# Official Transcript of Proceedings

# NUCLEAR REGULATORY COMMISSION

Title: Part 53 Risk-informed, Technology-Inclusive Regulatory Framework for Advanced Reactors Rulemaking - 10 CFR Part 26, Fitness for Duty Programs: Public Meeting

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NUCLEAR REGULATORY COMMISSION

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PART 53 RISK-INFORMED, TECHNOLOGY-INCLUSIVE

REGULATORY FRAMEWORK FOR ADVANCED REACTORS

RULEMAKING - 10 CFR PART 26,

FITNESS FOR DUTY PROGRAMS

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PUBLIC MEETING

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THURSDAY,

JANUARY 6, 2022

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The meeting convened via Video Teleconference, at 1:00 p.m. EST, Bob Beall, Facilitator, presiding.

PRESENT:

BOB BEALL, Office of Nuclear Materials Safety and Safeguards (NMSS)

SABRINA ATACK, Office of Nuclear Security and Incident Response (NSIR)

PAUL HARRIS, NSIR

JUSTIN VAZQUEZ, NRR

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P-R-O-C-E-E-D-I-N-G-S

1:01 p.m.

MR. BEALL: Good afternoon. I want to welcome everyone and thank you for participating in today's public meeting to discuss the risk informed, technology inclusive, regulatory framework for advance reactors or the Part 53 rulemaking.

My name is Bob Beall and I'm from the NRC's Office of Nuclear Material Safety and Safeguards. I'm the project manager for the Part 53 rulemaking and will be serving as the facilitator for today's meeting.

My role is to help ensure that today's meeting is informative and productive. This is a comment gathering public meeting to encourage active participation and information exchange with the public to help facilitate the development of the Part 53 rulemaking.

The feedback that the NRC receives today is not considered a formal public comment, so there will be no formal response to any of today's discussion.

Once again, we are using Microsoft Teams to support this public meeting on the Part 53 rulemaking. We hope that the use of Microsoft Teams

will allow stakeholders to participate more freely during the meeting.

Slide 2 please. This is a continuation of a series of topical public meetings on various sections of the Part 53 rulemaking.

The agenda for today includes a discussion of the preliminary proposed rule language to 10 CFR Part 26, "Fitness for Duty Programs," as part of Part 53 rulemaking. There will also be an open discussion of other publicly released Part 53 preliminary rule language. We will also have a 15 minute break this afternoon.

Slide 3 please. I would now like to introduce Sabrina Atack. Sabrina is the director of the Physical and Cyber Security Policy Division in the Office of Nuclear Security and Incident Response. Sabrina will give the opening remarks for today's meeting. Sabrina.

MS. ATACK: Thank you, Bob. Good afternoon, everyone. I am very pleased to see that we have a good number of participants in today's meeting. I'm very much looking forward to the discussion.

Today is our first discussion regarding the proposed rule language for fitness for duty programs for facilities licensed under Part 53.

As has been the case in other topical areas, you'll see that our Staff has put great effort into developing risk-informed and performance based regulatory framework provisions that can be applied regardless of the technology used. Our framework includes flexibilities that are designed to make Part 26 more agile in responding to changes in worker substance abuse patterns and drug testing technologies.

Of particular note, we are interested in hearing views regarding the framework and its ability to ensure that individuals will be unimpaired to perform their assigned duties. And that they will be trustworthy and reliable so as to be appropriate afforded unescorted access to the facility, and the sensitive information therein.

We look forward to hearing your feedback and answering any questions you may have regarding the framework as we progress through the subject matter. With that, I hope that you find today's presentation informative and helpful in understanding our plans for the Part 53 framework. And I will now hand it over to Paul Harris of the NRC Staff for the presentation.

MR. BEALL: Okay, thanks, Sabrina. Before we get to Paul I have a few more introductory steps.

So now I would now like to introduce the NRC Staff who will be leading today's discussions. Myself, as the meeting facilitator, and also from the Office of Nuclear Security and Incident Response we have Paul Harris and Justin Vazquez from the Office of Nuclear Reactor Regulations.

If you're not using Microsoft Teams to attend the meeting and would like to view or have a copy of the presentation slides, they are located in the NRC's ADAMS document database and also on regulations.gov. I've also placed a link to the slides in the Teams chat window for today's meeting. The ADAMS Accession Number for today's presentation is ML21295A259.

Slide 4 please. The purpose of today's meeting is to exchange information, answer questions, and discuss the Part 53 rulemaking. Today's meeting will focus on the preliminary proposed rule language related to Part 26, "Fitness for Duty Programs," as part of the Part 53 rulemaking. I have placed a link in the Teams chat window for this meeting, to the Part 26 preliminary proposed rule language. In addition, there will be open discussions of other Part 53 preliminary proposed rule language that has been made public.

This is a comment gathering public meeting, which means that public participation is actively sought as we discuss the regulatory issues.

Because of the number of attendees, we may need to limit the time for an individual question or discussion on a topic to make sure everyone has a chance to participate. After everyone has a chance to ask their questions, we will circle back and allow people to ask additional questions as we have time.

Today's meeting is using a workshop format to allot more time for open discussions on the various topics. This will require all of us to continue to ensure that our phones are muted when you are not speaking and to do our best to not speak over each other.

In addition, please turn off your camera when you are not speaking to the Staff. This will minimize any internet bandwidth issues during the meeting.

To help facilitate the discussion, we request that you utilize the raised hand feature in Teams so we can identify who would like to speak next. The Staff will then call on the individuals to ask their question. The raised hand button, which is shaped like a small hand, is along the top row of the

Teams display area. You can also use the chat window to alert us that you have a question.

Please do not use the chat window to ask or address any technical issues about the Part 53 rulemaking. The chat window is not part of the official meeting record and is reserved to identify when someone has a question or for handling any meeting logistical issues.

To minimize interruptions, the Staff will call on participants who have used the raised hand feature, or the chat window, to identify that they have a question or comment.

If you joined the meeting using Microsoft Teams bridge line, you may not have access to these features. If you would like to ask a question or provide a comment, you will need to press *6 to unmute your phone. The Staff will pause at the end of each topic to ensure all participants have had an opportunity to ask questions before moving on to the next topic.

This meeting is being transcribed, so in order to get a clean transcription and to minimize distractions during the meeting, we ask everyone to please mute your phone when they are not speaking, and to identify themselves and the company or group you

may be affiliated with. A summary and the transcript of today's meeting will be publicly available on or before February 4th, 2022.

Finally, this meeting is not designed nor intended to solicit or receive comments on topics other than this rulemaking activity. Also, no regulatory decisions will be made at today's meeting.

Please note that towards the end of the presentation there are slides containing acronyms and abbreviations that may be used during this meeting and a set of backup slides that contain additional information about the Part 53 rulemaking.

Slide 5 please. And with that, I'd like to turn the meeting over to Paul Harris who will start today's discussion over the Part 26, "Fitness for Duty Programs." Paul. Paul, you're on mute.

MR. HARRIS: Thank you, Bob. I am sorry about that.

MR. BEALL: It's okay.

MR. HARRIS: That started out well. So anyways, as Bob mentioned, my name is Paul Harris. I am the senior program manager in the NRCs Office of Nuclear Security and Incident Response. I provide regulatory project manager of the requirements in 10 CFR Part 26, "Fitness for Duty Programs." Principally

all elements except fatigue management.

I will be presenting the staff's preliminary draft fitness for duty program for commercial power reactors licensed under Part 53.

And as Bob mentioned, I am joined by my colleague, Justin Vazquez, the reactor operations engineer. He will provide slides and information on the preliminary draft fatigue management program, as it would applied to Part 53 licenses, after I present the drug and alcohol technical area.

During my presentation I'll be happy to take questions. So either raise your hand or interrupt me, like Bob mentioned.

And also, we have a number of things to go over, and so we do have an open session after my presentation to discuss questions, so you may want to wait. I also must be sensitive about time as I tend to talk too much.

Next slide please. As Bob indicated, we are allocated two hours to cover Part 26. Part one of my presentation will be relatively simple, I'll try to move quickly and cover what we already covered during a brief presentation on June 10th of last year. But this previous information is important because it did set the stage for our future efforts. And it

established a baseline level of knowledge for interested stakeholders.

In part one I'll present some illustrations. I think Nan placed the link to these slides, so you might want to pull up any slides independent of what you see on the screen because some of the fonts I used are small. I apologize for the small fonts, but I love pictures and flow charts because they really do help consolidate and present the story we're trying to tell.

Part two is a section-by-section review of the Part 53 proposed framework. This is a high-level overview of what it will look like. What we proposed it to look like. For some technical topics I'll present illustrations to help inform our discussions.

Next slide please. And before I get started I have to tell you a quote. And the quote is, "two guys walked into a bar, it's a wonder that the second did not duck." This short statement underscores the core purpose of the FFD program to ensure people are fit for duty and trustworthy and reliable. Not only does the statement beg two obvious questions, I guess you're not talking about a drinking establishment, and why did the second individual walk into the bar in the first place.

It makes one wonder about other questions. Why was the bar located in the hallway and why were not safety precautions taken to identify the bar, or trained individuals to duck.

From a selfish Part 26 perspective I asked the following questions. Why didn't the first person identify the hazard and inform the second person. Or was the first and second person, or both individuals, mentally or physically impaired such that they did not see the bar or act. Or perhaps worse, did the first person purposely not inform the second person of the hazard, or did he purposely cause the hazard. This last question is the insider threat, which is part of the FFD program.

From this example I cannot overemphasize the importance of human behavior, even if individuals argue that future power reactor facilities implemented advance designs and passive safety systems and security systems and that they are so safe and secure that individuals can actually walk away from a transient or accident with a radial, significant radiological consequence occurring.

Individuals who are working at a NRC licensed facility subject to the rule must not only operate the facility but they must maintain, surveil,

and protect the facility. They must ensure the facility operates within its designed and licensed conditions. That conditions adverse safety, security, and quality are promptly identified and timely resolved and that human actions, when needed, are taken to effectively respond to abnormal situations. These necessities cannot be accomplished if the individuals are unfit for duty or not trustworthy and reliable.

Next slide please. During the June 10th meeting we presented six topics listed on this slide. I will summarize these topics in the presentation, hoping to provide a little bit information in clarifier intents of the FFD program for Part 53 licensees. Before moving off this slide, please look at Bullets 3 and 4 together. They are both focused on the FFD criterion.

Based upon feedback from the June 10th meeting, and more Staff evaluation, the principle change we identified was the need to assess our proposed FFD criterion by deleting one and slightly modifying the other. This change should improve regulatory clarity. I'll discuss this criterion in a later slide.

Using the model of trying to obtain early

and effective external stakeholder input, we now desire to seek public input on two additional topics that we'll discuss later. One is the use of hair specimens for drug testing, and two is the applicability of fitness for duty requirements at facilities licensed to operate and/or fuel a reactor module.

Next slide please. This slide lists four key messages, which we covered at the last meeting, which you may read. Perhaps most important is Bullet Number 1. Here we state that we're proposing to use Subpart K, "Fitness for Duty Program for Construction," as the originating framework for the proposed, the implemented FFD program for facilities licensed under Part 53. That strategy has not changed.

What is interesting though is that after the June 10th meeting the NRC lawyer challenged me with one simply question. And I paraphrase.

He asked, essentially he asked, why a new Subpart M, why not use the same old Part 26 framework that has been in existence since about 2008, and prior to that, in 1989. You say you built Subpart M from Subpart K, why not just use Subpart K.

Well actually, I think my answer was

complete silence in disbelief. It's a simple question, difficult to answer. So we summarized four reasons why we proposed this approach on Page 1 of the preliminary rule language documents, that's in double-column format. Please take a look at it when you have a chance. I'll note however that the underlying, pardon me. I note however that underlying each of the four reasons are many pros and cons. And we can discuss the merits or significance of each later. Let's not do it now because it will take too much time.

But I will say at this junction we have determined that the individual topics assessed contribute in the aggregate to the preliminary decision to go with a Subpart M that parallels the current risk-informed framework inside of Part 26 using Subpart K as a foundational keystone.

And as Sabrina, my boss mentioned, we have labored really hard to not impose new requirements or to enhance existing requirements without some preliminary assessment of why the change is needed. Namely, did it improve regulatory effect in this, does to contribute to safety and security, and is the cost justified.

Unfortunately, I have the inherent

propensity so I'll just grab the bull by the horns. To incorporate innovation, leverage lessons learned, take advantage of advances in technology, focus on performance based results and make preliminary draft decisions that internal and external stakeholders can see and weigh upon in an open forum. We'll see a sprinkling of this throughout the next slides. But the bottom line is, does the aggregated framework include sufficient requirements to provide reasonable assurance that the FFD program implementation can meet the FFD for Part 26 performance objectives and that worker protections are maintained. In this manner, Part 26 will be part of the Commission's defense-in-depth strategy designed to protect people in the environments.

Next slide please. This slide was presented during the June 10th meeting. It shows the administrative requirements that all licensees subject to Part 26 must meet. These requirements, or their appearance, have been in existence since 1989. So the need to cover them here is not necessary.

Next slide please. This slide simply shows that on June 10th we presented two FFD criterion, A and B. A was focused on the radiological consequences, and B was focused on human performance.

As I mentioned, we plan to maintain Criterion A as a remaining FFD criterion to be used in the determination of which fitness for duty program the licensee may implement. And we continue to ensure that this criterion is aligned to the security based criterion that have been already presented to the public and is applied to the physical protection and access authorization programs. And that which may be used for the proposed limited scope rulemaking. This is important because fitness for duty requirements are linked to the insider mitigation program. And licensee activities necessary to grant or maintain an individuals unescorted access to the facility.

Criterion B was a placeholder by the FFD, by the fitness for duty staff, that accounted for the necessities of humans to maintain safety and security, as I previously discussed. But based on subsequent review, we determined that this criterion is not needed for the FFD program implementation. Part of this determination was based upon staff efforts associated with Part 53 Subpart F, entitled "Requirements for Operations," which includes preliminary proposed requirements for the facility safety plan, surveillance and maintenance, configuration control, design changes, staffing, and

programs.

A public meeting for Subpart F were conducted four times in 2021. And these documents are listed on Bob's, on the NRC's website.

Part of the Subpart F framework describes human actions. And that these must be capable of being reliable formed under postulated environmental conditions present, and be addressed by programs to provide confidence that those actions will be performed, as assumed, in the required analyses.

For example, for licensed operators, their actions center around the management of in fulfillment of safety functions, in addition to the manipulation of facility controls. And for the staff and the facility, the staffing plan must describe the personnel who provide support in the areas such as plant operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering and security. Oh, and I forgot to mention emergency response. These categories are comparable to those already listed in the current Part 26 requirements at Section 26.4. And of course, are used in a preliminary proposed Subpart M requirements for Part 53 FFD programs.

Clearly these individuals all need to be

fit for duty. And this demonstrates why there is a strong connection between all the frameworks that the NRC is proposing.

Next slide please. I colloquially call this my bubble chart, but it's a flow chart of the proposed FFD framework and its principle requirements. I know that there is a lot of words here, and this was presented during the June 10th meeting, but the flow chart is really simple. It demonstrates the options a forwarded to the Part 53 licensee. Notice how the single fitness for duty criterion, based upon risk consequence, sets a demarcation between what I call the 26.604 and 26.605 fitness for duty programs. This created approach in employing Part 26 requirements to facilities based on risk, is already within the existing Part 26 framework for Part 50 and 52 licensees.

Additionally, all Part 53 licensees must implement the common FFD requirements to ensure program effectiveness. These are here in the big box and includes the administrative requirements that were on the slide presented earlier.

And we'll see that the requirements listed here are almost identical to those presented during the June 10th meeting. Minus, of course, the B

criterion. And also, we deleted a behavior observation auditing statements for the 26.604 fitness for duty program that we found to be redundant.

Before I move on to the next slide I just want to make sure that this slide is clear to everyone in that the licensee has flexibility and implementation of its program. And if it voluntarily elects to evaluate the fitness for duty criterion and it meets the criterion, then it could implement what is called the 26.604 fitness for duty program.

Next slide please. As I already mentioned, we are seeking public input on two elements. The Part 26 applicability to certain holders of manufacturing licensees, and the use of hair specimens for drug testing.

Next slide please. Let me read this slide because I want to make sure I get it right. Currently, for facilities licensed under Parts 50 and 52, Part 26 does not apply to holders of the manufacturing license. However, Part 26 does apply to licensees when assembling and fueling a reactor vessel at a reactor construction site licensed under Part 50 or 52. The staff is proposing that select Part 26 requirements apply to holders of a Part 53 manufacturing license if they assemble and fuel a

reactor module at the manufacture's site. This staff proposal provides analogous treatment of assembly operations for safety-related structures, systems, and components, such as the reactor vessel and associated equipment.

So we are proposing a regulatory framework that helps ensure that these individuals who assemble and inspect the reactor module, and/or fuel the module, are fit for duty and trustworthy and reliable. The outcome would be a level of fitness for duty assurance equivalent to that currently applied to large light water reactors. We are not proposing to apply fitness for duty requirements to the reactor vessel supply chain. I hope this makes sense. If there are any questions on this, please raise your hand.

Part of the reason to apply fitness for duty requirements is that many important components will be located inside your reactor module and may not be available for inspection, or test, after the module is completed and shift to the Part 53 site license for reactor operation.

At the large light water reactor currently de-constructed, the individuals installing and assembling and testing these and other components and

providing quality assurance are currently subject to fitness for duty program requirements.

In the Part 50 and 52 case, as well as the Part 53 case, the fitness for duty program provides the defense-in-depth of human related activities within a defense-in-depth framework that includes quality assurance training, individual qualifications, inspections test and management oversight.

Okay, so let's go on to the next slide please. So these are the two questions that we would like to ask for external stakeholder input.

The first of which is, should the NRC consider the application of Part 26 to the assembly of the reactor module?

And two is a little bit bigger and more difficult to identify, so input would be, might be necessary. How should the NRC describe the milestone for when the fitness for duty program should start?

Okay, so those are the two questions. So now let's talk about using hair as a biological specimen for drug testing.

Next slide please. Again, let me read this.

Currently, for facilities licensed and operating under Part 50 or 52, Part 26, Subparts A

through I, N and O, do not allow licensees or other entities to use hair specimens for drug testing. However, for facilities that are being constructed under Part 50 or 52, the Part 26, Subpart K framework in Section 26.405, does not preclude the use of a hair specimen, or oral fluid specimens for that matter, for drug testing if the following six bulleted requirements are met. And you can read those six bulleted requirements.

I note that there is background for enabling the use of hair for drug testing. Not only does federal law HR 22, Fixing American's Surface Transportation, direct the use of hair testing as an acceptable alternative to urine testing for the drug testing provisions implemented by the U.S. Department of Transportation, but on September 10th of 2020, the Department of Health and Human Services [HHS] published its draft mandatory guidelines for federal workplace drug testing programs using hair. These hair guidelines would allow federal executive branch agencies to collect and test hair specimens for pre-employment drug tests and random drug tests. The Department of Health and Human Services is currently evaluating public comments and has not yet issued final hair guidelines.

That is why we're asking questions to the public.

Hair testing is also currently being conducted and accepted, and its results are accepted by motor carriers, such as trucking companies, child welfare custody, custodians and criminal courts. And based upon an informal internet search that anyone can perform, hair testing is also conducted in the food and gaming industries, the oil and gas and financial industries. Furthermore, many laboratories exist that conduct hair testing. Such as LabCorp, Omega Psychometrics, Quest, Smart Test Labs, to name a few.

The society of hair testing publishes guidelines and best practices. And it looks as though the College of American Pathologists provides an accreditation program for hair testing laboratories.

So why hair? Why are we looking at hair? There are a number of benefits for hair testing. It has a significant long detection window, it's not invasive, it's easily collected, it's easily transportable and stored. There is no bio-organisms and no bio-fluids. There is really no viable subversive technologies yet identified. In fact, hair can also be used to determine alcohol abstinence. Although we're not thinking about doing that, it can be used. And at the risk of cherry-picking technical

studies, and promoting the concept of confirmatory bias, a 2018 study by the Alliance for Driver Safety and Security found that urinalysis drug testing missed 90 percent of illicit drug use in the population tested.

But hair testing does come with many challenges and these are, and many of them are technically challenging. HHS is resolving a number of these challenges through their evaluation of their public comments prior to any issuance of their final hair testing guidelines.

I note that hair testing could be a method to help us address the applicant of the currently proposed 50 percent random drug and alcohol testing rates of licensee, employees and contractor vendors. This is because the window of detection of hair is up to 90 days therefore it can possibly be used to maintain program effectiveness. And I'll talk about this in a few slides later in the presentation.

Next slide please. These are the four questions we would like to ask regarding hair testing and we would like input. At this time I would like to point out that the Nuclear Regulatory Commission is far from being anything close to being United States leading expert in hair testing. I definitely am not.

So we definitely do leverage the fine work done by the Department of Health and Human Services. And we use their technical evaluations, and guidelines, as part of our historical technical bases supporting changes to the Part 26 drug and alcohol testing framework.

At this point I'd like to point out some subtle factors before moving on. The federal law that I mentioned was focused on utilizing hair as a testing method, as an alternate to urine testing. The staff has looked at that and that is not part of the questions that we're looking at as agreed question number one. We're looking at, hair should be used as a supplement to urine or oral fluid testing. In addition, the draft HHS proposed hair guidelines would allow the use of hair for pre-employment and random testing. And this would have a connection to the random testing program being preliminary proposed for Part 53 licensees.

Okay, next slide. I'm going to then turn to what's called Part 2 to summarize fitness for duty framework, section-by-section review.

Next slide please. To set up the section-by-section analysis I'll provide these slides. This slide and the next slide.

This slide is a comparative illustration of the current fitness for duty framework to that presented for Part 53 licensees. It is a rather simple illustration that generalizes the framework. So it's not 100 percent perfect, but it does a pretty good job of illustrating 90 pages of regulatory texts and the preliminary proposed rule text for Part 53 licensees.

The top line are the gray boxes. And this the current fitness for duty program. Below are the yellow, green and blue boxes for the Part 53 preliminary proposed framework. You will notice everything is segregated by construction, criterion, requirements, milestones and operation. There is a small box to the right. You will see fatigue managements. And it's important to note that risk-informed frameworks are based upon radiological consequences presented by construction and operation.

For facilities licensed under Part 53 please look at the green boxes. This is a subordinate control door presented for those facilities that elect to voluntarily evaluate the one proposed fitness for duty criterion to enable the utilization of the fitness for duty requirements in Section 26.604, that I'll cover in a second. I also want to bring to your

attention the note that is squeezed between the two rows of boxes. This note, I can't even read it, sorry about that. But this note illustrates that this illustration does not address the assembly and fueling of the reactor vessel module by a holder of a manufacturing license.

Okay, next slide. Another slide I tried to develop to inform the members of the public, and licensees and other entities, is this one here. All this one is a generalized illustration of the applicable fitness for duty requirements. And it crosswalks these requirements between all the FFD requirement, all the FFD programs that we're contemplating. On the left-hand side, of course, is the existing requirements. And the yellow and green represents the preliminary proposed requirements for the Part 53 licensee. I don't want to spend any time here, but it does provide a nice crosswalk.

Okay, next slide please. Getting into the section-by-section analysis, this slide just shows that to incorporate Part 53 licensees into the Part 26 structure, these three existing requirements will need to be amended. You will note that Section 26.4 details the categories of individuals subject to the fitness for duty program. As I previously mentioned,

this listing generally comports with the descriptions in Subpart F of the proposed Part 53 framework. And additional alignment work may be needed here as we work through the kinks. This Section 26.4 requirement is also currently linked to a requirement titled, 26.602, that you will see on the next slide. So let's go to the next slide.

This slide starts out showing Subpart M as a fitness for duty program for commercial power plants licensed under Part 53. This title may need to be modified to include or possible reference holders and manufacturing licenses. If that's the case, if that's the path we pursue. Of course we need an applicability statement. And here is that 26.602 where the program describes the categories of individuals who are subject to the fitness for duty program.

Section -- we're getting some feedback, if people can mute their phones that would be helpful.

Section 603 are general provisions. And this is in the open, pardon me. 603 is the fitness for duty criterion. And as presented earlier, we are only presenting one criterion. This section requires the analysis and the evaluation by the licensees. If they elect to perform them.

Next slide please. These are more general provisions. This is a preliminary proposed rule language for the performance monitoring and review program. I expect we might get some questions on this proposed review program, but it's important for me to point out that we're not just making this up. We are utilizing current existing requirements in Part 26 to frame the preliminary proposals for Part 53 licensees. Specifically Sections 26.41, 26.415 and 26.717 are three of the requirements we used to generate a proposal on 26.603 performance monitoring review program.

We could discuss these three requirements in detail later, but we also used existing requirements in the 10 CFR, such as 10 CFR 50.47, "Emergency plans," Section 50.48, "Fire protection," and Section 50.65, the maintenance rule. I believe 10 CFR Part 55 also implements a performance monitoring program. I note that part of this justification for this effort is because of the flexibilities afforded in the preliminary proposed FFD program for Part 53 licensees. And this is to enable these licensees the drug tests, their workforce, using procedures suitable for them, respond to future changes in drug testing methods, changes in the nuclear workforce substance

abuse profile, and to incorporate innovative drug testing technologies.

With this type of program flexibility to perform its monitoring program demonstrates where the licensee was, where it is, and where it's going. It's a monitoring program designed to maintain performance through licensee administrative corrective actions in a continuous fashion as trends and changes occur at the sites.

Significant important or difficult fitness for duty program changes should not have to wait five or seven years for the NRC to conduct rulemaking because of societal substance abuse trend, or testing issue, is already occurring long before the HHS or NRC can issue regulatory changes.

For me, another key consideration is the FFD performance objectives. That's described in Section 26.23. Here the NRC uses the words such as providing reasonable assurance and reasonable measures. Unfortunately, one can see that reasonable assurance and measures has never been defined, and the quantitative outcomes are not measurable. So any change in performance is obscured by the assessment that has a potential to conclude that, yes, our FFD program provides reasonable assurance until found

otherwise by another participant.

This is part of the reason why quantitative measures provide -- based upon actual FFD performance data should be pursued to identify trends, compare performance, and drive corrective actions to maintain performance. Only in this way could a truly performance based drug and alcohol testing program be implemented and be compared to the reasonable assurance standard discussed above.

Okay, next slide please. I'd like to give an example on a quantitative performance measuring program. Here on this slide, which is a little bit difficult to see, but it's a good illustration of performance monitoring, the slide shows a random positivity rate for licensee employees. The X axis would list every nuclear power plant site subject to Part 26 and the y axis has four vertical dots. Each dot is colored based upon the data of the calendar year from which it was obtained, mainly calendar year 2016, 2017, '18, and '19. We can see that the preponderance of all sites or all years had a very low positivity rate for licensee employee random testing.

One might say that this is an expected performance level, a good performance level and, based upon historical performance, a comparable performance

level at which a site can at least be in the ball park of demonstrating or providing some reasonable assurance of program effectiveness. You can also see that there are a few outliers.

Next slide please. On this slide, this shows a random positivity rate for contractor vendors. Again, the x and y axis information is the same, sites and positivity rates, over the course of the four years.

One can immediately see that the random positivity rate for contractor vendors appears all over the place. The dot spread is not an indication that you're impaired. But let's really look at this. The licensee that performs its year-to-year performance assessment, and compares its assessment to other sites within its FFD program, similar facilities in the generic industry values, we believe that the licensee is smart enough to see where their performance ranks and to take appropriate actions if necessary to improve or maintain performance.

Within a null set though, we clearly do not want licensees to reduce their program effectiveness to achieve a higher positivity rate if indeed their FFD program is performing extremely well, and the industry rates are higher. This would

definitely be contrary to the performance monitoring program. We also note that there are some challenges with doing this. The licensee's assessment is not conducted in a vacuum, because they will evaluate other variables such as was our facility in an outage. Did the majority of positive test results occur in one group of contractors? How much rework resulted within this population? Were there changes in the for-cause and post-accident testing rates? And lastly, how are the pre-access positivity and subversion rates doing?

Next slide please. This slide shows a preliminary proposed fitness for duty change control process that is based upon similar Part 26 requirements in four sections. Those sections are 26.31, 26.137(f), 26.713(d), and 26.713(g). I don't want to discuss in detail what those requirements are, but again we're trying to utilize the current requirements within Part 26 to establish the Part 53 proposed preliminary framework.

The change control process is also based upon, again, other 10 CFR requirements such as, again, Part 50.48, "Fire protection," 50.54(p), security plans, 50.54(q), emergency plans, and Part 50.59, "Changes, tests, and experiments."

So now let's investigate why we're proposing a change control process. The answer is quite simple. It's the flexibilities afforded in the preliminary proposed framework. These are listed on the next slide.

Here on the next slide you could, Slide Number 27, you could see the program flexibilities listed in bulletized format. What is not listed on this slide but was on the previous slide is an example that if HHS issues a change to its guidelines, then the licensee may implement the change without NRC approval, that said, great thing about a change control process, if the licensee can demonstrate that the change does not reduce programmatic effectiveness. However, there is a vulnerability here. Let's assume that HHS reduces the number of drugs and drug metabolites on their drug testing panel or changes cutoffs to a point which adversely affects FFD program performance, then this change would require NRC approval.

So if we could just go back to Slide 26 real quick, and I just want to point out that type of discussion is in bullets, Echo 1 where it says changes not requiring NRC approval, and then Echo 2 which are changes requiring NRC approval, note that the NRC

plans to issue a regulatory guidance on other examples which the licensee might implement and would meet these requirements.

Okay. So let's move on to Slide Number 28 please. Note that this slide starts us into the actual FFD programs that must be implemented. As I previously mentioned, this is the 26.604 program where the facility meets the FFD criterion. And these would be the proposed preliminary requirements, and they are all based upon the elements in Subpart K. Notice that Item Number, small roman numeral v, or I'm sorry, vi, is the behavior observation program. And also notice that drug and alcohol testing is not a requirement for this program. People might argue why is this the case. I'm sure we're going to get questions upon that. Essentially, it's based upon the radiological risk presented by this facility. This facility is required to implement a performance monitoring program and conduct audits. This facility implements multiple independent safety systems and passive safety systems that minimize the need for immediate human action. And this facility might involve a much smaller footprint of structures, systems, and components that need intensive maintenance and surveillance, and yet if fitness for duty performance does decline, the

preliminary proposed draft ruling which enables the licensee to implement a drug and alcohol testing program.

Okay. Let's move on to the next slide, please. The next level, I might say, on FFD programs is the 26.605 program. This is for the facilities that do not meet the fitness for duty criterion or is a holder of a manufacturing license for assembling and fueling a reactor module. These would be the requirements here on the slide. Notice that drug and alcohol testing would be required, and yet the requirements tend to parallel those in 26.604. Notice also in subparagraph 3(ii), the Subpart I which is managing fatigue. Justin Vasquez will discuss this shortly.

Okay. So now let's move on to the next slide please, Slide 30. Oh, wait, let's go back to (a). Scroll up one slide. Notice that this is for construction and construction activities of the Part 53 facility and the holder of a manufacturing license for the assembly and fueling of the vessel. So this is like the first tier in the 605 program, construction, when the radiological consequences are lower.

Okay. So now let's move to (b) which is

the next slide, 26.605(b). This is the operating portion. This again parallels the risk informed framework of the current Part 26 requirements. Here you will see the requirements that the licensee must meet and implement prior to operation. And you could read the words in Paragraph B, specifically the three elements there, unloading fuel, integrating the reactor module, and operating, testing, and performing maintenance. Notice here Items 3(i) through 8 [viii], I'm sorry, 7 [vii], are all the subparts that this licensee must implement. The robust requirements of the existing Part 26 requirements must be implemented for this program here as proposed.

Okay. So let's go on to the next slide. This slide starts to talk about written policies and procedures, clearly you shouldn't operate an operating nuclear power plant without policies and procedures, or fabricates, pardon me, assemble or fuel a reactor module without a policy or procedure.

In 26.607 we start describing what the alcohol testing program looks like, drug and alcohol testing program looks like. Items 1 through 10 list some of the more interesting provisions in this section. You could read through those, and I'll take questions on those when the presentation is completed.

Notice things like you have to use a Food and Drug Administrative cleared device for the utilization of, like, oral fluid testing. We are proposing that licensees are enabled to use a point of collection testing device for screening. And this would be for random testing only. And there's requirements associated with the use of that type of device.

Pardon me. Let me get a drink. I'm losing my voice.

Okay. Let's move on to the next slide. This is an example of random testing. And this is why I mentioned hair testing. And we'd like to get some feedback on the utilization of hair testing. What we are concerned about is a facility that has very few individuals on site, so subject to random testing, a small facility, a facility that has maybe less than 100 individuals.

But before we get to that specific condition, let's take a look at this slide here. This is the random testing rates. All the licensee needs to do in the current program is to implement an annualized 50 percent random testing rate for the population of individuals subject to the FFD program. This is data taken from the current existing light water reactor fleets. The top bar, the top chart

shows licensee employees. The red bar shows the 50 percent random testing rate that they need to meet, okay, for the entire population.

But when I segregate out licensee employees from contractor vendors, it's easy to see that licensee employee's meet the 50 percent random testing rates. On the graph below, which is the contractor vendor testing rate, you will see that contractor vendors sometimes do not meet the 50 percent random testing rates. This is a principle reason why the preliminary proposed framework for random testing for Part 53 Licensees includes the provision of and, that the 50 percent random testing rate must be applied to both licensee employees and contractor vendors.

Let me grab another drink here please.

Based upon facts from operating experience, contractor vendors typically test at a rate three to four times higher than licensee employees. And contractor vendors represent about 96 percent of all subversion attempts. Therefore, one might say that a contractor vendor represents a higher risk than the licensee employee. And if they represent a higher risk, why are we testing them at a lower rate? This makes no sense to me. This issue

might compound itself for facilities licensed under Part 53, because Part 53 licensed facilities may have very small numbers of licensee employees. And some Part 53 licensees might have a relatively large contracted workforce that only comes on site for short durations and at very low periodicities which would skew the random testing population to the licensee employees. Because these are the individuals that are on sites all the time, and easy to find, and easy to test.

Okay. Next slide please. This is a slide talking about the fitness for duty program training, behavioral observation, sanctions, protection of information, review process, and audits. The proposed preliminary ruling which again is based upon Subpart K, of which these requirements are in Subpart K, the few key points I want to point out here are that fitness for duty training is not an element of Subpart K, but it is an element within Subpart B of Part 26.

The behavioral observation program is connected to the behavioral observation program for the access authorization program requirement. So there is a linkage there, and we want to maintain that linkage.

Sanctions must be administered, and they

must be based upon severity of the issue and must escalate with the numbers of occurrences. And you could read the exact words in the two-column format of the proposed preliminary ruling, how we phrased that. But clearly, if an individual violates a fitness for duty policy or a procedure, the sanction must be imposed on the individual as a deterrence value and to facilitate any corrective action such as treatment.

And the last slide please. For drug and alcohol testing, this is the last slide. Again, these licensees have a record keeping reporting element and a suitability and fitness determined element identified in 26.119. The importance of the 26.119 provision is high, for it's this process that provides assurance that individuals are fit for duty and trustworthy and reliable. If a substance abuse expert or medical review officer has concerns about the fitness of an individual, that individual must be removed from those duties and responsibilities making him or her subject to the program. If not, a significant potential degradation of defense in depth occurs. Because we no longer maintain the assurance of effective human performance. And fitness determinations should never be doctor-shopped or decided by an untrained medical professional.

And the final slide in the drug and alcohol area is a generic slide that opens the floor to any questions or comments that you might have on what I covered or in the two-column formats document that was issued with the public meeting notice.

MR. BEALL: Okay, thank you, Paul. If anybody has any questions or comments for Paul, please use the raised hand feature of Teams.

MR. BEALL: No questions from the public?

Prasad, you have your hand up?

MR. KADAMBI: Yes, thank you. This is Prasad Kadambi. I'm a consultant. I'd like to ask, how can a licensee take credit for defense in depth features in a design in implementing the graded application of fitness for duty requirements?

MR. HARRIS: Yes, Prasad, this is Paul Harris. That's a great question. And that's why we have the initial Criterion B within the proposal described on June 10th. We are concerned about human performance, and we do know that there is a link to human performance and the design features of advanced reactors.

As I mentioned earlier, the staff work and the stakeholder inputs going into Subpart F, which is staffing and operations as well as other elements, is

looking at human performance elements of when people are needed, what functions they have to perform, when can people not be needed. So that spectrum is going to be evaluated in the proposed staffing plan described in the proposed Subpart F.

Within the fitness for duty arena, we have the same strategy. As described in the current requirements in 10 CFR Part 26.4, the FFD program must apply to certain categories of individuals. Those categories of individuals are described in detail. However, it does allow the licensee some flexibility to credit from a risk based, I'm sorry, risk informed determination evaluation on what individuals a program must apply to, should apply to, or does not need to apply to. I believe Justin is going to talk to that a little bit more regarding this fatigue management area. So we do have that.

However, as I mentioned earlier, individuals are still required to maintain the facility, and its operation and maintenance activities, within licensing and design parameters, conduct maintenance and surveillance to ensure that set points and indications are accurate and precise, and that emergency response activities by people such as a fire brigade, or radiation protection

individuals, or chemistry individuals, are all fit for duty. These individuals are performing activities that do not have a link to a structure system and components that is a design feature like a passive safety system or a safety system which does not require operator actions. Does that answer your question?

MR. KADAMBI: For now, yes. Thank you, Paul.

MR. BEALL: Are there any more questions or comments?

Okay, so I'd like to move on to the next section. Next slide please. So Justin is now going to talk about the managing fatigue part for Part 53. Justin?

MR. VAZQUEZ: Thanks, Bob. Can you hear me clearly?

MR. BEALL: Yes, sir.

MR. VAZQUEZ: All right, great. All right, thanks for that. As Bob and Paul mentioned, my name is Justin Vazquez. And I'm with the NRC Office of Nuclear Reactor Regulation. I'm with the human factors team, and we also handle the oversight of the fatigue management programs for the NRC. And so today we'll be talking about the considerations for applying

fatigue management requirements as discussed in 10 CFR Part 26, Subpart I, for Part 53 licensees.

So move to the next slide please. All right. So one of the key takeaways for today is that, as we've begun looking into how to apply fatigue management requirements for licensees, we've determined that we expect to be able to apply fatigue management under the current framework as discussed, for the most part, in the existing rule text. And so there won't be much changing moving forward for applying to Part 53 licensees. And that can be seen in the two-column format preliminary proposed rulemaking document that Paul mentioned just a few minutes ago.

Most of the changes that we're proposing at this time are administrative in nature. And they will be simply to apply the existing framework to those licensees in accordance with tie-ins to the appendix via Subpart M language that Paul discussed during his presentation. However, one main consideration for what will be changing for Part 53 licensees and what will apply to consideration, risk-informed considerations moving forward, will be the fact that the NRC will be considering the enabling of flexibility under the existing framework established

by Subpart I. Now that degree of flexibility will be dependent on the risk profile of the plant as discussed in an applicant's design. And applicants may be able to demonstrate in the risk informed safety evaluation that they've put forward that, in particular for work hour controls under Part 26, Subpart I, as discussed in Part 26.205, that it may be the case that work hour controls may not be needed for same individuals or in the same circumstances as they would for a traditional large light water reactor design as we see in the current operating fleet.

So to kind of dig a little bit more into what we're talking about when we are bringing up this idea of flexibility, we'll walk through a couple of examples.

So for the first example, we'll go on to the next slide. So one example that comes forward as we begin to conceive some of the technology designs that we might see moving forward, are that we may see designs that have less reliance on operator actions for safe operation. Now, under the current framework, as discussed in Part 26.4(a), which discusses the classifications of certain staff, and of Subpart I requirements, call all these classifications to determine the applicability of work hour control

requirements.

In particular, we'll look at 26.4(a)(1) which ties an individual whose duties include operating or onsite directing of operation of, and this is a key consideration here, system and components that a risk-informed evaluation process has shown to be significant to public health and safety. So we're considering, potentially with Part 53 licensees, is that if an applicant were to determine, through their risk-informed evaluation, that operators at the given facility for a particular design will not actually be operating, responsible for the operation of risk significant systems or components, those operators may not need to be subject to work hour controls in the way traditionally seen for large light water reactors.

Now, such facilities would likely be those that incorporate designs relying on a greater degree of automation, potentially passive safety features, or inherent safety characteristics for safe operation. And that risk informed evaluation brought forth by the applicant would need to demonstrate that these systems, the ones relied upon for safe operation, are adequately robust and incorporate an adequate degree of defense in depth including the proper -- having a

diverse technology inclusion, set separation, and other considerations for safety parameters such that it can be demonstrated that the operator is not a key component in that safety profile and is not relied upon for that safe operation.

So we'll go on to the next slide for another example. So another possibility that we could look on would be, rather than looking at whether or not operators are relied upon overall, would be the time dependency for when operators are relied upon. And specifically, we might see designs for which operator actions are only relied upon for safety during certain periods of operation.

A licensee's risk informed evaluation could determine that, for example, operator action is only relied upon for safe operation during certain periods such as plant startup, if there were manual actions that were necessary for the safe startup of a reactor and control of reactivity. However, that evaluation could possibly, conceivably come forward with the conclusion that during steady state operation, or other periods of operation for a plant, operator action is not relied upon. And you might have this kind of time or reactor state dependency on whether or not you're relying on operator actions.

And in such instances, the operators may only need to be subject to work hour controls during those periods of operation which that risk informed evaluation has determined, during which those operators are actually being relied upon for safe operation. So there may be certain exclusions at certain times that could come forward. And that would, again, be dependent on the licensee's evaluation.

So we'll move on to the next slide for probably, I'd say, is the big key takeaway as we're considering these flexibilities, is that regardless of the conclusions that the licensee reaches regarding how to apply work hour controls and other fatigue management considerations, it's going to be dependent heavily on the conclusions that are reached in that risk informed evaluation as discussed in 26.4(a) and the criteria for the various individuals there.

Now some other considerations, and these are discussed in that two-column format, some other considerations that might also come into play for whether or not work hour controls specifically apply, there could be different conclusions for some of these technologies regarding the degree to which an emergency response organization is relied upon or the

degree to which security officers are relied upon.

And that may also result in different types of organizational considerations that will entail different applications of work hour controls for the technologies that we'll see coming in under Part 53 that have not been encountered for the traditional operating fleet under Part 50 and Part 52. And these are considerations that, again, we'll be reviewing as they come in on a case-by-case basis and as the licensee determines, in their application content, how the fatigue management needs to be applied for the technology of a specific design application that's coming in.

I want to talk about one other consideration which is also discussed in the preliminary proposed language that's out there. So we'll go on to the next slide. This is one that came up regarding the potential for remote operations and specifically the applicability of work hour controls for remote workers.

In various instances throughout that 26.4(a) language there is the reference to onsite directing of activities associated with risk significant SSCs, structures, systems, and components. And there is the expectation, or there's the potential

that we could conceive that some facilities coming in under Part 53 may, as part of their design basis, perform certain operation or maintenance activities from a remote facility.

For example, there's been discussion in, I believe it's the white paper that went out about potential operations organizations' considerations that we could see remote control rooms, remote control stations or consoles, and actual operation of a plant from a remote facility. And we do want to clarify that when we're talking about the applicability of work controls and the applicability of that 26.4 alpha language, that the use of the term site, and onsite directing in particular, we would consider, in a facility that is not at the same location as the operating reactor but from which the operations are being controlled, we would consider that to be essentially part of the extended site. And therefore individuals that are performing actions, and in this case performing directing at those sites, would be subject to work hour controls just because they're not at the exact location of the reactor. That control station would be considered to be conceptually an extension of the facility site.

So that is all we have as far as prepared

slides and prepared remarks go. One thing I should mention is that we have some additional discussion that's contained in the two-column preliminary proposed language document that has gone out.

One thing that there is there to note is that, as I mentioned earlier, most of the changes that we anticipate to the actual ruling, which was Subpart I, we see as administrative in nature. There is one potential that could be seen as an exception to that we're currently working with in the preliminary language that's out there. And that is that we are actually proposing the possibility of introducing a new section of general requirements that would be specific to Part 53 licensees. This is currently listed in that preliminary proposed rulemaking document as Part 26.202. But it should be noted that that new language in 26.202 is essentially identical to what is currently contained in the general requirements that are listed in 26.203.

And what we have --- the reason that we've taken that approach is that we're putting it out there for preliminary discussion purposes as to how we're going to apply the general requirements as discussed in that language to Part 53 licensees.

And if we do, as we're engaging with the

public and gathering comments, determine that there are different ways that it would be optimal to approach those general requirements by having a separate section that's separate 202 as opposed to 203 section available.

It would give us the ability to work flexibly and adapt new ideas without significantly impacting the requirements that are currently contained in 203 that apply to the existing operating light water reactor fleet.

However if moving forward, as we get into discussions with stakeholders and discussions from comments that we may receive from folks on the call today, and as we get into eventually proposed rulemaking space, it may actually come to be that substantial changes are not needed for the general requirements. And we may end up actually eliminating that 26.202 approach and just incorporating general requirements for Part 53 licensees under Part 26.203.

So that is one point of clarification that we wanted to put out there. And it's also, again, discussed further in that right-hand column language in the document that's out there and referenced in the meeting notice for today's meeting.

So that's all we have for Subpart I,

fatigue management considerations. And at this point, I will take any questions that you may have or any comments specific to the fatigue management considerations for Part 53 reactors as discussed in our preliminary proposed language.

MR. BEALL: Okay. Thank you, Justin. If you have any questions for Justin, please raise your hand with the Teams' hand.

Do you have any other questions for Paul for his sections, Paul Harris, from the Part 26?

Okay. All right, thank you, Justin.

MR. VAZQUEZ: All right, thanks, Bob.

MR. BEALL: Okay. Next slide please. Okay. Actually, can you go to Slide 44 please? So this slide provides a partial list of the Part 53 preliminary proposed rule language subparts that are currently out for public comment in their respective ADAMS accession number. These documents are also available on regulations.gov.

The staff would like to see if there are any questions from the public on these or any of the other Part 53 subparts at this time.

Okay. I'm not hearing anything so let's go to the next slide please. Go ahead, next slide please. Are there any final discussions or comments

on the Part 26?

Okay. Now go to Slide 47 please. The staff is planning to host additional topical public meetings on the Part 53 rulemaking. The next public meeting is scheduled for early February 2022 and will be oriented towards the non-governmental organizations. All new and revised preliminary proposed rule language will continue to be posted in ADAMS and on regulations.gov under the NRC Docket ID, NRC-2019-0062, prior to any public meetings.

The staff is also continuing to meet with the Advisory Committee on Reactor Safeguards [ACRS] to receive feedback on the Part 53 rulemaking. The next meeting with ACRS will be on February 2nd, 2022. The topic will be detailed in Subpart F.

Slide 48 please. If you have additional input or suggestions for future topics related to the Part 53 rulemaking, please send an email to Nan Valliere and I at the email addresses on this slide. Your interest and comments will improve our rulemaking effort. I also encourage you to monitor the Part 53 rulemaking docket ID. Again, that's NRC-2019-0062 on regulations.gov website, for updates and important documents related to this rulemaking.

Finally, we're always looking for ways to

improve our public meetings, and your feedback is important to us. At the end of the meeting, please go to the NRC public website, click on the recently held meetings button, and look for this meeting. The feedback form will be at the bottom of the meeting announcement.

I'd like to thank everyone today for participating in today's meeting, and I hope everyone has a good evening. And this meeting is now officially closed.

(Whereupon, the above-entitled matter went off the record at 2:26 p.m.)