside of our control.

So we do rely upon HHS to produce the federal custody and control form. They also update their guidelines. The proposed change would be to eliminate references to the HHS Guidelines, most importantly, because our current definition is out of date anyway.

So the last -- if you look at the last reference, April 13, 2004, that's the 2004 HHS Guidelines, which is not valid. The current HHS Guidelines are the 2017 HHS Guidelines, so there are no HHS-certified laboratories that comply with the old guidelines. So our proposed rule requires licensees to use the current certified laboratory.

So revisions here are addressing that inconsistency. We're saying that you're going to be using a laboratory that's compliant with the current HHS-certified guidelines, the HHS Guidelines at the time you're doing the testing. And that will eliminate in the future any inconsistencies in terms of references to old HHS Guidelines.

That said, that doesn't change that if we have different cutoff levels that we're using at our labs. It just means -- and those cutoff levels and how we do our testing is in the contracts that each of the licensees are going to have with those laboratories. That doesn't change any of that. All it means is the certification process here. Next slide.

So this is an alignment with the 2008 HHS Guidelines with the exception of referencing the criteria in our rule, which would result in an invalid

result being reported out. The prior definition was more descriptive, but it didn't provide the actual elements that resulted in a specimen being reported out by a laboratory as an invalid.

And basically, when a specimen is reported invalid is it can't report it as positive or negative. The validity test result is adulterated. The validity test result is substituted. The only other outcome there would be that it's invalid.

And the reference to section 26.161(f) in our rule are the provisions that mandate HHS-certified laboratories reporting a specimen as invalid to the MRO. This is also a lessons learned because people sometimes inconsistently would refer to specimens that were substituted.

A substituted result is actually a specific result returned from the laboratory. An invalid result is a specific result returned from the laboratory, and they have very specific criteria that they're using to report those results out. Next slide.

Shy bladders. This is a lessons learned for us where our current rule requires that if a donor cannot provide a specimen on their initial collection that the donor and the collector that initiated that

process must stay with that individual until they complete this process, and it could be up to three hours.

So if an individual cannot provide the minimum quantity of urine, they're provided fluid over up to three hours, and they will provide a specimen when they're physically able to do so. Our rule, we believe, was overly restrictive in tying up that collector to that individual for three hours.

And what we're proposing is that other individuals in the FFD program, specifically FFD program personnel, would be permitted to observe that individual while they were hydrating in a controlled environment.

That would give additional flexibility to use that collector under other collection circumstances. And so we know that collectors have unique training qualifications that other members of the FFD program personnel may not, so could be a cost savings measure. Next slide, please.

MS. HOGG: Hey Brian?

MR. ZALESKI: Yeah.

MS. HOGG: Question. Lisa Hogg with NEI. I was just wondering, what's the reasoning behind the donor or the monitor being a Fitness for Duty program

member.

MR. ZALESKI: Yeah, so that's a good question. I think that the rationale was that the FFD program personnel are fully aware of the program. They are adhering to a higher standard, background checks. And the process in place to validate those individuals would give us assurance that that individual would be acceptable.

That doesn't mean that you couldn't provide a comment to say we believe that we can treat other individuals that could equally provide that service. Other federal agencies, like Department of Transportation. I don't believe they have FFD program personnel per se, but they have people that observe individuals hydrating. And I don't even think the HHS Guidelines has that kind of requirement. Do they? No. So that's something that please provide a comment on if you believe that it's more appropriate that other personnel would be also acceptable under that circumstance.

MR. HARRIS: Yeah, this is Paul Harris at the NRC. One of the examples that we might think about is backshift operations where the individual can't perform a lot of sufficient volume of urine, and you have the FFD program personnel on backshift like

that.

So the consideration that we're, you know, brainstorming is an alternate collector, like a security officer who is informed and trained and inspected on observation techniques and requirements. So we have thought about this internally.

MR. ZALESKI: And one other piece. So this is a big deal. When someone's in a shy-bladder process and observing them, if someone believes they're demonstrating aberrant behavior, they're refusing to participate in the collection process.

That can be in and of itself enough information to make a subversion determination, which is a permanent denial. So ensuring that we administer that process in an effective manner is critical to protecting the donor and also protecting the licensee from challenge for a decision that way.

In fact, one of the three elements of the proposed reg guide that's proposed for issuance once this rule's finalized would be to provide information on hydrating. The hydration process, how to do it, and we look forward to talking with you about that later today. Paul will take the lead on that.

MR. SCHNEIDER: Operator, can you check if anyone else on the line has a comment or a question?

OPERATOR: I'm showing no questions at this time.

MR. SCHNEIDER: Thank you again.

MR. ZALESKI: So in order to do that, in order to make this change, we'd have to update the FFD program personnel activity. So an activity, if an individual performs a specific type of activity, that will qualify them to be considered FFD program personnel. So in order for that to occur, we need to see a line item, observing individual hydrating, would make you an FFD program personnel.

Other pieces of the process are also updated because there are elements that require the collector to observe that individual any time they're in front of them until the point that a specimen is sealed up and put in a bag.

And that's to protect the donor and protect the licensee as well to ensure that that specimen, from start to finish, the chain of custody is intact.

And so, if the collector is handing off the observation of an individual, there are some revisions that we've made to say that that direct observation requirement would be handed off to a hydration monitor.

We'd also allow for individuals that are also trained collectors so another collector could observe somebody. It might be helpful in an instance where you need to do a same gender collection, you know, direct observation. You might want to swap out a collector that's tied up in the hydration process. Next slide, please.

This piece is basically 26.109(b)(1) is providing some information that you need to provide to the hydration monitor because they're performing a critical function in the collection process.

They're observing that individual, so they need to be vigilant about any kind of donor behavior that would suggest they may not be following directions. If they leave the collection area or the hydration area, if they try to consume a liquid that's not what you provided to them.

Part of the hydration process is ensuring that the individual is only consuming up to 40 ounces of fluid, and so that fluid is controlled. Do you see an individual trying to discard a subversion product in the collection area, et cetera? Do they just leave?

Those are elements that we propose in the rule to make sure that we educate any hydration

monitor on these things that the collector, as part of their normal training, would be aware of but may not be the case for an FFD program personnel per se. Next slide, please.

Here's another donor protection. It's not a lesson learned, this is actually more clinical information. Testing of specimens over time demonstrated that some invalid specimens could occur because of the handling of the specimen and transit to the laboratory and at no fault to an individual.

So let me step back for a second. So an invalid specimen is one indicator that an individual is attempting to subvert the process. It's not a definitive indicator because the laboratory, like I said before, they can't report out an adulterated specimen or substituted specimen.

But the laboratory knows there's something wrong with the specimen and they can't get a valid result. One way of evaluating a specimen is through the pH.

So the pH range through clinical data demonstrated the pH in the range of 9.0 to 9.5 can occur because a specimen was left on a counter over a weekend at room temperature, for example, or the specimen was shipped in a packing truck, and it was

150 degrees in that packing truck and there was a breakdown, and the specimen was exposed to high temperature.

So why is this important? So if there's an invalid result, the MRO speaks to the donor and asks them if there's any medical reason or evaluates if there's any medical reason. Are they taking a prescription drug that could interfere with the testing, with the initial test.

And that is a possible explanation for an invalid result. In that discussion, if there isn't any valid reason, they would also now be required to take a look and see if there was any information to demonstrate that handling of that specimen could have resulted in that 9.0 to 9.5 pH.

And ultimately, the outcome of this would be that the individual would be not subject to an observed collection on the second collection that they would be subjected to. So if you're invalid and you don't have a medical reason, you're coming back in for a second test.

It's whether it's observed or non-observed. It's a donor protection because the NRC and every licensee in this room does not like to conduct observed collections on individuals unless this is

warranted. And we're very protective of individuals in this circumstance. It's obviously a very significant situation to do this to somebody.

MR. DIPIETRO: Is there a lot of examples of that now in the industry, do you know?

MR. ZALESKI: We don't collect the pH. You know, we don't collect the actual outcomes of these results. So Ron may be able to offer any information about what they're seeing in the federal workplace drug testing program in terms of MRO views.

I'm not aware of that, but I do know that we do have a couple instances every year where a specimen's invalid, and it ends up being positive. The individual comes back in, and it's a positive result.

So we know that people are attempting to subvert the process by introducing something in specimens or using some other specimen that's not detectable, but it's not able to screen out.

MR. SCHNEIDER: This is Stewart Schneider. Just for the record, could you identify yourself?

MR. DIPIETRO: I'm sorry. This is Nick DiPietro with First Energy Solutions.

MR. SCHNEIDER: Ron, do you want to answer that?

MR. ZALESKI: Yeah.

MR. FLEGEL: This is Ron Flegel, HHS. We found that at the higher pHs, 9.0 or above it actually degrades any metabolites, cocaine specifically and morphine, so that's why we set those standards at 9.0 to 9.5.

The other part, as Brian spoke about, is in situations where there's higher temperatures, they are raised by the MRO to look at those individual results and determine, not saying there's not -- there's quite a few adulteration or subversion products that raise the pH specifically to the grade above. So that's why we set the standard there.

MR. ZALESKI: Right, so in either case we're collecting a second specimen. And remember, one of the proposed special analyses provisions in the proposed rule is that an invalid result, when you're brought back in, we would apply special analyses testing provisions. So you're dropping the cutoff level much more significantly in that way either if it's observed or unobserved. It would be in both cases.

MR. SCHNEIDER: Brian, this is Stewart Schneider, NRC. I have one question. If there were multiple samples in that truck that you identified

where the temperature was excessive, would they all be damaged to say or would just one, meaning --

MR. ZALESKI: That would be -- I would say if you had six specimens, and all six of them you had an invalid result and the pH was all in the same range, the probability of that occurring normally would be probably lower than, you know, the MRO has ever seen in the past. And it might be sufficient information to demonstrate that. But it's --

MR. SCHENIDER: But if one is damaged, would they all be damaged, or it's random or something.

MR. ZALESKI: No, I mean you would -- I mean Ron, I guess human physiology is different and it is possible, what constituents is in everybody's urine, how much bacteria is in their urine.

MR. SCHNEIDER: Okay.

MR. ZALESKI: But if for example, let's just say that there were four specimens and all four of them in that truck that were exposed to high temperature ended up being in the 9.0 to 9.5 range, that might be reasonable information for an MRO to make a determination that it wasn't an intentional subversion attempt by those individuals.

MR. SCHNEIDER: Thank you.

MR. ZALESKI: Okay.

MR. SCHNEIDER: Operator, anybody -- can you inquire if anybody else on the line has a comment or a question?

OPERATOR: As a reminder, press star 1 if you have a question. And at this time, I'm showing no questions.

MR. SCHNEIDER: Thank you again.

MR. ZALESKI: Okay, next slide, please. This is an alignment with the 2008 HHS Guidelines. So when an individual tests positive or they have an adulterated or substituted specimen, they're given the opportunity when they speak to the medical doctor to challenge that result if they believe it's inaccurate.

They can challenge that result and ask the MRO to proceed with having retesting on that specimen by a second independent HHS-certified laboratory to validate the initial result.

The current rule allows the donor to make that request within three days and within writing or to make it an oral request. Many of these interviews are done remotely through telephone, and so an oral request is more timely than a written request.

So two things that we're proposing in the rule. One is to align with the requirement. In the

2008 HHS Guidelines it says if an individual makes an oral request for retesting, the MRO needs to document that they received that request.

In all practical matters, of course the MRO that receives that request is documenting that in their records because they're demonstrating that they've received that information.

So that's not going to change this practice for an MRO, but it's making sure that that information is demonstrating compliance, that one, the individual made the request within three days and two, when did that MRO get that result, get that request and if they are adhering to the requirements in the rule. Next slide, please.

There was some inconsistencies in administering of 26.165(b)(3). So as I said, 26.165(b)(2) allows an individual to request a retest from the MRO either in writing or orally. 26.165(b)(3) says basically an individual has to provide written permission to proceed with retesting.

And it was interpreted by some licensees that they had to wait for written requirement. They couldn't get that oral request in the previous provision, (b)(2), to proceed with testing. So they were holding up testing until they got a written

request.

And that wasn't the intent of the rule. The intent of the rule for 26.165(b)(3) was providing written permission for other entities to request that testing on behalf of the individual, my understanding.

So the revision here is basically clarifying that only an MRO can make a request of the retesting of that specimen, only what's permitted in 26.185(l). And that 26.185(l) just basically says the MRO is the only individual, and they request retesting on the donor's behalf, and they can also request testing if they believe something was wrong in the process, the testing process.

It looks invalid to them or -- I've never heard of anything like that, but they have that latitude. So this basically will ensure that if an individual makes an oral request, we're not holding up the retesting of that specimen until we get a written document from them. And this is consistent with the guidelines. Next slide, please. Thank you.

Another donor protection provision. So yeah, you got it. As I said, when the 2008 Part 26 final rule came out, the Agency had no understanding of the extent of the subversion attempts, and it's continued to increase over time, the prevalence.

The donor protection that we're putting in place here is just to reiterate the steps that should be taken if an individual is determined to have refused a test during the collection process. And these steps are taking place, but it's ensuring that we're getting a uniform process.

One would be to inform the donor that a refusal to test has been determined, terminating the collection process, documenting the description on the chain of custody form of what action they took that resulted in that refusal, discarding any specimens they have been provided.

And this is an interesting one that we've added in here and it would be worthy of note if people want to comment on it, except if you collected a specimen and it was for a post-event test. And the thinking in that case is that if you get a specimen from an individual, and it's for a post-event test, it may be beneficial to test that specimen for root cause analysis.

Is it possible? Now the likelihood is that an individual who gets identified as potentially subverting is most likely it's a temperature issue, and it wasn't their specimen anyway. But that could potentially benefit us if it was a specimen they

provided.

And then the final step would be to immediately notify the FFD program manager. These are all steps that are taken right now. This is just ensuring that a uniform process is taking place. Again, this is a permanent denial on the individual, so making sure that we are crossing T's and dotting I's and being uniform in this process is something that the NRC is proposing that we incorporate into the rule.

Okay. An other lessons learned. So over the years, there have been blind performance test samples. What are blind performance test samples for members of the public? A blind performance test sample is a specimen that's formulated to challenge the laboratory's testing.

The laboratory doesn't know what they're getting, but the licensee knows what their sending. If there's an inconsistency in that testing outcome, it's a way of verifying that the laboratory is either correctly functioning, or it's a way of identifying that the laboratory is not correctly functioning and stopping that process from occurring so it doesn't impact a donor specimen, which is what we want.

We want our specimens to be validly tested

by the laboratory. One of the things that we introduced in the 2008 final rule is that we put an expiration date on specimens, on blind performance specimens. We said the lot you were drawing upon could be in service for no longer than six months.

But what we learned from blind performance test manufacturers is their lots could be in service for much, much longer, and so this was not beneficial to them. And it really had no impact on the validity of the specimen. They could maintain the specimen to the standards in our rule for much longer.

So we're proposing to eliminate that six-month in service requirement from the rule. There are other provisions in the rule that require them to certify that specimen, so that means they test that specimen before it's being sent over to another laboratory to challenge it, that it's going to be a valid result, whether it's positive for amphetamine or methamphetamine, or it's going to be a dilute negative specimen, et cetera. Next slide.

So LTFs, Licensee Testing Facilities. As I said before, the industry has mostly moved away from using licensee testing facilities, I think in part because the HHS-certified laboratories now can turn results around very quickly.

You can get a negative result within 24 hours, which previously was not the case in time past. But when the rule came out in 2008, there was an inconsistency introduced in that rule associated with quality control samples at licensee testing facilities.

And so we received a request from NEI to evaluate that inconsistency, and the NRC agreed that there was an inconsistency, we incorrectly used terms like donor specimen instead of a normal specimen.

So what a donor specimen means is licensee testing facilities usually have one analyst running the equipment. So in order for them to know that a specimen is a donor specimen, somebody else would have to introduce that specimen into the process somehow that was a blind. And that would cost money, that would cost another an individual to do that.
That was never the intention. It wasn't in the proposed rule. It wasn't in the previous rule, so what the NRC did at that point was they issued an enforcement discretion which said that this provision, and Howard, you could correct if I'm mischaracterizing this provision is no longer applicable.

We made a mistake. We're not going to take action on you if you're not -- if you're using

one analyst to introduce these specimens into the testing process. So what the proposed rule would do is correct the language that we described in this enforcement discretion, and it would rescind this document if the final rule was proposed.

Again, this is a very limited circumstance. It only applies to three sites that conduct this testing. And that's the presentation on the most noticeable proposed rule changes that the staff believes were worthy of talking about.

If there are other provisions in the proposed rule that individuals would like to talk about, we'd like to open up the floor for that. Or do you want to take a break, Stew? I don't know. We're a little bit ahead of schedule, I think.

MR. SCHNEIDER: We have a scheduled break now, but --

MR. ZALESKI: Oh, do we? Are we over the --

MR. SCHNEIDER: No, no. You still have a few minutes, but if those participating would like to ask a question or provide feedback, we'll take it now.

MS. YERKES: Brian, this is Mary Fran from Exelon, just a little feedback. There is a concern that we're requiring too much to be documented on the

chain of custody, and there's very little real estate on those chain of custodies.

And we would like the option to be allowed to document, not necessarily on the chain of custody, especially when it comes to the monitoring process. There's, you know, very little. There's so little space on those that you're not going to be able to read it if you require too much information on there.

MR. ZALESKI: Okay. That would be -- if you would provide that comment in your response and how you would recommend doing that, that would be the most helpful. Yeah, any comment that we receive, the most beneficial ones are to actually cite the provision that you have a comment on, and if you have a proposed change to provide that, and if you have information to support that decision that's beneficial for us understanding the significance of it or cost associated with it, those are also helpful information to provide that bolsters the decisionmaking process.

MR. SCHNEIDER: Any other questions or feedback in the room? Operator, can you request feedback or questions from those participating on the bridge line?

OPERATOR: Yes, we have one question from John Nielsen. Your line is now open.

MR. SCHNEIDER: Thank you. Please identify yourself and your organization again.

MR. NIELSEN: It's John Nielsen from INPO.

MR. ZALESKI: Hi, John.

MR. NIELSEN: I actually had several questions, but user error, when I tried to key in wasn't picking up that I was submitting a question. So I don't mean to take this backwards, but my first question was with regards to the hydration monitors.

I understand some of the thought on that, but we already have provisions in there for monitors for the entire collection process, and we have a provision in there for someone doing a direct observed.

Neither one of those people is listed in 26.24. Neither one of those people is required to be under the program. Neither one of those people require anything except for they have to be trained. And if what we're looking at is, you know, this is somebody who is ensuring that the practices are correct, whatever, it would seem that if we have somebody that's watching over an entire collection or they are in a stall for somebody trying to make sure they're not subverting and trying -- all the reasons that you gave for the hydration, it would seem that if

we already have something that's working for the other type of monitoring, why don't we just expand monitoring to include hydration monitor and make sure that the person who's doing it fully understands what their job is before we allow them to take it over.

MR. ZALESKI: That's a fair point.

MR. NIELSEN: It's an extra burden to put the things on that.

MR. ZALESKI: Yeah, and John, just to provide a little context for other folks. So one of the circumstances you're talking about is if there is a need to do a directly observed collection but there is not a collector that's of the same sex as the individual.

And in that case, you can choose somebody that is not a trained collector to observe that individual provide a specimen, and you could provide that option to that individual as long as you instructed them on what they needed to do. And that obviously is a significant situation under the rule, to collect a specimen under direct observation.

So I hear that. And then there was another one, and I can't remember the other provision, or did I capture it? I just want to make sure I'm reflecting back with you.

MR. NIELSEN: Where there's a personal relationship with someone --

MR. ZALESKI: Oh, right.

MR. NIELSEN: -- that you have to have a third person monitor to make sure that you do everything appropriately.

MR. ZALESKI: Right. Okay. Yeah, I definitely understand that, and that makes sense to me pointing out the difference in the current rule with regard to similar circumstances. That's helpful.

MR. NIELSEN: The one where you were talking about the pH. Are you also looking at the portion of the rule which talks about the timeframe because right now there's a provision that allows from the time that something leaves us until the time it gets to the lab can be no more than two business days.

So if we've got the day before Thanksgiving, and then there's, you know, two days of holiday and then two days of weekend, two business days would be next Tuesday. And to go from a Wednesday to a Tuesday sitting in the hot truck just seems like we're allowing something to take place that we probably want to be looking at and control that a little bit better.

MR. ZALESKI: Yeah, I mean I think there's

obviously runtime, right? We've been doing testing for a long period of time, and if these types of circumstances were occurring, I think you could provide that feedback to us that would be resulting in these kind of outcomes.

Are you suggesting that we take a look at the requirement of how long we're providing licensees to hold a specimen before they're sending it out?

MR. NIELSEN: No, I'm, you know, once we turn this over to the courier, we don't have control anymore, but you know, the timeframe of the courier getting it to the lab could be the thing that pushes us into an invalid result or whatever.

So here we have a part of the rule that's allowing, you know, essentially time to percolate in the vehicle or freeze or whichever it may be. And it seems like we would want to have that tightened up a little bit that, you know, from the time of pickup to the time of delivery must be within 24 hours or, you know, the lab would have to notify us what's going on.

We understand that there may be a traffic accident or whatever, but you know, for us to have it out of our control but now it's going to affect us and it's going to affect our people. It just seems like there's a mismatch there.

MR. HARRIS: Is he commenting on the current rule or the proposal?

MR. ZALESKI: I think he's commenting on the current rule. He's not -- yeah, so the only provision that we're making -- we would recommend that you submit that so we understand it. And if you have data that supports that there's a problem, that would be most helpful.

I'm personally not aware of any circumstances where this is occurring, but we also don't collect that type of information. It's not a required report to the NRC, but it may be occurring. The proposal that we're making is just basically to protect the donor from getting an observed collection in an instance where a specimen may have been mishandled, you know, or the handling of that specimen.

Now you all know how many invalids you're getting every year. I don't. I only know when an invalid result is also paired with either a positive result or a testing refusal. So that's the only amount of information I have.

So that would be helpful information. How many invalid specimens do you get, right, which are ending up being negative, you know, do you have a

large number of those? That might be beneficial for that point.

MR. BENOWITZ: You've got to be careful what you ask for. The Paperwork Reduction Act doesn't allow us to ask for just anything. The FRN requested comments on certain things and on the proposed rule. You've got to be careful of going beyond that.

MR. ZALESKI: Thank you, Howard. Let me rephrase that.

MR. SCHNEIDER: And that was Howard Benowitz.

MR. ZALESKI: Thank you, Howard. Let me -- sorry. Let me rephrase that. So if you have a position that you would like to make in terms of invalid specimens, it could be helpful to present information to the NRC in whatever manner you feel appropriate that would help us in that decisionmaking.

MR. NIELSEN: Okay. My comment was basically an ounce of prevention is worth a pound of cure, so if we're trying to prevent these type of things from happening, I just looked at the bigger picture. I'll get that to you.

MR. ZALESKI: Okay.

MR. NIELSEN: And then my final comment is about the lots. The biggest issue, we don't have

anything right now that has it so that a blind provider can only certify for six months. What we have is a requirement that they must certify that it's valid for six months.

What we've had issues with is the definition of open lot and trying to identify whether that lot is still available and so forth. So if you don't use up your blinds in a two-month period, then you have to verify that it's still an open lot and so forth.

That's the period of time where you find out that blind provider has been continually sending out information to everybody and re-certifies it almost on a daily or a weekly basis. So that's how we're getting past the six months. It continues to be an open, valid lot.

The problem is when they run out of the quantity. Once they run out of the quantity, it is a closed lot, and there is a problem that if you've got a specimen that came out of that lot and they no longer have a specimen to be able to do the validation, that it's still an open lot, then we have to deal with that.

I don't think that the comments that were provided truly address the issue that we've been

experiencing.

MR. ZALESKI: Well, we would appreciate if you provide that in written format so we can evaluate it further.

MR. NIELSEN: Okay. That's it for me.

MR. ZALESKI: Any other questions on the phone or in the room? Sorry, Stew, if that's your role.

MR. SCHNEIDER: No problem.

OPERATOR: I'm showing no further questions at this time.

MR. SCHNEIDER: With that said, we'll take a 10-minute break. If you need to use the restroom, someone will escort you.

(Whereupon, the above-entitled matter went off the record at 10:23 a.m. and resumed at 10:42 a.m.)

MR. SCHNEIDER: This is Stewart Schneider again, NRC, and we're about to start the meeting again. The next topic on the agenda is specific requests for comment, and Brian will start again.

MR. ZALESKI: This is Brian Zaleski, Fitness for Duty specialist. So the specific requests for comment are questions that appear in the Federal Register notice where the NRC is asking stakeholders

to provide feedback on these seven areas.

And so we're going to take some time to go through each of the questions, and if folks have any questions or would like to talk about them, we'll have the opportunity to do that. Next slide.

Okay. One of the areas that we worked on in this rule was seeing if we could remove redundant provisions in Part 26 that are also in the HHS Guidelines. So should we be parroting requirements in the HHS Guidelines that we really have no need to be modifying, no operational constraints or concerns to be addressing, and we evaluated two provisions and propose to remove them from Part 26.

One is the personal qualifications requirements in 26.155. They speak about the HHS-certified laboratory personnel qualifications. Well, the NRC does not establish those qualifications. We have no involvement in those qualifications, and it's not something that we would be commenting on. Or at least the staff's position was it wasn't something that we would be commenting on, so we proposed to remove that from the current Part 26.

The second one was HHS-certified laboratory procedural requirements where they were requiring maintenance of procedures that were

guidelines procedures, not specific to Part 26.

So the proposal was to remove anything that is in the HHS Guidelines already because it's already reviewed by the NLCP, the National Laboratory Certification Program, and only include the specific requirements to NRC-specific procedures.

So if there's something that deviates from the guidelines, the laboratory would still maintain those, and that's something that licensees, you know, we would be reviewing. So that's -- those are the two proposals that we had in terms of removing duplication.

We're calling it duplicative rule requirements. Are there others that licensees and other entities feel would be appropriate to not appear in Part 26 because they're already successfully captured in the HHS Guidelines.

MR. SCHNEIDER: Brian, I just want to mention that each of the seven slides that you're going to discuss are as they appear in the proposed rule Federal Register notice. So it's the issue and the NRC's request for comment on that issue, so these are more or less verbatim.

MR. ZALESKI: Yeah, I think I may have edited one of them, like took a word or two out to

just tighten it up, but yeah they're almost exactly copied right out of the Federal Register. Thank you, Stew, for that.

MR. HARRIS: Yeah. This is Paul Harris from the Nuclear Regulatory Commission. There's a lot of history behind this number one item. As the industry may know and staff definitely knows, we struggle all the time when HHS Guidelines change and what that change means to the industry because we do incorporate elements of the HHS Guidelines into our proposed rule or into our rule.

So when the guidelines change, the NRC staff looks at the changes in the guidelines and we evaluate whether or not it's necessary to even propose a rulemaking to align with the guidelines again.

One of the outside of the box thoughts was how can we get out of this endless cycle of rulemaking when the HHS Guidelines change. So that was an issue that we identified probably back in 2009. And we started working on and we had a lot of internal thoughts and discussions and reached out to the industry regarding this issue.

And so I would consider this first number one item here, align with the guidelines of the removal of two sections as a baby step. You know, we

don't want to have a dual regulation on the HHS laboratories. HHS does a good job doing that through their processes.

However, are there other elements within that subpart H in which we can remove because it's a redundant type of requirement. HHS already has regulatory responsibility on the certification of those laboratories.

One of the key considerations is if the -- we have to account for these changes in our burden assessment. And Brian will talk about the burden assessment later on this afternoon right after lunch. But that is one of the considerations we look at when we remove items out of our rule because it's already being done under National Laboratory Certification Program.

MR. DIPIETRO: This is Nick DiPietro with First Energy. I got a comment on it. First of all, I totally agree with it because it's redundant. The second part of it is I would look at other pieces of the HHS guideline as well as DOT testing and try to align to that.

So like in my company we're moving away from regulated generation to competitive generation. So right now, we have three drug testing pools. We

have the Nuclear Regulatory Commission.

We have the DOT guidelines for like our tugboat operators or whatever, and then we also have another expanded panel that we use for contractors, which we get a lot of positive tests on that because we are using an expanded panel.

But what I'm saying is if we would be in alignment with the HHS Guidelines and other drug testing programs, federally mandated drug testing programs, then we would not have to negotiate a separate contract with the labs.

We could probably get our testing done at a cheaper price because it's going to be in alignment with testing that they're already doing, a lot more testing than what we are doing with the NRC. So there's some economies of scale that I think we could take advantage of.

And a second piece of that is again, just to be in alignment so utilities don't have two or three, four different drug testing pools that they could manage. They have to manage all to say they were in alignment with the DOT requirements and the HHS guideline.

Then we could fit our provisions under that program and then add on the extra things that the

NRC has as far as the alcohol testing or whatever and maintain the rigor that we have with the NRC program because from my experience, the things we're doing for the NRC program is much more -- I'll just use rigorous for lack of a better term as far as the collection and testing process than some of the other programs that I looked at.

But I think this is definitely the way to go, baby steps, giant steps, whatever it takes to get there. I think it's definitely something that the industry can benefit from and make us more competitive.

MR. ZALESKI: So Nick, can I ask a follow up question on that? Are you talking about aligning -- it sounds like you're talking about aligning with the panel, like the current panel that's in the current HHS Guidelines. Are you also talking about like collection procedure or is it more specific to the panel that's being used?

MR. DIPIETRO: Well, the panel would definitely get us the economies of scale within probably a reduced rate from the laboratories. So that's number one. The collection procedure, you know, I think we grew up with that collection procedure, so we're comfortable with it.

And I think it's accomplishing a lot of the things that we're looking for as far as the subversions and the attempted subversion. So I don't know exactly how that would fit because I don't get into a lot of the DOT collection other than, you know, they have satellite collection facilities which we have ours, just isolated to our plants.

So that was something that my company was looking at because we've got operations right now across six states, and they'd like to take advantage of something like that. But those collections facilities, at least in my opinion, don't have the rigor that we have in our program.

MR. ZALESKI: And one other follow up question. I thought I heard you say that the cost for NRC testing might be higher than in your other regulated tests or in your corporate testing, the third group. Is that right? You're saying even with an expanded panel, you're still paying more for the NRC testing. Is that right?

MR. DIPIETRO: Well, the NRC because there's the different cutoff levels. It's just a separate set of rules that the lab has that they have to test by versus the bulk of their testing, which is mostly DOT.

This third testing panel that we have, that was something that we just implemented where most of our fossil facilities are at that the drugs of choice are more prevalent I guess than we see with the NRC population, so we implemented that upon ourselves.

MR. ZALESKI: Yeah, well, that's very useful information to share if you have that available because it helps us understand the rule better.

MR. HARRIS: Holistically, we've looked at complete alignment, you might say, with the HHS Guidelines or the DOT regulations associated with drug and alcohol testing. And there's definitely pros and cons associated in each of those.

The difficulty comes down to the administration or you might say the legal challenges we had to utilize another guidance document such as the HHS Guidelines which are published in the Federal Register or by reference to the DOT regulations, which are also published in the Federal Register.

So there's a lot of internal hurdles that we'd have to meet. And the guidance from OMB right now does make it a little bit more difficult to do that type of alignment. So that's an activity that we're working on internally. We could have discussions of that later as well.

MR. ZALESKI: Yeah, we could talk a little bit more about that when we talk about the regulatory analysis and backfit. And everybody knows about backfitting, and that's something that for Part 26 anything that we're going to do that's going to implement a new requirement on the industry is going to be a backfit.

We're not exempt from the backfit rule, and so therefore, we have to evaluate the effectiveness of each of those provisions and whether they justify the cost that we're imposing on folks. So that's the additional wrinkle on that piece that we'll talk about this afternoon for sure.

MR. SCHNEIDER: Operator, can you let us know if any individuals on the phone line would like to ask a question or comment in response to this issue?

OPERATOR: As a reminder, please press star 1 if you have a question. I'm showing no questions at this time.

MR. SCHNEIDER: Thank you. We'll continue.

MR. ZALESKI: Okay. Let's move on to question 2. Question 2 pertains to Special Analyses Testing. I talked about this before in terms of the

proposal to lower the cutoff level from 50 percent to 40 percent.

I talked about mandating this testing for dilute specimens instead of it being optional under the current rule. I talked about the proposal to expand the special analyses provisions for specimens collected under direct observation conditions under 26.115(a)(1) through (3) and (a)(5).

Question in the Federal Register notice is should we apply special analyses testing to individuals that have a prior Part 26 positive. So an individual has already violated the rule, tested positive the first time or the second time. If they test positive a third time, they're permanently denied, so that's why that's not in there.

If they test positive the first time or second time, should any of their specimens be collected or should a subset of their specimens be collected in applying the special analyses testing provisions, which effectively lowers the cutoff level.

That's the question there. And the reason for consideration there is obviously these individuals have already violated the rule. They demonstrated that they've been using and to ensure that they're abstinent. Applying a lower cutoff level might make

sense.

I know that there are a few licensees out there that are doing limit of detection testing, special analyses testing for followup tests and for-causes, and it might be even be for post-event. There's I think one licensee with a few sites that does that, just for information's sake. Does anybody have any comment on that?

MS. YERKES: This is Mary from Exelon. My only comment would be are you proposing only the initial testing after a positive test or every single time they test. Many of these people are in and out of the industry for years, and it would be a huge administrative burden to track which ones would need this versus which ones didn't, but if we went to the philosophy of the initial observed test after a confirmed positive test needs to have this testing it would be much easier to track.

And then basically you're saying pretty much saying in observed test would fall into this category already.

MR. ZALESKI: Right, so we would capture that one already in the current proposal. So you're commenting to suggest we limit it to observed collections as proposed?

MS. YERKES: Correct.

MR. ZALESKI: Because of the administrative burden and also tracking these folks?

MS. YERKES: Correct.

MR. ZALESKI: Got you.

MR. SCHNEIDER: Any further questions in the --

MR. DIPIETRO: This is Nick with First Energy. Just a comment in our old program we had a provision that anybody in the followup testing program that tested positive would be permanently denied versus waiting for the third strike. Just a comment.

MR. SCHNEIDER: Operator this is Stewart Schneider again. Can you check on the phone like to see if anyone has a comment, question, or response to this issue.

OPERATOR: Yes, we do have a question from David. Your line is now open.

MR. BONTHRON: Hi. It's David Bonthron Florida Power Light Next Era Energy. I just wanted to go back to the last question with the alignment with the DHHS Guidelines. I think this is crucial if we can get alignment especially with the panels because when HHS expands their panels it would be nice to rely on that versus waiting for a rule change because many

of us can't do expanded panels because of union contracts.

And if was something we could into the program quicker when HHS changes that would be more beneficial to us to rely on that so we could impose those stricter panels and not wait for rule change in the NRC room.

MR. ZALESKI: Thank you for that comment.

MR. HARRIS: David this is Paul Harris with the NRC. Brian and I have discussed what elements could possibly be used in the drug panel and its cutoffs in HHS was one of the examples that we came across. Thanks for the comments.

MR. BONTHRON: Yes, sir. Thanks.

MR. SCHNEIDER: Operator are there any additional comments, questions, or statements that someone may want to ask?

OPERATOR: I'm showing no further questions at this time.

MR. SCHNEIDER: Thank you. We'll continue.

MR. ZALESKI: The third question relates to conducting additional specimen validity tests. So currently the rule is restrictive in terms of the validity testing in Part 26 and it says that a

licensee is prohibited from testing for anything other than the assays that are listed and at the cutoff levels listed.

Is that too restrictive? Part 26 has always given licensees the ability to test for any scheduled substance to accommodate for any local drug use trends. That may not be the case nationwide and it also accommodates for licensees to use lower cutoff levels as long as they've been reviewed by a forensic toxicologist and validated.

However that's not the case with validity testing. Now one thing and I'll bring it up here that's in the 2017 HHS Guidelines in addition to removing MDEA they also adjusted the criteria they use for an adulterated specimen. So they shifted the pH by one, and I think it was from 3 to 4. Is that right Ron?

MR. FLEGEL: Correct. 3 to 4.

MR. ZALESKI: So in doing that to the pH range means that what would previously be an invalid specimen would now be an adulterated specimen and would therefore be a determination that someone subverted. That said we rarely see an adulterated specimen and we do not collect data on how many invalids come back negative after an additional test.

But it's one consideration. Should licensees be provided flexibility to implement validity testing that's in the current HHS Guidelines. Just like we have the provision in our rule now that says if the HHS Guidelines change you don't need to have a validation by a forensic toxicologist. You can use the panel as is. We're proposing to apply that standard to validity test. If HHS changes it you can apply it in your program.

Any questions? I feel obligated to ask if there are any questions because we're literally asking a question on each one of these topics. So does anyone have a comment or question?

MR. SCHNEIDER: Does anyone on the phone line want to provide a comment or discuss anything further?

OPERATOR: I'm showing no feedback at this time.

MR. SCHNEIDER: Thank you.

MR. ZALESKI: Okay. Nick you partly alluded to this when you're asking about the schedule for the final rulemaking process and pushing it out until 2021. Well this is another topic that we as an agency solicit feedback from industry on is the effective date.

So the effective date once this rule is published there's going to a period of time that you'll have the opportunity to implement it before you actually required to comply and what we're proposing is a 60-day implementation period be included in that final rule. So when the final rule, if is determined by the Commission that we move forward with the final rule, is published you'd have two months to comply. Is that an appropriate amount of time to comply with the changes.

MR. SCHNEIDER: So this is Stewart Schneider, rulemaking project manager. With respect to this issue during the final rule stage there is going to be another public meeting to address something known as CER, which is known as cumulative effects of regulation, and in that meeting we also discuss the effective date of the final rule and that's provided in the Commission paper that we provide to the Commission for their final vote on how to go forward.

So that information in your feedback is necessary at that stage to let us know will there be impacts. How do you want it implemented is the date that Brian is talking about here agreeable to licensees here. Just to let you know that's part of

the process.

MR. HARRIS: Just a question. Maybe you explain the process by which we get to final rule and how long that will take?

MR. SCHNEIDER: Okay. So at the close of the comment period which is December 2, we will then look at all the comments that were provided to us through all the different avenues that are in the Federal Register notice and we will address those and revise the rule accordingly.

We then put a package together which includes revised draft guidance, the revised regulatory analysis, procedural documents, as well as the Federal Register notice for the final rule and adjust the regulatory language as appropriate, and all of that is packaged into an overarching document called the SECY Paper.

The SECY Paper is then provided to the Commission and they vote on all of the things that are in there, and they provide us information on whether or not to change certain things. Again, they deliberate, the Commission votes, we make the changes, the changes are issued in something called a staff requirements memorandum to that SECY Paper, and then once the staff makes those changes per the direction

of the Commission, the Federal Register notice and the accompanying supporting documents will be published.

MR. HARRIS: And what timeframe that'll be?

MR. SCHNEIDER: Usually it's a one-year timeframe. For this project we added a few extra months simply because we were not sure how many comments we would get and we wanted to build into it in case we got a substantial number of comments to adequately address and provide responses in the package. But, typically it's a one-year process.

Then when the Commission receives it we like to have them do it as, you know, as soon as they can, but typically it can be several months, and then it's about from the time we get the SRM directing staff on how to proceed it can be anywhere from four weeks to eight weeks to get the document published.

MR. HARRIS: The reason why I asked you to provide that type of detail is the final rule package probably will be what will you say a year from this date?

MR. SCHNEIDER: Our typical schedule is one year from the time we'll say from the Commission from the comments are received on the Federal Register notice.

MR. HARRIS: The reason why I'm asking is that demonstrates or provides you some time to identify your own procedural changes you need to make based upon this rulemaking that's going before the Commission.

MR. SCHNEIDER: But it's also important to note that as I said a few moments ago that prior to the package going back to the Commission for their vote again on the final rule we will hold another public meeting on the cumulative effects of regulation and implementation date for this rule. So you'll be able to provide your comments at that meeting and that will be captured in the SECY Paper.

MS. YERKES: This is Mary from Exelon. Are you looking for initial comments now based on that or are you proposing --

MR. SCHNEIDER: On the implementation?

MR. YERKES: Yes. The timeframe? Are you proposing we wait until the second round?

MR. SCHNEIDER: You can provide comments now on any aspect of the rulemaking.

MR. YERKES: So many of us in the industry feel 60 days is not enough time. We have contracts that need to be changed, procedures that need to be changed, training that needs to be updated, NANTeL

training, FFD(Box) training needs to be all updated, possibly gap training needs to be included, contracts with the lab, computer programs needing to be readjusted. All of that is going to take time in addition to requesting addition funding, budget concerns.

Sixty days at the end of the outage season when people are just ramping up we feel that is not enough time.

MR. GREER: I have a question. This is Ken Greer from NFS. Just for my clarification are we talking about the implementation date going back to slide number 8 we show the proposed rule comment period closing December of this year like we discussed, then the final rule to the Commission the 26, February of '21, and then the final rule publication date of May 26 of '21.

Are we saying with this particular question a 60-day implementation is that 60 days past the May 26th date we're talking to?

MR. HARRIS: Yes. From the target date.

MR. GREER: So essentially we would have all of next year to begin prepping and getting the program changes?

MR. ZALESKI: But the sticky part about

that is if we change some of the requirements you're hitting a moving target, you know, so there's that piece of it.

MR. GREER: One comment or suggestion I would make let's say it does play out that way and goes 60 days past the May 26 date. We're talking July 26 would it not be better to begin the implementation at the very beginning of a month or maybe even a quarter timeframe, something of that nature just for ease of transition maybe?

MR. HARRIS: This is Paul Harris with the NRC. If I could tell the Commission that. Most of the time they give us direction and we act upon the direction they give us and it's at the discretion of the Commission to issue their staff requirements memorandum. So even though that would be something nice to do, we can look into it as a staff member, but sometimes we don't have control over that.

MR. ZALESKI: Now the one thing about this that we're talking about you're talking about costs, and you're talking about timing, and the things you need to account for. We'll talk a bit about that when we talk about regulatory analysis because that's the part of this we try to quantify the burden that we're going to be placing on industry to comply with these

rule requirements.

And we'll talk a little bit more in detail. We costed out that, you know, you'd be updated your policy and procedures, you're training people, you'd have to modify your contracts with your laboratory, your contract likely with your blind specimen provider, etc.

But if we were incomplete in that analysis or our assumptions are inconsistent in what you believe would be the case for you, those are great opportunities to provide information on that and that kind of feedback into the end result in terms of effective date.

MS. HOGG: Hi Brian. This is Lisa Hogg with NEI. I've already heard a lot of concern over trying to implement. You told me you need a robust change management plan to implement these kind of changes and you can't just go off trying to do it before you really know what, you know, the real rule in the end is going to say because I've seen these change quite a bit.

I've lived through the Part 73 rule re-write with several exceptions or exemptions or whatever we had to, you know, put into place back then, and that was just a nightmare. You should be

focused on how to implement the changes versus oh my goodness we have to rush this through, and we've wasted a lot of money trying to implement those changes. I've heard a lot of concern over being able to implement this and get it right the first time.

MR. ZALESKI: We'll be looking forward to feedback that'll help us understand what might be more realistic from your perspective.

MR. SCHNEIDER: So with your feedback and also including when we have the next meeting on implementation it's important that you provide that information to us what you're discussing because that will be captured in that SECY Paper and then if there is a change to the effective date it would be predicated on the information that industry and stakeholders provide.

So that is very important to be able to communicate that to the Commission.

MR. SCHNEIDER: Operator Stewart Schneider again. Can you just check if anyone else on the line would like to ask a question a provide a comment?

OPERATOR: Yes. You have a question from Jerry Woods. Your line is now open.

MR. WOODS: Thank Brian. One other factor I would ask you to keep in mind you look at an

implementation date is how along with the administrative burden that have already been shared we'll have outage schedules that will also impact our ability to implement changes of this significance.

So I appreciate you taking that into consideration when you look at our implementation that.

MR. ZALESKI: Thank you Jerry. Any other questions on the line? On the conference line?

OPERATOR: I'm showing no further questions at this time.

MR. ZALESKI: Let's move on to question five in the Federal Register notice. This question asks about are there other methods to collecting a second specimen that would not require a direct observation of that specimen collection. So this is a recognition that obviously direct observations are a very invasive process.

Are there other acceptable means of collecting another specimen that would meet the requirements of our rule which would be to collect the specimen from the individual understanding that there was likely a subversion event or another event that warranted collected that individual under direct observation?

MR. HARRIS: I'll break the silence in the room. So, you know, this a proactive step that Brian decided upon to place into the industry to be forward looking and to think outside the box on other ways that a direct observed specimen could be conducted more effectively or more efficiently with plant staffs, with your plant staffs.

Things like an alternate specimen testing would be in the realm of this item. Possibly changing the direct observation process would be within this, although that would be looked upon as a significant change, but that's the basis of this question to the industry.

MR. ZALESKI: For example, one consideration that might be instead of waiting three hours you collect the second specimen with an oral fluid specimen. That's one provision that's out there in certain regulated workforces. HHS just published their final oral fluid guidelines I think a week ago. Right? Or maybe it's two weeks ago.

Two weeks ago. Congratulations Ron. So that might be something for consideration. Part 26 already accommodates for the collection of an alternate specimen in certain circumstance. One of which is there's a medical issue that an individual

cannot safely or physiologically provide a urine specimen. Or there's another condition that warrants collecting -- they're in end stage renal failure and they don't produce urine.

So there are certain circumstances right now within Part 26 that support the use of collection of an alternative specimen. That may be some area to do some further review on.

MS. HOGG: This is Lisa Hogg with NEI, you know, just going on record of saying that, you know, industry is interested in pursuing that particular oral fluid testing.

MR. HARRIS: NEI just stated that the industry is interested in oral fluid testing and clearly that was demonstrated by Ameren trying to implement an oral fluid testing program and another licensee trying who's implementing oral fluid testing as well.

So the NRC staff is aware of those activities and any information you could share with us to demonstrate the effective of those programs would be highly beneficial --

MR. ZALESKI: Paul we can't do that. I'm sorry. You were out of the room the last time we brought it up as a question. I think the final

register notice you're challenging the Paperwork Reduction Act. Let's put it that way by asking certain questions like that.

MR. HARRIS: Okay. Thank you.

MR. ZALESKI: Sorry.

MR. HARRIS: So my point still stands that the industry is implementing those programs and they're subject to inspections.

MR. DIPIETRO: Just one comment on this. So right now like our process is if we suspect a subversion attempt, you know, we'll take the individual give somebody of the same sex and we'll do pat down, search them to see if there's any subversion products on them or whatever. You know, there's a myriad of things that we find.

So if we just said okay we suspect a subversion now we're going to go oral fluid testing I think that process needs to be defined on what the expectation is because I could see somebody having these different subversion products and just say we'll okay we'll I'm just going to go do the oral fluid and be done with it.

And then the part of it where you do the search and you actually find something that pretty much makes it a done deal and they're permanently

denied and it's over. So, you know, just to jump to say okay we think it's suspect let's go do something else there should be some other parts or pieces to that to give us that assurance that we're doing the right thing.

MR. ZALESKI: So I'm hearing you correctly you would potentially advocate your current collection process, which would be evaluate the physical person before you would proceed to any other collection to see if there's any subversion paraphernalia in their boot or whatever or, you know, the conversations you have with these individual or whatever else you're doing?

MR. DIPIETRO: Yes. I would. I would say yes.

MR. ZALESKI: I mean there's a lot of information we receive in the annual information reporting under 26.717 and 26.419 for collection construction sites where subversion paraphernalia is identified in the process of collecting that second specimen. So you're right. There is a lot of valuable information obtained initiating that second process. That's helpful.

MR. SCHNEIDER: Any further comments or questions in the room? Operator this is Stewart

Schneider again. Can you just check the line to see if any bridge line members would like to make a comment or raise an issue?

OPERATOR: I'm showing no questions at this time.

MR. SCHNEIDER: Thank you.

MR. ZALESKI: Question six. Question six is talking about the 2017 HHS Guidelines. So the Commission is asking this proposed rule whether Part 26 should consider adding the semi-synthetic opioids that were included in 2017 update to their HHS Guidelines. That's Hydromorphone, Hydrocodone, Oxymorphone, Oxycodone, and the question is specifically asking if this is something we should be considering now.

MR. MOGAVERO: Brian, this is Rich Mogavero from NEI. I agree with the comment there, but now that we know the HHS related to oral fluid testing are now available during the scope of this review of the rule if we find it acceptable that we consider maybe incorporating those as well as part of this rule?

MR. ZALESKI: So oral fluid is a specimen. The panel -- I don't believe -- it's a single panel. The panel we're proposing is different than the 2017

guidelines, but the oral fluid panel that just came out in 2019 and the urine panel that was updated in 2017 they're the same. It's just a different specimen being collected.

So the previous question -- I'm not sure if you were here for the previous question. Okay. We're just talking about are there other ways that we could collect a valid specimen from an individual under a direct observation situation, and this one is asking if we should include the additional opioids.

So I will say and we'll talk about this more in the regulatory analysis piece of this is the framework that we use here at the NRC is we apply the backfit rule and the backfit rule requires us to demonstrate that we're going to get a significant improvement in public health and safety from the provision that we're proposing and that's it's cost beneficial. That it's justified.

And so we need to make sure that the information we have on these substances and rates that people are using them at are warranted to impose the cost.

MR. REED: Hey Brian, Teddy Reed, Duke Energy. So you had mentioned that your analysis is showing a 10 to 12 percent increase with the proposed

rule. Do we have any data if we incorporate the HHS data, the HHS 2017, what that increase of the percentage would be in our continued ability to protect the public.

MR. ZALESKI: So no, we do not right now. So the way we evaluate -- the way historically the NRC has evaluated changes to the panel is we look at other stakeholders implementing the testing.

And if they get detection improvements or they see a drug that's prevalently used in a population that's consistent with ours, you know, they're doing similar types of work, that's information that's very supportive of us moving forward with rulemaking.

In fact, that's the methodology we use to propose the changes to our rule right now. We looked at what the DOT -- analogous modes within the DOT, what their test results were when they made the changes. So we looked at FAA. We looked at the FTA.

Those are transit drivers, federal rail, operating locomotives. So we looked at analogous populations and saw what detection they had of specific drugs and changes in the existing panel. And we applied it to our rates.

I'll talk more about that later on, but we

have not performed an assessment specific to the 2017 guidelines for our program.

MR. REED: Please keep me honest because I want to make sure we stay within protocol of when to submit comments and when to talk about it, but if HHS believes it's important for them to change their guidelines, would it not behoove us to consider it for Part 26?

MR. ZALESKI: Yeah, and these are very valid questions. And these are questions that we in the Agency have asked, and we talk about the backfit. So the backfit. There are certain instances when the backfit requirements don't apply.

In the instance where we do have to apply backfit, we always have to have a cost/benefit that works out. So it's a two-tiered system. Even though HHS may be including these drugs in the panel, we have to demonstrate that we're going to get value from that testing in our program.

So that complicates things. Complicate is not the right word, but it's a more in-depth way of reviewing these to ensure that we're doing the right thing.

MR. SCHNEIDER: As we'll discuss later, there's the quantitative and the qualitative aspects

that we look at, so if the quantitative being the cost benefit is not going to give us what we're looking for, we can then provide the qualitative aspect to it to make the final argument so it becomes packaged together to make the backfit argument, which was part of this rulemaking as well.

MR. ZALESKI: And as I said before the licensees have the ability to test for any substances, and there are a few instances of licensees that have expanded their testing panel to test for these semi-synthetic opioids and we can use the data to support whether they're seeing prevalence or not.

Typically, when we see it in the NRC's regulated Part 26 regulated workforce support testing, it's a for-cause test and it's a for-cause test where you're getting a credible report that someone's using the substance like that. But that's the only way because we don't test for it normally, so we would never get a positive, right. But if someone is -- if you have credible information they're abusing prescription drug or illicitly using prescription drug, that panel gets expanded. Yes.

MR. SCHNEIDER: Again, Stewart Schneider. Operator, is anyone on the line who wants to ask a question or provide a comment.

OPERATOR: As a reminder, if you would like to ask a question or a comment, please press star 1. I'm showing no questions.

MR. SCHNEIDER: Thank you again

MR. ZALESKI: And I will say one key element of this in terms of -- so when you conduct testing for additional drugs, you're evaluating the cost per specimen, right. How much will that change your fixed cost of testing the 10,000 employees you have in your program in that year or the industry. We test about 150,000 under Part 26 every year, 150,000 to 175,000.

So say for instance expanding the panel was a dollar, you just imposed a $150,000 on the industry per year. What's the value of that? How many more positives are we getting? The good news about Part 26 and our testing program is that we primarily identify drug users on pre-access testing.

We would screen most people out before they ever enter our power plants unescorted or a fuel cycle facility. Almost 70 percent of individuals who test positive, and this has historically been the case since 1990, give or take a percentage or two, are screened out.

And so as a licensee or another entity,

the cost savings of screening somebody out before they're employable and before you've trained them and done a bunch of other things or depending on the types of contracts and return to work requirement, those are other costs you may avoid by having a more robust testing program.

So we'll talk about this more this afternoon, and hopefully, we could give you some more optics in terms of the elements that went into the regulatory analysis to kitty up your ability to respond to us if you so choose to on that element of this. Any other comments on the expanded panel?

MR. SCHNEIDER: Operator, does anyone else have a comment or want to say anything at this moment?

OPERATOR: I'm showing no questions at this time.

MR. SCHNEIDER: Thank you again.

MR. ZALESKI: Okay. Question 7, and that is the last question that's included in the Federal Register. And let me be clear, just because the Federal Register notice only asked seven questions doesn't mean you can't comment on every single word that's written in the Federal Register notice.

Anything that's being proposed, any rationale, any supporting statement that's put in

there of why we're proposing a change is fair game for you to comment on in this process, so please be mindful of that. Howard, did I correctly say that?

MR. BENOWITZ: If you don't like his last name?

MR. ZALESKI: Okay, so methylenedioxyethylamphetamine, MDEA. This is one of the substances we're calling ecstasy drugs that was included in the 2008 HHS Guidelines, but in the 2017 HHS Guidelines for urine testing was removed. And the reason it was removed was the prevalence just wasn't there in the period of testing that was conducted at that time.

And so when we proposed the package, when we sent the package up to the Commission, we also alerted them to the fact that the 2017 HHS Guidelines had been published, but at that point it hadn't been implemented. It was going to be implemented later in 2017 at the end of the year, so we had no run time. Theresa Clark spoke about that this morning. Earlier today, she alluded to that fact.

MR. SCHNEIDER: This is Stewart Schneider again. It was February 22, 2017 when the Commission actually received this proposed rule package.

MR. ZALESKI: Right. So one change that

we did make to our proposal based on the 2017 HHS Guidelines was to eliminate MDEA because we had initially been proposing that to be included in the panel, but because HHS removed it, we received direction to remove it from our testing panel.

So this is asking a question about that decision. And I mean it basically underlines the previous question where you're talking about expanding the panel and then also a similar question where we're talking about validity testing and changes to the HHS Guidelines in 2017. Should NRC be considering additional changes to this rulemaking consistent with more current guidelines that HHS published.

MS. YERKES: This is Mary from Exelon. You indicated that MDEA is no longer on the table basically because the labs don't support that there's enough positives. Has there been any analysis for the MDA since they started testing for it?

MR. ZALESKI: So MDMA and MDA are the two that we're proposing to include. And while they are low prevalence drugs, right Ron, they are low prevalence drugs. They are getting detections. I don't know what the rates are. I can point them out this afternoon in the regulatory analysis, what the rates are, but they are low. They are definitely low

positive rate drugs.

MR. FLEGEL: This is Ron Flegel. Just one comment on the MDA, MDEA removal. Also, that's a minor metabolite of MDMA, so we can detect it through that if it's actually used. So therefore we didn't want to duplicate effort, and it was such a low prevalence. So therefore we don't have it.

MR. ZALESKI: Right. So MDMA and MDA you can use them independently, and also MDA is a metabolite of MDMA, right?

MR. FLEGEL: Correct. MDEA.

MR. ZALESKI: Right. Okay, but you're right. It's a low prevalence. It's a very low prevalence substance. It's higher than I think what we see in PCP. PCP we get one positive every like three or four years in our program, so there's an analogous substance in our panel right now, but yeah, it's low. And I'll point that out in the regulatory analysis so you can hone in on that.

And what we modeled in the regulatory analysis for detection on those is what DOT was seeing in their testing program because the Department of Transportation tests roughly 5 to 6 million people per year, civilians in similar regulated positions to what we at NRC use, a subset anyway.

The federal government and the NRC tests orders of magnitude less. And their data is available so we can model some of the information and detection trends. We'll talk about that later a bit more.

MR. SCHNEIDER: Operator, again does anybody on the line want to ask a question or provide a comment?

OPERATOR: I'm showing no questions at this time.

MR. SCHNEIDER: Thank you. Are you done?

MR. ZALESKI: Yeah, that concludes the section of the presentation talking about the specific request for comment in the Federal Register notice.

MR. SCHNEIDER: So, this is Stewart Schneider again, NRC. At this time we set aside a period for open discussion on the prior two topics, which were the proposed rule changes and the specific request for comment that we just completed.

So in the room does anyone want to do further discussion on those two topics? No. Operator, on the line does anyone want to further the discussion on those two topics?

OPERATOR: I'm showing no one in queue at this time.

MR. SCHNEIDER: Okay. So it's 11:33 now,

and we have put aside one hour for lunch, so is it agreeable to come back at one hour from now? Okay. So we will adjourn now for one hour and be back around 12:33. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:33 a.m. and resumed at 12:35 p.m.)

MR. SCHNEIDER: We will now proceed with the second part of our meeting, the afternoon. And this is Stewart Schneider again, NRC project manager. We will now start with draft regulatory guidance and presenting that discussion is Paul Harris.

MR. HARRIS: Thank you, Stew, for that introduction. This is Paul Harris. I'm the senior program manager for drug and alcohol testing, 10 CFR Part 26 requirements. I apologize for the typo on the very first page of the slide. It is draft Regulatory Guide 5040, so that little period point there is incorrect. It's 5040.

Title is Urine Specimen Collection Test Results Review under 10 CFR Part 26, Fitness for Duty Programs. Next slide, please. Purpose and applicability. Draft reg guide describes the methods and procedures the NRC staff considers acceptable for licensees and other entities to demonstrate compliance

with the requirements that we're publishing in Part 26.

The guide was written to provide guidance for the NRC staff proposed rulemaking that we discussed about this morning. It is the Commission's policy that the staff consider publishing guidance with every rulemaking and therefore this publication of this guidance is consistent with Commission policy.

Guidance performs a number of functions, one of which is provides consistency across the industry. It enables inspectors to understand the regulatory basis for a number of the activities that the licensees are performing that are in accordance with the requirements.

And throughout this presentation that we made this morning, you heard Mr. Zaleski discuss a lot about the worker protections that were being evaluated by the staff and proposed rulemaking such that workers are protected even though we're changing the requirements.

And you're going to hear a little bit about that in these next slides. But I must say that worker protections need to be balanced against the NRC's mission of public health and safety and common defense and security.

Every worker that does go onsite of the nuclear power plant has diminished privacy considerations because of the acknowledgment that they're subject to random drug testing and behavior observation programs.

So even though we want to improve and enhance worker protections, we also have to balance that with the NRC's mission to provide for the public health and safety. And the balance was taken into account in the development of this guidance. Next slide, please.

There's very little NRC guidance on Part 26 drug and alcohol testing. I listed on this page here the two guidance documents that we currently have, Regulatory Guide 5.84. That's focused on the Fitness for Duty programs at construction sites.

The second one is referring to Department of U.S. Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs. The HHS mandatory guidelines are available to the public on their website at the Substance Abuse and Mental Health Services Administration .com or .gov under workplace drug testing programs.

You'll also find on their website the medical review officer manual. That provides guidance

to medical review officers. That was recently published March of 2018 to include additional guidance to the medical review officers.

Some of the guidance that we provide in our regulatory guide is reflected and parallel to the guidance in the HHS MRO guidance manual. The HHS has also documented on their website some medical review officer case studies.

These case studies, we acknowledge, are based on operating experience in the HHS area, and we acknowledge that they are good guidance documents for medical review officers to review. Those case studies are also on their website. Next page, please.

Summary of the guidance parallels what we discussed this morning. The draft regulatory guide is going to cover three areas, monitoring of the donor during the three-hour hydration process, optimal use of mirrors that assist in conducted an observed collection, and the conduct of additional review by the medical review officer of urine specimens that have high pH values of 9.0 to 9.5.

I'm not going to provide a lot of detail on this because we did discuss a lot of detail earlier on this morning. Next page, please. The disclaimer I have for the audience is that the NRC does not conduct

-- I'm sorry. The NRC staff associated with this rulemaking does not conduct collections. We don't inspect collections unless we have the company of other NRC inspectors on collections.

Therefore, it's very important that the industry provide its guidance or provide its comments on this draft regulatory guide so it can incorporate real lessons learned in operating experience and guidance development.

There is a fine balance providing too much detail and not enough detail. It's important and my belief it's consistent in the implementation of guidance and that one licensee is not doing something significantly different than another such that the NRC inspectors are then in a quandary when they visit different sites. So the benefit of the guidance is consistency across the area.

The first area was monitoring a donor during hydration. The scenario presented here is an individual subject to Part 26 drug testing and is unable to provide a sufficient volume of urine during the collection process.

In this case if the volume of urine is less than 30 milliliters, the collector shall enable the individual to drink water to hydrate. And the

details of this hydration process is in the current rule, but essentially it is 8 ounces of water every 30 minutes over three hours.

The principal guidance that we're going to implement in this regulatory guide based upon the proposed rulemaking is to provide additional guidance on this hydration monitoring. So principal guidance on this first page I listed six items.

The monitor who is monitoring one or more individuals has to be instructed. We're not saying he has to be trained, but he must be instructed. That monitor must have a direct line of site and aural ability to listen to the donor or the multiple donors in the room.

We visualize something as what I observed here at the NRC. The NRC has a drug collection facility in this building that the NRC employees are subject to drug testing. They have a room in which people sit in. There's a hydration mechanism in that room, and these individuals are observed by an individual in the collection facility who works for the collection branch, and they observe the individual sitting there. So that's the experience we have plus the experience that Brian and I have obtained visiting your sites.

The collector and monitor should have a communication control and documentation protocols. Within the rule -- it is required to be documented on the control and custody form that if a collector transfers an individual to a monitor, the monitor's name will be placed in a handwritten format on the CCF to document who is observing the individual during the hydration period.

There must be clear communications between a collector and the donor and the collector and the monitor to ensure that if the individual does have to urinate during the three-hour period that a collector is available to facilitate that activity.

Number 4, again there must be control of the donor's personal belongings. There's nothing new there. The monitor must be familiar with attempts to subvert the testing process and that's part of the training element.

And there is guidance on whether or not -- there is guidance on the case where the donor decides to leave the collection facility. And I'll discuss that in a second. Next slide, please.

Hydrating the donor. Once an individual provides 30 milliliters, the collection is over, but if the individual does not provide 30 milliliters,

then he's into the hydration process. The donor is not allowed to bring his own liquid into the collection site. That's not new.

What is also not new is the amount of liquid provided to the donor, which is in the rule, 8 ounces approximately every 30 minutes not to exceed 40 ounces. A jug of water and a cup is not an acceptable delivery method. Liquid consumed must be at a reasonable rate. I already talked about that, of 8 ounces every 30 minutes.

And there's guidance in the regulatory guide of not urging the individual to drink water. The individual does not need to drink water. You can't make the individual drink water.

In addition, there's guidance in the regulatory guide, what if the individual wants to drink more than 8 ounces of water. Similarly, the guidance says if the guy is definitely famished for water, the guidance still is 8 ounces every 30 minutes.

What's new here is that there's guidance on when do you let the individual try to provide a specimen. So it's item number 6 on this page. It is about 15 to 30 minutes prior to the three-hour hydration period. You should inform the donor of the

inevitable end to the hydration collection process, which occurs at three hours.

At three hours, the donor should be provided one last opportunity to provide a urine specimen. There's no guidance on plus or minus a minute here and a minute there. It's three hours. Allow the guy or gal to provide a urine specimen. Let them go try to urinate. So there's no specific guidance on there.

MR. DIPIETRO: This is Nick with First Energy. That's a question that I was going to bring up in this section because some people like oversight say it's three hours, it's a hard stop. It's done.

And I know we've had over the years, after the three-hour period then you're explaining to the individual, hey, if you can't come up with a reason why you can't provide, it could be a subversion attempt. You could be permanently denied. Here's all the things that you have to do as far as going to the urologist or the specialist or whatever.

And then during that process and maybe the lightbulb comes on. And these are like 25-year employees. It's not somebody that you would suspect of trying to subvert the process, but anyway, all of a sudden the light comes on. They say hey, can I try

now. And we talked to our MRO, and he said yeah, let them go ahead and have a crack at it to see if we can get the volume that we need.

So that was my question. You're saying plus or minus a couple minutes, but you know, it could be 10, 15, 20 minutes after the three-hour period.

MR. HARRIS: So the guidance is at the three-hour point you give the individual the opportunity to go and give a specimen. That's what the guidance says, okay. The rule says three hours, a hydration period of three hours.

What we're saying in the guidance is at three hours allow the individual to try to urinate again. It's not three hours and 10 minutes. It's not three hours and 15 minutes. It's at three hours. And it's a balance. We have a subversion rate that Brian was talking about that's been increasing over six years.

We're concerned about subversions. However, on the other hand, we give the individual an opportunity to provide a specimen at the three-hour point, and that's what's in the guidance. Okay? Physiologically, three hours is more than enough time. Typically two kidneys will produce about 550 milliliters per day.

When you divide that over the day, that's approximately 50 milliliters per hour. So in three hours, the individual has accumulated 150 milliliters of urine and a normal bladder is sized to hold 150 milliliters. It's probably up to 400 milliliters.

So the three-hour hydration period was looked at in the issuance of this guidance and that guidance is contained in the draft regulatory guide.

Do I have any questions on monitoring and hydrating a donor? I know I went over that relatively quickly.

It will be -- the guidance says that licensees and other entities shall have this proceduralized. We're not telling the licensee or other entity how many individuals a monitor can monitor at the same time. That's going to be a Fitness for Duty program manager determination.

The communication protocols is going to be a licensee determination. There's a lot of other things that we're not going to provide specific guidance on because it's not necessary. But if you do read the draft regulatory guidance in this area and provide comments, they'll be evaluated by the staff.

MR. SCHNEIDER: So we're going to ask the operator. This is Stewart Schneider. Operator, does

anyone on the phone line like to ask questions or provide a comment?

OPERATOR: Yes, we have a question from John Nielsen. Your line is now open.

MR. HARRIS: Yes, John. This is Paul. Go ahead.

MR. NIELSEN: Hey, Paul. Since the new rule and we were instituting this, one of the things that we've always done here is that when we are providing the next 8-ounce bottle of water, we're removing whatever they have left.

The thought was we're not going to let somebody stand by and have an accumulation and then just guzzle it all. Like you're saying, here's a jug. Is that an expectation, or is that just a nice business case? I'm wondering is that something that would be added to reg guide as to how you control the intake of water.

MR. HARRIS: The draft regulatory guide parallels rule language within the rule which is for example the water should be provided at a reasonable amount and controlled by the collector or the monitor in this case. And the guidance provided is 8 ounces every 30 minutes. If the individual does not finish his bottle, and there's some left over, we provide no

guidance on what to do with that because we have capped the limit at 40 ounces. Does that answer your question, John?

MR. NIELSEN: Yeah, I was just wondering does that allow the possibility that at the two and a half hours, they suddenly consume 40 ounces, which would, I mean physiologically we're probably talking about they're going to have a dilute anyway, but consuming that much at one time, would that cause us to have a dilute at that point?

MR. HARRIS: No. 40 ounce ingestion of water over a three-hour period is not going to dilute your urine specimen metabolites to such a point that we have a regulatory concern.

MR. NIELSEN: Okay.

MR. ZALESKI: And honestly, if someone delays consumption of water to the very end, they're kind of hurting themselves because their body can't produce urine that quickly, so if they waited until 2 hours and 58 minutes and guzzled the 40 ounces, they did not give themselves the opportunity to produce that urine So it's not in their best interest to do that.

MR. HARRIS: Any other questions? Okay. Next slide, please.

MR. SCHNEIDER: Thank you.

OPERATOR: I'm showing no further questions at this time.

MR. SCHNEIDER: Thank you.

MR. HARRIS: This next slide is dealing with the use of mirrors during the directly observed collection process. The proposed rule would add the following sentence to 26.115(f)(2).

A reflective mirror may be used to assist in observing the provision of the specimen only if a physical configuration of the room, stall or private used for urination is not sufficient to meet the direct observed requirements.

The use of a video camera to assist in the observation process is not permitted. So what we tried to do is try to make it very short, very explicit, provide sufficient information to the licensees to implement this provision.

However, we elected to provide guidance as well, and if we can, let's move on to the next slide. So the preferred methods remains to directly observe, for the collector to directly observe the urine stream leave the body of the individual.

We're enabling the use of mirrors in the collection stall and we're allowing these mirrors to

be either temporarily installed or permanently installed, and that should be established by the use of procedures and sole discretion of the licensee, the FFD manager.

Toilet mirrors, handheld mirrors and two-way mirrors are not allowed in the draft regulatory guide. Okay. We do maintain a reasonable expectation of privacy, and those types of mirrors, in our opinion, do not provide a reasonable expectation of privacy even though it's a directly observed collection. There are limits to what we want to do here.

We are enabling guidance, publishing guidance to enable an observer, collector to incrementally adjust a mirror. Okay. So if the mirror is temporary, if the mirror is permanent, it's got to be mounted on a wall.

If that mirror has a mechanism on it to allow incremental adjustments because it's on a pivoting type of action for like a hinge, the collector observer can incrementally adjust that mirror to facilitate the observation of a direct observed collection. And we're enabling that through the regulatory guide.

Again, what we said on the previous slide

is that this guidance is based upon the size and spatial relationship considerations. If the size and spatial relationship considerations between the observer, the donor and the size of the stall do not facilitate a direct observed collection, the licensee has the opportunity to provide a permanent mirror or temporary mirrors on a case by case basis.

So let me explain that a little bit more. Licensee decides not to install mirrors for any direct observed conditions. However, one case comes up in the future where the individual cannot be directly observed. The Fitness for Duty manager can on a case by case basis implement a temporary mirror to facilitate that collection.

Scenario 2, licensee decides or elects to install all mirrors or mirrors in all their collection facilities to subject individuals to the same requirements all the time to have mirrors in the collection facility.

There's benefits to doing that because the individuals at your site now know there's mirrors in your collection facilities, and it doesn't surprise them. It also provides consistency with the direct observe in that the individual is subject to direct observed are not also playing under the same ballpark

as everybody else. So there's benefits to both ways.

We are not going to dictate whether or not these temporary mirrors on a case by case are permanent. It's going to be a licensee decision. There's guidance also in the draft regulatory guide on the very rare situations where even with all of the considerations of a direct observe collection and the use of mirrors, that possibly we still can't do a direct observe collection.

The two examples that we provided in the slide, inside the guidance is a case where an individual is significantly obese or the individual has a medical appliance needed for urination. So there is guidance in the draft regulatory guide on that as well.

That guidance quickly transitions to incorporation of a concept of a medical condition that needs consideration. Okay. So if you have a medical condition that needs medical consideration during a directly observed collection, the guidance says get the FFD manager involved and the medical review officer involved to make a medical determination in how best to collect the urine specimen even though it is a directly observed collection.

And that paragraph within the draft

regulatory guidance talks about the use of funnels. On one occasion on operating experience that condition came up. If the funnel is used, the funnel is considered to be part of the collection device and consideration has to be made for the temperature of the urine.

So if the individual elects to use a funnel and the temperature of the urine goes outside the specified range, that is a consideration that the donor has to take into account because we did not relax requirements for adequate -- for acceptable temperature limits. Do I have any questions on that? Any questions on the phone?

OPERATOR: I'm showing no questions at this time.

MR. HARRIS: Okay. The third and last item I'd like to discuss on the draft regulatory guidance is paralleling what Brian was talking about earlier regarding the invalid pH of 9.0 to 9.5.

On this slide here, I just provide that background on what is pH and when is pH determined and what is normal pH. What is a normal pH in urine? I don't intend to spend any time on this. It's just for background information. Next slide, please.

Part of the discussion on pH is as we

already discussed earlier is that pH is used for a number of areas within the Part 26 drug testing requirements. And again, this slide is background demonstrating where pH is used for adulterated and invalid specimens. Next slide, please.

What the proposed rule does is provide guidance to the medical review officer on the evaluation of pH when it's greater than 9.0 but less than 9.5. There are no changes to the adulterated and invalid testing result criteria.

The new 26.185(f)(3) provision for the review of that, invalid test results states that the medical review officer shall consider whether there's evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for a pH value in the range.

So the MROs give you the discretion of looking at time and temperature and both. If an acceptable explanation exists, the MRO shall report a canceled test result to the licensee, cancel the test result and direct the licensee to collect a second urine specimen from the donor as soon as reasonably practical. Next slide, please.

There are two major areas where a medical review officer can seek this guidance. One, of

course, is in the draft regulatory guide. In seeking that, of course we mentioned earlier that the medical review officer will discuss with the donor whether or not there is an acceptable medical explanation for a high pH.

There are situations where an individual can give a high pH. Let's say they have a urinary tract infection. That's probably the easiest one to talk about. If that's the case, then the medical review officer can evaluate that situation.

If there's not an acceptable medical evaluation, then the recollection should be done as soon as reasonably practicable. However, the MRO still has to evaluate the high pH. So on the next slide, we provide guidance on that.

Number 1, we say during an elapsed time greater than 48 hours consider canceling the test and requiring a second unannounced collection not observed. So we put a time limit on 48 hours. So that's a time limit between -- a time limit of -- from collecting the specimen to collecting the specimen.

The second one is for elapsed time between 24 and 48 hours, a little bit shorter, when the urine was transferred or stored at a temperature greater than 98 degrees Fahrenheit, consider canceling the

test and requiring a second unannounced collection.

And the third one, during an elapsed time of less than 24 hours, considering canceling the test and requiring a second unannounced collection on a direct observation. So this is the guidance we're providing.

Now this guidance is based upon a number of sources. As I mentioned, HHS guidance in their medical review officer guidance book and also we use the medical review officer handbook from the American Association of Medical Review Officers. It has that list down there under the asterisks.

And does anyone have any questions on this? Any questions on the phone? Okay.

OPERATOR: I'm showing no questions at this time. Oh, I'm sorry. John Nielsen has a question. Your line is now open.

MR. HARRIS: Yes, John. Go ahead. John, it seems like you're on mute.

MR. NIELSEN: Okay. Can you hear me now?

MR. HARRIS: Yes, sir.

MR. NIELSEN: Okay. For the three examples given for the MRO guidance. The first one is excessive time. The second one is it seems to be conditional. If it's between 24 and 48 and there was

a heat element. I'm just wondering is there ever a timeframe, because the third one it just talks about less than.

I was just wondering, for the third one if it was less than 24 hours, however, it was extreme heat could that, according to the MRO handbook, could that have also contributed to it. Is that something else that's an add on to number 3.

MR. HARRIS: The NRC staff did not do an independent assessment on urine temperature profiles with respect to time and temperature. What we did was parallel the guidance from what we consider other experts in this field. That's why we referenced the American Association of Medical Review Officers and also the HHS guidance.

I am sure that there are a number of scenarios out there in which we could saw including your example there where the pH has significantly increased over a very short period of time, and that was not one of the scenarios that I observed in any of the guidance documents that I reviewed.

MR. NIELSEN: Okay. The only reason I'm bringing it up is that we continue to hear about kids dying in cars or dogs and so forth because of the escalation inside the vehicle so quickly. And I'm

just wondering with the couriers parking their vehicles in the sun and so forth, are they contributing to this percolation, if you will.

MR. HARRIS: Yeah, so the guidance in both the HHS guidance and the NRC guidance and the draft reg guide provide some suggestions to the medical review officer to interview individuals not only at the power plant but also at the transportation company moving the specimens.

It also enables the MRO to query the laboratory whether or not any other specimens in the same package had the same increase in pH. So the guidance is there for the MRO to do a quite thorough review with other individuals to assess whether or not it was one specimen or multiple specimens and whether or not the situation on the vehicle contributed to it because it would not be likely in my sense that only one specimen out of 20 in a van that's been exposed to extreme high temperatures is going to have a high pH whereas every other specimen there is going to have a reasonably equivalent pH because we don't assume that everyone has bacterial concentrations inside their urine that increases pH at such a high level in such a short period of time.

MR. NIELSEN: Okay. Thank you very much.

MR. HARRIS: And that's my presentation on the draft regulatory guide. The NRC staff would look forward to your comments on the guidance, and I thank you very much.

MR. SCHNEIDER: Do we have any questions? This is Stewart Schneider. In the room, comments? Operator, does anyone want to express a comment or discuss something further?

OPERATOR: I'm showing no questions at this time.

MR. SCHNEIDER: Thank you. We'll now move on to the regulatory analysis. Brian Zaleski will discuss that.

MR. ZALESKI: Fred, would you like to join us at the table?

MR. SCHOFER: I'm good.

MR. ZALESKI: So I was fortunate enough to work with Fred on this analysis, which is not typically the case with a lot of the regulatory analyses. Fred's shop does them entirely on their own, but I did assist with this one.

MR. SCHNEIDER: That's Fred Shofer.

MR. ZALESKI: So he's given me the option of presenting this information.

MR. SCHNEIDER: No, it's Fred Schofer.

You only said Fred.

MR. ZALESKI: Oh, I'm sorry, Fred Schofer. He introduced himself.

MR. SCHNEIDER: For the record.

MR. ZALESKI: I'm sorry, Fred Schofer, NRC. So regulatory analysis can be very complicated and clearly trying to evaluate the benefits and impacts of the proposed rule with incomplete information makes things difficult.

So what's important about this is that we're very transparent in terms of the assumptions that we make to come up with the results, the data sources that we use and where we come up with our assumptions about these things.

This analysis was based on NRC data in large part. We evaluated six years of licensee testing data. And we adjusted that data for any site that was in decommissioning or projected to be decommissioning by the time of the final rule, so we pulled some of that information out of the analysis.

We also used the six-year period of time because it would be -- it's not very telling to use one year. A year does not make a trend or something similar -- Barry Sample from Quest Diagnostics always says that when he's talking about his data.

So you need a time series of data to evaluate with a reasonable level of certainty of the variability. And we model that variability by doing sensitivity analysis or uncertainty analyses. How we model changes in detection for the existing panel of drugs?

So we looked at other federal testing programs and detection changes that they had after they implemented the guidelines changes. As I said before, earlier in the presentation, the largest civilian testing program in the United States that tests similar types of workers to those in the nuclear industry is the Department of Transportation.

They test 5 to 6 million people a year. A good majority of those tests are coming from truck drivers, Federal Motor Carrier Safety Administration. We eliminated those from our sample to be conservative because the data suggests that there's a higher rate of drug users than what we see in our populations.

And we limited our data to Federal Aviation Administration, so that's pilots, that's security at the airports to transit operators. And also to Federal Rail Administration, those operating heavy rail. We looked at the results for those

populations in only the year that the testing change is implemented.

So one thing we wanted to control for was these populations may have different drug using behavior, but if we only looked at the change from one year when the panel changed, we would be limiting how much variability in that population. Are they using more drugs? That change is not going to occur that fast in one year or they're going to limit that much.

We also looked at other data sources that support similar jumps in detection for amphetamines and cocaine in the year that they were implemented. So I mentioned this also before. Quest Diagnostics, they're an HHS-certified laboratory. Some of our licensees use them.

As one of their business model or public service, they publish their test results data on an annual basis and it's one way of us looking at unverified, meaning non-MRO reviewed test results in federal workforce population.

And that includes anybody that's from the DOT or federal employee that's tested by Quest laboratory and then general workforce, which is any employer that's using them to do testing. And so you can get some information. And it's helpful

information because there's not a lot of information that you're getting in real time from large samples of populations to demonstrate effectiveness.

So we looked at that data, and then we looked at what our positive rates were for amphetamines and cocaine and modeled the changes based on what DOT saw. So that's how we came up with our methodology to adjust for detection improvements.

So we talked about estimated 10 to 12 percent increase in detection from the panel changes. That was in part based on what DOT saw in the jump in detection applied to our existing positive rates for amphetamine, methamphetamine, and cocaine.

And then there are these new substances that we haven't tested for, so for instance 6-Acetylemorphine. That's the heroin metabolite. In our program, again we only test for that if someone is also positive for morphine.

Well, we have no real data to understand if you were screened for that as well. So we looked at the same DOT populations, FAA, FRA, FTA and looked at what their positive rates were for four years. So we took an average of each positive rate. That was the best data that we had available to model what we potentially could see in our population.

And then like I said, we also did sensitivity analysis, which means we had that average and then we had a lower point and a higher power point and saw if that shifted the needle much. Did we jack up costs a lot because we detected more or less?

I also mentioned earlier in our meeting we had a number of public meetings over the years starting back in I think 2009 timeframe when we first started talking about the guidelines and understanding what impacts they may have on the program.

In doing those meetings and in conversations subsequent with many stakeholders in the room and not we were able to formulate some of our assumptions in terms of cost.

For instance, when we formulated the cost of conducting a test at a licensee testing facility, we in fact reached out to the four different licensee programs that used licensee testing facilities. And we took their data and came up with an estimate.

So that was formulated based on industry-specific data. And it's a small number of people. And so therefore, Howard was correct before to point OMB requirements. We can't reach out to too many entities and ask the same questions. But in this case it was only a few, so we could do that.

So we tried the best we could to identify data sources internal to the industry because that's the most telling, right? It's our information and it would be most beneficial because it's the employees that are subject to testing. And when we couldn't do that, we looked for the available resources and we used conservative assumptions, meaning we estimated on the low side of things in terms of the benefit.

And the last part on this slide that I want to make sure that you're aware of. So this document, it's a quite sizable document, and I believe it's a very transparent document in terms of giving you each of the assumptions we use, the data source, where it came from and the reference for that so that you can challenge an assumption if you believe we are underestimating the cost or we were completely off in how much you pay a particular type of laborer or workforce. So those assumptions are there for you to review in the document.

So that's some of the highlights. The costs and the benefits of this rule are primarily related to the changes in the testing panel. Our detection improvements and our significant improvement in public health and safety and common defense and security is that we identify additional drug users and

we remove them from the population that's working at a power plant or we prevent them from working at a power plant or a fuel cycle facility so that they can't harm -- they can't be impaired or not do their job as they're required to do. Okay. Next slide.

MR. SCHNEIDER: Just Stewart Schneider here. Here's the document.

MR. ZALESKI: Yeah, and it's on the regulations.gov website.

MR. SCHNEIDER: Anybody can look at it.

MR. ZALESKI: Yeah. It's referenced in a number of places. If anybody wants it, I'm sure the public can reach out to any of us. We're listed in the Federal Register notice, Paul Harris, Brian Zaleski and Stewart Schneider.

Second page of this is -- so affected attribute, what is an affected attribute. That's regulatory analysis handbook lingo. So the NRC -- and Fred, correct me on this one. We're required as an agency to review a rule based on impacts on these affected attributes.

So what you do is you look at each of the affected attributes and you make an assessment of whether you believe the change in the rule will impact those areas. So there were three areas where we could

quantify benefits and costs. So quantify means we could put a dollar figure to those impacts or benefits, those costs or benefits.

Those were industry implementation, industry operation, and NRC implementation. So industry implementation is what are you going to do when you have to change to align with this new requirement, change your contracts, update your blind program, train your people.

Industry operation is what is going to occur once this has been implemented. You're going to get more positives on an annual basis. So you're going to deny more people, and it costs you money to deny people and add their information into PADS and what not. So those are more industry operations.

NRC implementation of this rule is to do this, what we're doing right here, a public meeting, and to do the final rule and the regulatory guidance. And there's a cost associated with that. We don't directly bill you. It's an overhead of the Agency, but that's what that cost means.

There are also a number of attributes that we could not quantify. And it's difficult, but we couldn't reasonably quantify them. So what's that mean? It means that we're not going to try to come up

with assumptions without having reasonable information because that's not very helpful and it's not supported by, you know, the rigor of a strong analysis.

So for instance, public health accident, so if an impaired individual caused an accident at a nuclear power plant and it affected public health, that's an attribute that may improve. You may get some benefit by improving the testing program.

However, we have no ability to quantify that benefit if we do. So we just qualitatively discuss it. And the regulatory analysis has descriptions of each of these topics, public health, occupation, public health accident, occupational health accident.

Did somebody fall at the site because they're impaired and break their ankle, or is somebody getting dosed, offsite property damage from a release, onsite property damage, regulatory efficiency.

Well, we're doing a bunch of changes to the rule, right? We're adding definitions. We're trying to improve the clarity of our rules, so you're not calling Paul Harris or Brian Zaleski and ask what does this mean.

You're not spending four hours trying to figure out whether something's reportable to the NRC

or not. So in improving how our regulation works, there is some benefit if you encounter a need for a particular provision. But we can't quantify that. We don't know how frequently it occurs. We don't have any information to support a calculation that way.

The last one is these other considerations, and there's a number of them. There are positive aspects of testing your workforce. For instance, you may have lower insurance rates because you test your employees, and they're less likely to injure themselves and so therefore, you might have lower workman's compensation claims because you have a strong Fitness for Duty program.

We don't have information that we can use to say well, you're going to get a decrease of 25 percent in your insurance premium because you test for these additional drugs. We don't have that kind of information, nor do we have information that the public might improve their confidence in the regulator and in the industry by having more stringent testing because we're testing for other drugs that are used in society.

That's the affected attributes part. So once you go through and you identify the affected attributes, that's sort of like a screen level of

review. Then you start putting the rubber to the road and you start identifying how you're going to calculate up specific benefits or specific costs.

Okay, benefits of the proposed rule. The number one benefit of this proposed rule is the estimated 10 to 12 percent increase in detection that we are modeling based on what I described before in terms of detection improvements from the DOT workforce and also in our own rates, our own positive rates.

MS. MONTGOMERY: Brian, can I ask a question?

MR. ZALESKI: Yeah. Sure.

MS. MONTGOMERY: This is Cheree Montgomery from Southern Nuclear. When you talked about doing the comparison of DOT to ours, I heard you say earlier that the DOT information was prior to MRO confirmation. Is that the way ours was when you compared it, or did you just look at what was at the lab itself?

MR. ZALESKI: So let me clarify. So DOT, there's two different data sources we looked at. One is an unverified dataset from DOT, it's laboratory testing data which is not like our results which are verified. That means all of our rates are verified positive, all from performance testing data that we

get on an annual basis.

We also chose to use the DOT's data on verified test results. So it's a subset, and that was the one for FAA and Federal Transit Administration. So those were verified results as well. So it's a more conservative way.

Because for instance, amphetamines, you can get a prescription for an amphetamine because you have ADHD. Well, we don't want to make an assumption that all those are illicit drug users because they're not, right. They have a prescription for them. So we want to make sure we're adjusting for that and only basing what we think is going to be improvement detection on the verified result.

MS. MONTGOMERY: Okay. Thank you.

MR. ZALESKI: Hopefully that helps.

MS. MONTGOMERY: It did. Thank you.

MR. ZALESKI: So one of the other benefits of this proposed rule is coming into closer alignment with Part 26 with HHS Guidelines, being mindful that of course HHS has subsequently expanded their panel further as we've talked about before for 2017 guidelines.

But those 2017 guidelines do not change the fact that the cutoff levels for amphetamines and

methamphetamines are lower. They're the same in the 2017 guidelines as they are in the 2008 guidelines, for example.

One of the significant benefits that we see, we believe is supported in this proposed rule is that we've had trending over time in several areas. We've seen increasing amphetamine and methamphetamine positive results.

And we've also seen a high prevalence of subversions, high prevalence in terms not only of the number as I mentioned. This past year in 2018, 30 percent of the drug testing positives in the industry were subversion attempts that were identified.

In the dataset we looked at, it was closer to 20 percent. So our analysis would be more benefit to this rule now because more people are cheating in the data subsequent. So we modeled data from 2009 to 2014. We have data now in house for 2015, '16, '17, '18. So we have that data. We would adjust that data. If we move forward with the final rule, we would have a final regulatory analysis that would use updated data. Correct, Fred? Yeah.

MR. SCHNEIDER: And just one comment. The reason it's that time period is because the package provided to the Commission was developed in the 2014,

'15 timeframe and we did not add later information once it went out to the Commission.

MR. ZALESKI: Right. The Commission had this package for about two years before they were able to make a vote on it. And so therefore, there's nothing really you can do to a package once it's there before a vote.

I mean you could pull it back and adjust it, but we didn't see any differences in the trends other than we'd get more benefit from the rule because we have higher rates now. Same thing with amphetamines, the rates.

We took averages over a period of time and then we did sensitivity analyses, a lower rate, a positive rate to see how it affected the benefits. And the trending on amphetamines continues to go up. I've shown it at a number of industry conferences as well as at the Drug Testing Advisory Board our substance detection over time. And cocaine has been trending downward and amphetamines have been trending upward.

And over the past five, six years, both of those substances are about the same. They're roughly around 10 percent of our positives. So it's one stimulant versus another. Cocaine is an illicit

substance under most circumstances. Occasionally, it's used in a surgical procedure.

Amphetamines is a prescription drug, but it's also illicitly used. And so therefore because we're seeing prevalence in subversion attempts and we're seeing increases in the drugs that we're modifying, the testing panel where we believe that we're addressing a trend. And so that benefit is a strong one in our mind.

If we didn't have anybody using amphetamines and we never had a positive result in the NRC workforce, it might be a different conversation we'd be having right now because if the population doesn't use the drug there's no benefit, right. It's just a cost at that point.

I mentioned this earlier in the day. The Part 26 testing program is a proactive testing program. We want to detect drug use and deter drug use. We want to detect before people are granted unescorted access to licensed facilities.

And that's true that there's in our test results since 1990 roughly 68 percent of positives have been identified at pre-access testing. So we screen out 68 percent, two-thirds of violators of the FFD testing protocols are on pre-access.

Interestingly, the majority of subversion attempts are also at pre-access testing because it's a predictable testing event. People know. They can prepare for it. When I got my random test two weeks ago, they told me to go to a random test. I couldn't prepare for that, but when I'm getting hired I have the -- I know that I'm going to be subject to a test as all the folks in your industry do. So they can prepare, so we do see that.

Averted training costs. This is something that we believe is a benefit of the program. Since we identify so much, so many users at the pre-access testing stage. If you identify a drug user and they test positive before you complete training of them, then you would not be expending resources on that training post the positive result. You're getting a savings there.

So we modeled capturing some of that benefit. That would be an area to review in the regulatory analysis which I believe that those assumptions are consistent with your experience. We didn't assume every licensee incurred a benefit or recognized a benefit and incurs a cost, but we did estimate a decent number of licensees would assume some benefit for a portion of training that was not

conducted on an individual.

Okay. Costs of the proposed rule. So there's two types of costs. There's the one time, that's the implementation, and then there's the operating cost annually. So the one-time costs, as I'm sure you're all aware because you're all administering the FFD programs for your sites, you're going to have to revise your policies and procedures.

You're going to have to update your contracts with your laboratories and/or your blind performance test samples with suppliers. I know you have to have contracts with your labs because we have that in our rule requirements. You may or may not with your blind specimen providers.

If you're a licensee testing facility, and I said there are three sites that still have licensee testing facilities, there are some additional activities that they're going to have to do because they're going to have to train the technicians that are conducting the test.

They're going to have to get validation on their initial test assays. It's a little bit different when you're talking about an HHS-certified lab because they're already doing this testing. Their assays are in place. They're already validated. The

NLCP has validated them. So it's basically they change the cutoff level and you're good to go there.

Interestingly, in terms of the modeling that we did, we believe that 85 percent of the one-time cost is going to be associated with actually training employees on the changes to the rule primarily because you have to give everybody information on the changes.

That's an assumption that you should take a look at, too, if you believe that to be inconsistent with your experience. On an annual basis --

MR. DIPIETRO: So Brian, conducting the employee training on a -- so that's basically your change management plan that you're communicating out to the workforce saying here's the new rule. Here's what it's all about. This is how it's going to impact you.

MR. ZALESKI: Yeah, like a read and sign or however you do it. We did assume that because this is going to take time to get in place and you're likely going to have an implementation time period, you could work it into the normal training. And there aren't that many changes here that are instructive to an employee per se.

We changed the cutoff level for

amphetamines is we changed the cutoff level, right. When you call the MRO, they're going to write something down. There's not a lot of complexity there, but you're required to inform them of these changes.

MR. DIPIETRO: For sure. And those of us that have bargaining units, that cutoff level will be a big deal. That needs to be communicated to those folks.

MR. GREER: Ken Greer from NFS. I guess what were the parameters that the average $5,031 per site was based upon because to me that seems low, really low. So can you explain that some.

MR. ZALESKI: Sure. So what we do is we look at the whole industry and we get a dollar figure for the entire industry and then we divide it by the number of sites. So we're mindful that the costs are going to be different for like a three-unit power reactor versus a fuel cycle facility.

Fuel cycle facilities don't have a lot of positives right. You just don't have that many positives compared to an operating facility. So there is going to be variability and part of the modeling was to look at that variability. But the average is just the total cost that we estimate for the entire

industry to comply with these requirements and then dividing that by the number of sites in the industry. Yeah.

MR. GREER: Okay.

MR. REED: Brian, Teddy from Duke Energy. Did the cost analysis include cost revision to FFD training and NANTel?

MR. ZALESKI: No. So industry, am I correct in understanding that you use NANTel primarily. Yeah, so we made assumptions in there, and you can look at what the assumption is. I think that our assumption is you would choose the lowest cost option for yourself in terms of informing people of the changes.

And it would either be that you would build that into your annual training requirement that's already in the rule. And because of the number of changes are very insignificant, it might not adjust that training per se, the amount of time that an individual is sitting in that training or you hand out a read and sign for them to review.

Now if those assumptions aren't consistent with what you're doing, that would be helpful information to understand.

MR. REED: Yeah, I think it should be an

analysis on what I would believe that test questions as well as the content for the required annual FFD training is going to have to change and be updated. And we as an industry, we do not own that per se. That's going to be an external entity.

MR. ZALESKI: Right. And yeah, Fred. You might have something to offer. I don't know exactly how we cost out when industry is choosing to use a representative to do training for them versus --

MR. SCHOFER: We can cost that out separately. That wasn't included, but if you provide some information, we can incorporate it into the final.

MR. ZALESKI: I'm not sure if that answers your question about that number.

MR. GREER: Well, I know with our side. I don't know about the other, the reactor side, but we would develop all of our training, FFD training in house and conduct it whether it's using CBT or some other format. I just feel like that number is pretty low for our side in comparison. I don't know about the other side. That's just something we'd have to work through.

MR. ZALESKI: Sure. Okay.

MS. YERKES: Brian, this is Mary from

Exelon. When you say medical review officer's time to evaluate additional positives, what percentage did you use because our MRO has anticipated a 40 percent increase.

MR. ZALESKI: So what we do is apply the amount of time that an MRO is typically going to take to review a test result. I don't remember if we have in there half hour or something like that. And we say you're going to get an additional positive.

You're going to spend that time because they have to talk to the donor. They have to look at it. And if it's a case of a prescription drug, we're adding more time. They're spending maybe an hour because they have to get a prescription and they have to validate and talk to the pharmacy.

So we did build that into our analysis. Now in terms of the 40 percent increase, if you have information that you can share how you came up with that assumption, that would be helpful to us in understanding whether we were costing this out correctly.

We understand that because some of these -- not all of these substances are Schedule I. So for instance, the ecstasy drugs, they're Schedule I drugs. There's no legitimate reason that a person has

that.

If you test positive for heroin, there's no call to the pharmacy for that one. It's a positive. But if you test positive for amphetamines, people can be using prescription drugs.

The assumptions that we used were based on talking to people and talking to licensees and how much time their MRO was reviewing, time spent talking to somebody and reviewing a test result. So we did build that in there.

MR. SCHOFER: Fred Schofer, one thing we did, we did look at high and low estimates or a high estimate and below what their MRO was saying, but the values we're talking about are the means.

MR. ZALESKI: And Ron maybe could offer some or maybe we could take a look at information if you have it, when the change was made. So if somebody's on a prescription drug for amphetamines, is the cutoff level change going to even impact them because the drug is in their body?

MR. FLEGEL: No. Actually, dependent. Actually I think 40 percent. This is Ron Flegel. 40 percent is relatively high. We looked at even when we had the synthetic opioids, it would be less than a 20 percent impact, 16 percent.

But we looked at all non-regulated testing as compared to federal testing to see the positive rate to verify positive or negative, so I think that's relatively high. But for the other specifically, you know, amphetamines, a lot of them are going to be reviewed. It's going to be one call to the pharmacy or the physician, the provider of the medical agency.

MR. ZALESKI: Right and I know in a lot of cases, licensees already have self-reporting policies in place, right, that individuals if they're taking a substance that could be impairing to them in the workforce, they are already disclosing that. So that may even reduce that review time.

I know for instance like in the military because they're giving them -- the soldiers are getting the drugs from the Armed Forces Medical, they already medically downgrade results before they even have a conversation. Of course we don't have that luxury here, but that's an example there. And yeah, I can try -- we can try to see if HHS has any data on --

MR. FLEGEL: We'll have the data that we provided in 2017.

MR. ZALESKI: Right. Generally, when you lower cutoff levels, you're expanding the window of detection. If someone's using the drug all the time,

it's going to be in their body whether we drop the cutoff level or not I think for this case, but we can double check that.

And yes, if your MRO team has reviewed these and believe a 40 percent increase in labor time to review test results is going to be the case, the information would be helpful in your submission so that we can understand that and model it correctly and make sure we're capturing the costs correctly.

MR. SCHNEIDER: Operator, do we have anyone else who would like to ask a question or discuss this further on the line?

OPERATOR: I'm showing no further questions at this time.

MR. SCHNEIDER: Thank you.

MR. ZALESKI: And again the annual cost, it's an average, but the reality is you know as well as I do if you have an outage, you're going to have more positive results because you're processing more people because again, two-thirds of the people that in the NRC testing program test positive on pre-access.

Likewise, you're going to see more subversions when you're pre-access testing people because that's when it generally occurs. So these costs are variable depending on your operating

environment and the year.

And it's also driven by drug use trends, right? Drug use trends are impacted by a lot of things. They're impacted by availability of the substances, the quality, the quantity. Are you near a main drug transportation interstate, you know?

Methamphetamine and cocaine have been upticking the last few years because the production has improved quite a bit. You know, we have pseudoephedrine behind the counter at the CVS because at one point meth was being cooked with pseudoephedrine, but it's no longer the case.

So drug use trends change over time and having a robust testing program means that we have scientifically valid measures for impairing substances that are used in prevalence, mindful that it's going to vary by year and by area of the country but that overall this was average cost.

And I should say, and I think we do on the next page, we looked at -- we modeled this for a 25-year period of time. So not only did we take six years worth of our own data, industry's data, and do sensitivity around that, which is fairly robust compared to prior analyses that we've been able to conduct. And that's because we have really good

information now.

We also looked at this over a 25-year period of time. And that's the next slide, which talks about the results. So when you see these rolled up costs, that's basically taking all the -- when we say burden, that's the cost that you're going to incur. Paul used that term before.

The one-time cost is $337,000 that we're estimating for industry to comply with implementing this rule. And then on an annual basis, it would be less. It would be $168,000. The net present value estimate is $2.4 million using a 7 percent discount rate and $3.4 million using a 3 percent discount rate.

What are these values? These are values that are required in the regulatory analysis handbook, and it has -- Fred, you can help me out with this one. It has to do with investing your money in a current activity versus it being somewhere else. So over time your money's worth less. Is that right?

MR. SCHOFER: It's a discounted cash flow analysis. We use 7 percent because of investment level of interest versus 3 percent, which is more government. So the 7 percent is somewhat equivalent to an ROE that you might be shooting for, for an alternate project.

MR. ZALESKI: Right, and so that figure, the way you can look at that is that's what we estimate over the 25 year period of time being the sum cost to comply with these rule changes.

And the annual cost -- the one-time cost is $337,000. The annual is $168,000 and those dollars are whenever we did the analysis. Yeah. So they'll be a little bit different when we do the final.

And I said NRC is estimating we're going to incur costs to produce the final rule to do this public meeting and then issue regulatory guidance. And that's on the order of $273,000.

This is a super high level of what we did with the regulatory analysis, and I encourage you to review the document if you have the capacity to do that because there are a lot of assumptions in there. And it would be beneficial to the Agency to have information to ensure that we're doing the right thing here.

And the last piece is just to talk about that backfit, talked about it before and issue finality. Part 26 is not exempt from the backfit rule, which means that in order for us to move forward with the rulemaking, we have to demonstrate that one, we're going to -- the rulemaking is going to result in

a substantial improvement to public health and safety and common defense and security.

And we believe that's the case through the increased detection primarily, the 10 to 12 percent increase. And we also think that the costs are low. That was the staff's position.

The Commission affirmed that by voting to move forward with the rulemaking at least to the proposed rule stage. And we -- most -- anything that was required in the rule is a backfit. That, by definition is a backfit.

There are voluntary things in the rule that are not a backfit, for instance, using a hydration monitor is not a backfit because you're not required to use a hydration monitor. You can continue your practice if you'd like to.

Do you want to use the six-month certification expiration on your blind specimen? You can continue to do that. You don't have to throw out your blind specimens you have in the freezer. So there's things like that. And that just gives you a little sense of where we're talking backfit or not.

Part of the significant improvement to public health and safety argument also is not only looking at are these drugs prevalent, meaning did we

get any positive results in the industry.

But also we looked at are these drugs showing up on random tests, on for-cause tests, on post-events, where are they coming from. And I think in the final rule stages we'll be even more -- I will be more able to drill further down because we have a longer time series of data from the electronic reporting system.

So I could tell you how many security officers tested positive for amphetamines, or was it a general maintenance worker. That's a different level of risk, right.

That's where we want to be as an Agency, move to risk informing our regulations the best we can. So I believe that we'll be able to build more of those analytics in the final rule stage if we get to that.

MR. SCHNEIDER: Earlier Brian, you said that if we change the rule, the final rule, to address 2017, you've got to meet the backfit for those changes. Can you discuss that a little bit further?

MR. ZALESKI: Right, so that gets back to the original two pieces, the two prongs or two legs of that stool. In order to meet the backfit rule, you need to demonstrate there's a substantial improvement

to public health and safety.

So if all the data we have says that there are no opiate users in our workforce, all I would be then doing would be imposing costs on the industry to conduct testing for additional opiates with a zero detection improvement.

And our general performance criteria, as I mentioned at the start of this meeting is providing reasonable assurance of a drug-free workplace. I would only hope that people applied to work at nuclear power plants that never used opiates or anything else.

So that would be one thing. We'd have to evaluate the prevalence and find information sources that were comparative to our workforce. And if the use rate was high, we already know that opiates are impairing depending on how you're using them.

If you're illicitly using them, you're not under any kind of medical professional's treatment, that would be an issue for sure. And then in terms of the cost again, that is the cost consistent with how much benefit we're receiving.

So for instance, the Commission voting to move forward with this indicated that our cost estimate was reasonable for the amount of benefit we were obtaining from this. That may not be the case

with other drugs depending on their prevalence. Does that help?

MR. SCHNEIDER: Yes. That actually clarified that.

MR. ZALESKII: And Fred, did I capture that correctly?

MR. SCHOFER: You did. We're looking at incremental costs such that if there was a single task that looked at a number of drugs and one of them is a drug that isn't prevalent, you know, the use is not prevalent in the industry because it's part of the same panel. There would be no incremental cost because you're just still testing for it.

MR. ZALESKI: Right. And here's another point I could make, too. So for instance, say you talk to your laboratory, and they say oh hey, you know, for us to expand the opiate panel, it's really only going to be 5 cents a specimen because you have hardly any drug users, and it's a cheap test to do. And on occasion, yeah, you're going to pay more money for confirmatory, but it's only 5 cents.

So to improve our screening criteria to make sure that people who are applying for access to power plants aren't using opiates. It's only costing 5 cents. That might be worth it versus if the cost of

the test was $10 and you had no positives, that's a much bigger financial hurdle or burden imposed on industry where we might not get a benefit from them.

Hopefully, that's helpful, too. And a lot of this comes down to the availability of good information and the conversations you may be able to have with your laboratories in terms of pricing. Nick, it sounds like you have some operational experience from your corporate fleet testing program that, you know, may be beneficial in terms of what the costs might be.

MS. HOGG: Brian, Lisa Hogg with NEI. Did you consider the impact to blind specimen testing in your cost analysis?

MR. ZALESKI: Good question. So yeah, I know that in the relatively recent time period and I can compare that in terms of this rulemaking time period, relatively recent time period.

Industry has been looking at trying to reduce the number of blind specimens that are submitted to laboratories, and it's primarily because fleet programs use the same laboratories for all their different sites.

And personally, Brian Zaleski and Paul Harris, I can speak for him because we've both said

this. That makes sense because you're challenging the laboratory with the same testing panel and you're providing enough quality assurance to ensure that they're testing specimens directly.

However, we did not at the time that this rule was before the Commission, propose any changes to that. That just wasn't a dialogue we were having with anybody, but I believe it does make sense. Howard, you can comment on this. We haven't proposed any changes there, so if you submitted a comment, that would be --

MR. BENOWITZ: Are you talking about whether we would have to re-notice?

MR. ZALESKI: Yeah. So it's outside the current rulemaking process. You're welcome to submit the comment, and if there was validity to it, then --

MR. BENOWITZ: We'd have to -- we welcome comments on anything here that we've said. If you want to -- one of your comments is to propose something that we did not propose, we will have to consider whether or not we would have to re-notice, issue another Federal Register notice to give the public an opportunity to comment on it.

It's not automatic. It's not a given that if you propose something that we would have to do it.

We would have to assess whether or not we would have to go off a comment. It's very fact-driven, you know, what we propose in our FRN.

What you're suggesting we do, that might be different. Just because it's different and we didn't propose it doesn't mean that we have to re-notice it through the Federal Register. Just again, it's very fact specific. I don't want to temper your work, your suggestions. We want to hear anything you have.

MS. HOGG: Well, it wasn't really a suggestion. I was just asking did you consider the costs of --

MR. BENOWITZ: I was talking more generally.

MR. ZALESKI: Yeah. No, to answer your specific question, no, we did not evaluate any differences on the blind program.

MR. FLEGEL: Just, Ron, I want to make one comment. Since you put the proposed rule forward to the Commission, since that time when DOT implemented their changes in 2018, they have discontinued the blind proficiency testing program, which is similar to that.

We did not really concur with that as a

federal agency because now there's laboratories that are actually having no proficiency samples at all. And that's concerning because when we go in for a laboratory inspection we're six months out.

So if there was a problem six months ago, there's a number of specimens that went through the system. So cautionary note, I think to eliminate proficiency testing, especially blind proficiency testing samples, would be a problem.

MR. ZALESKI: Yeah, and I think from what my understanding of what I've heard in the conversation before, folks aren't recommending to eliminate the process. It's just to reduce the number from a fleet program.

You had six reactor sites, and they're all going to laboratories A and B. Do you need to challenge them beyond the minimum? We have a minimum requirement in there on a quarterly basis, so.

MR. FLEGEL: And that is one thing that we allow federal agencies, if they cross that over to my laboratories, they could take the percentage of blinds being set from other agencies. So they don't have to submit it to us.

MR. ZALESKI: Right, and that is exactly what you're basically proposing, and what I

understand. And Howard, just one more question on that. So the process would -- it's not to re-notice the existing proposed rule. Would it be a supplemental or could it be if that occurred?

MR. BENOWITZ: If we had -- Howard Benowitz --

MR. ZALESKI: I know we're speculative in all this.

MR. BENOWITZ: If you had to re-notice, it depends. I mean all right, say it's one aspect that we want to maintain our rule -- this rule. We just want to add something to it, and we want to give the public an opportunity to comment on our new proposal.

So it would be a supplemental proposed rule, meaning supplementing the current proposed rule that is currently out for comment as opposed to something, a brand new rulemaking. This would keep it within this particular Part 26 ruling.

MR. ZALESKI: And I believe that's -- yeah, that's everything that I had on the backfit analysis and the regulatory analysis.

MR. SCHNEIDER: Now it's time for -- I'm Stewart Schneider, your rulemaking project manager, the open discussion and question section. So we'll start first in the room. This is open to anything

that was discussed at this meeting.

MS. HOGG: Well, Lisa Hogg from NEI, we do appreciate this open dialogue we've been able to have today and the process you have to get more clarity and to understand, especially given the comment period to review and provide, you know, helpful comments. I mean we do appreciate this forum.

MR. SCHNEIDER: By the way, you can see the comments that people submit on regulations.gov. So once someone submits it through that process, we process it inside, you know, see it up to that point until we make it public on regulations.gov. But they will be up there, so you can see how other people are commenting during the time you're putting your comment together.

MR. ZALESKI: I will say in reviewing the comments from the prior rulemaking, the 2008 final rule, public comment definitely changed the outcome of the final rule. There were a number of very, very persuasive comments in there that changed positions in that rulemaking, in the final rulemaking.

And we're obligated to review these comments and to take them seriously, and so it's an important part of the process. And we encourage people to submit feedback.

MR. SCHNEIDER: No further comments?

MR. DIPIETRO: No, Nick with First Energy, just one comment. I appreciate the guys from HHS being here because they always bring so much to the table. It's just nice to have them in the room once in a while. So thanks, appreciate it.

MR. FLEGEL: And I actually want to commend NRC for the proposed rule changes. And I think as an overall for all federally regulated testing, I think it's a huge benefit. I think Nick spoke to the fact that if you consolidate, it might be actually a cost benefit overall for the programs, so.

MR. HARRIS: Stewart, I want you to clarify whether or not the individuals who made public comments during this session also have to provide written comment on what they stated, or is their public comment part of the record you might say?

MR. SCHNEIDER: So it is part of the record as far as the transcript goes because that's why we wanted the transcript. As I said earlier, we can consider what was stated in here as part of the development of this final rule. It is not an official comment.

MR. HARRIS: Not an official comment.

MR. SCHNEIDER: Meaning that for an

official comment, it has to be submitted through the process as identified in the Federal Register.

MR. HARRIS: And it's addressed.

MR. ZALESKI: Yes. We're not formally addressing it.

MR. HARRIS: Okay. Thank you. That's exactly what I wanted to say.

MR. ZALESKI: I had to get the word formally out.

MR. HARRIS: I think that's important because during the meeting today there's a number of examples where licensee's set specific data and then operating experience. Ken mentioned some and Mary Fran, you mentioned some as well.

And it's important, and Brian harped on it a number of times today to hear those comments again in writing with some documentation such that we can evaluate it. And I'll bring it forth to our management whether or not we want to make proposed changes to the proposed rule.

MR. SCHNEIDER: Yeah, and another reason why we transcribe today's meeting is because of the length and the breadth of the topics being discussed.

It would tie one of us up on the staff to have to summarize it and take the notes, whereas we

now have an official record that we can look at for developing the meeting summary as well as we can look at later before we finalize the rule, such as the information discussed on the regulatory analysis.

We now have that on the record. Are we finished in the room? Okay. Stewart Schneider again. Operator, is there anyone on the line who would like to ask a question or provide a comment?

OPERATOR: I'm showing no questions at this time.

MR. SCHNEIDER: Okay. Then we'll move on to some more procedural parts. So as I --

OPERATOR: We have one question from John Nielsen. Your line is now open.

MR. NIELSEN: I know that during this session, there's been a number of questions with respect to making changes that were not necessarily part of this proposed rulemaking. I know that a lot of these comments have been brought up because a number of us in the industry have looked at things and have had previous dialogue on it and so forth.

Just wondering, outside of like this session, how would we get those in front of the NRC, not necessarily just to Paul or to Brian but in front of the NRC for consideration for the next rulemaking?

MR. SCHNEIDER: This is -- Paul, do you want to? I will. Okay. So this is Stewart Schneider. One way you can do that is through a petition for rulemaking, and in Part 2 of our regulations is the exact process for submitting a petition for rulemaking.

MR. HARRIS: And that process needs to be followed in that if the industry or licensees desire changes to the regulations, we have to follow the rulemaking process.

Licensees have always had the opportunity to submit site-specific licensing exemptions and amendments from the requirements and they're free to do that themselves, but if we wanted to do a holistic change to the rule, it would have to be through the petition process. That answer your question, John?

MR. NIELSEN: Yeah. It does.

MR. ZALESKI: Or as Howard said.

MR. NIELSEN: One thing that the public meeting does, it formally brings comments forward and so forth. I'm just --

MR. ZALESKI: Yeah, John --

MR. NIELSEN: Will they send something in without having some conversation first with somebody just to see if it's even a possibility. So I guess

besides the rulemaking, formally making a note, how would we have any type of conversation about something?

MR. BENOWITZ: This is Howard Benowitz. We, as members of the government, are serving the public. If you have a question, you can call us, especially if it's outside the rulemaking process. I mean this is considered informal rulemaking.

I don't want to get too technical. I mean it's not like if you say something you're going to get in trouble or anything, but if you have a general question about something in Part 26, you can call Paul and Brian or email them and just say hey, there's this provision in Part 26. Here's what I'm thinking or here's some concern.

You can talk generically about it or whatever, just -- and you can have that conversation, you know, any member of the public can call a member -- can call one of us. I every now and then get a call.

MR. HARRIS: I'm going to build upon what Brian said. So we have an initiative right now. We're in a good place, you know. We haven't been in a good place, but now we're in a good place. We're developing a regulatory guide right now for the

industry.

It's still licensees' decision whether or not they want to voluntarily commit to a regulatory guide. However, this regulatory guide provides a framework by which we could answer questions into.

So for all these years we've done frequently asked questions and responded to members of the public and responded to the licenses in a manner that Paul and Brian and Howard made some magical decision that this is the good guidance to implement, we can now formalize that guidance until regulatory guide is to a NUREG.

So this NUREG that distinction 5040 is an excellent example on how we could address your concerns, John. And the process to implement this guideline or implement this regulatory guidance over the next year is going to be -- it's going to be informed by comments such as yours.

And once this Regulatory Guide gets published, now the NRC can go in and revise this guideline to incorporate other regulatory guidance that the industry desires.

MR. SCHNEIDER: Stewart Schneider here again just to reiterate what Paul said. If you look at the Federal Register notice, the action statement

is requesting comments on both the draft guide and the proposed rule, so we are asking for comment on both, not just the rule.

MR. ZALESKI: Right. And this Regulatory Guide. This Regulatory Guide is specific to the rule that we're proposing, and the guidance that's in it is specific to areas where we're changing things in this current rule. It's not beyond the current proposed rule

MR. HARRIS: Right.

MR. ZALESKI: And what Paul is saying is that if this rule is finalized and the reg guide is finalized, that would be one method to update guidance for the industry where we do not currently have a vehicle other than the FAQ process in posting those on our website or emailing them or responding to an FAQ.

The industry occasionally sends those to us as well, right. That's more of the informal, let's give you some more information about the rule, it's not very clear kind of thing versus structurally changing the rule, which is normally a rulemaking type of activity or a petition or an exemption, right.

MR. HARRIS: It's important to note that we have to stay on the path of this reg guide on being the guidance document that is before the Commission

right now, so we cannot change this regulatory guide right now based upon some other industry consideration unless it's associated with this rule.

So after the Commission weighs in on the final rule and final regulatory guide, then we can implement the subsequent changes.

MR. NIELSEN: All right, gentlemen. Thank you very much. Collectively, you've answered everything I could possibly think of. I appreciate it.

MR. HARRIS: Thanks for the questions.

MR. FLEGEL: I just wanted to make one comment. I'm not sure within Part 26, but within the mandatory guidelines, we basically have a natural outgrowth from comments in the sense that if you didn't change something in the rule, but it was a natural outgrowth from a comment, we are allowed to change that unless it's a significant change.

MR. HARRIS: Right. That's true.

MR. FLEGEL: So I don't know if Part 26 you can do that or not, but that is something within the mandatory guidelines.

MR. BENOWITZ: Howard Benowitz. Logical outgrowth.

MR. FLEGEL: Logical outgrowth.

MR. BENOWITZ: It's a doctrine, a legal

doctrine that yeah, depending on -- the proposed rule is supposed to be -- the final rule is supposed to be a logical outgrowth of the proposed rule.

It doesn't have to be exactly the same as the proposed rule of course. We're allowed to change it, just the change is supposed to be a logical outgrowth. So yeah, that's the test we would mention.

MR. SCHNEIDER: Operator, do we have anyone else on the phone line?

OPERATOR: Yes, our next question comes from Joshua. Your line is now open.

MR. ZALESKI: We're not hearing you if you're speaking. Are you on mute?

MR. SCHNEIDER: Operator, can you check again to see if that person is still on the line?

OPERATOR: Yes. Joshua, your line is open for the Q&A. Are you able to hear us?

MR. SCHNEIDER: We can still not hear the person.

OPERATOR: I think he's self-muted on his end.

MR. SCHNEIDER: Okay. If you can ask him to unmute. Otherwise, we will go to the next question if there is one.

MR. ZALESKI: And the public comment

period is open until December the 2nd, so there are options to continue to communicate on these.

MR. SCHNEIDER: Are there any other comments, or does anyone else want to talk?

OPERATOR: I'm showing no further questions at this time.

MR. SCHNEIDER: Well, that ends that portion, the technical discussion portion, a little bit more on the administration portion of the meeting. Where can you find information on this rulemaking? Well, you can find information on this rulemaking on regulations.gov.

And this is the homepage you come to when you go to regulations.gov. What you need to do is put NRC-2009-0225 into the search. And it will bring up everything that we've done on this rulemaking going back many years, back to the reg basis.

Public meetings are up there. The comments are up there. Reg analysis, all the documents that you see in the Federal Register notice that are publicly available.

MR. ZALESKI: And they'll be in the document section of the Federal Register.

MR. SCHNEIDER: Yes. A summary of this public meeting will also be posted to this site within

30 calendar days after today, and again, to keep up to date on rulemaking-related activities, you can sign up for email alerts at this site. You just open the docket folder and click the link to sign up for email alerts.

MR. ZALESKI: And that by the way if you sign up for that, you'll get an alert if someone posts a comment on the docket of the rulemaking.

MR. SCHNEIDER: Yes.

MR. ZALESKI: So if you're trying to keep track of that, that will give you the option to do that.

MR. SCHNEIDER: Yes. And additionally, as I mentioned earlier, you can go to the NRC public website for rulemaking, and you can also see the status of this rulemaking there as well.

So next, how did we do? Please let us know if you were satisfied with today's public meeting or if you have any suggestions on how we could make this a more effective process. There are feedback forms located on the back table of this room, and we request that you fill them out and leave them with an NRC staff member or drop them in the mail later.

You can also scan the QR code, and that will bring you directly to an online feedback form.

That's the QR code. So the NRC contacts are myself, the rulemaking project manager, and the lead technical person is Brian Zaleski and also Paul. All three of our names are in the Federal Register notice, if you need more information.

And finally, thank you. If you didn't sign the attendance list, I'd appreciate if you did that now. And thank you for attending, and have a great day. This concludes the meeting. Also, people on -- hello. For those on the phone, you, too, can go to the website and pick up that form, and you can send it in electronically. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:07 p.m.)