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NUCLEAR REGULATORY COMMISSION

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10 CFR PART 26 FITNESS FOR DUTY DRUG TESTING

REQUIREMENTS FINAL RULE

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TUESDAY,

APRIL 13, 2021

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The Public Meeting convened, via Teleconference, at 10:00 a.m. EST, Stewart Schneider, Project Manager, presiding.

PRESENT:

Stewart Schneider, Project Manager

Brian Zaleski, Rulemaking Technical Lead

Fred Schofer, Regulatory Analyst

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P R O C E E D I N G S

10:03 a.m.

MR. SCHNEIDER: Hello, Operator. Thank you.

As you said, you took the callers out of standby and you're keeping them in listen-only mode, so we don't hear the background noises. And I'll let you know when we're ready to take comments and questions later from the callers in this meeting.

Good morning. I would 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 10 CFR Part 26, Fitness for Duty Drug Testing Requirements rulemaking.

Before I go any further, I just want to let you know that there were some problems with my laptop. So, you're not able to see me on the video on the Webex. I apologize for that. You see me as Stewart Schneider.

I'll be acting today as the facilitator for today's public meeting, and my role today is to make this meeting as productive as possible for everyone involved.

Also presenting will be Brian Zaleski, the

NRC Technical Lead for this rulemaking.

At today's meeting the NRC staff will discuss the cumulative effects of regulation as it pertains to the implementation date of this final rule for this rulemaking. This meeting will also provide an opportunity for the NRC staff to address questions and solicit feedback on the proposed implementation date.

Please note that today's presentation is available by using the link provided in the meeting notice or by going to the NRC Library at the NRC public website. At the NRC public website, use the Agencywide Document Access and Management System, otherwise known as ADAMS, and enter Ascension No. ML21096A010. Again, ML21096A010.

Next slide, please.

This is the announcement.

Slide 2.

Before we begin, I'd like to make several announcements.

Today's meeting is categorized as an information meeting with a question-and-answer session. Attendees will have an opportunity to ask questions of the NRC staff and provide feedback on the

regulatory issue concerning the effective date of the final rule. However, the NRC is not actively soliciting feedback on any other regulatory decisions at this meeting.

Additionally, no comments will be accepted and no regulatory decisions will be made during the meeting. There will be ample time at the end of the presentation for questions and answers and for you to provide your feedback.

At today's meeting, audio is only available via the bridge line and WebEx is the only way to view this presentation. Please note that, for today's meeting, the WebEx chat function has been disabled.

Next slide, please.

Meeting guidelines. Because today's meeting is being transcribed, I'm requesting that those participating over the bridge line clearly state your name and organization before you provide feedback and/or questions.

For the NRC staff, please state your name and organization, so everyone knows who is talking.

The bridge line operator will keep you in listen-only mode until I request that the operator

take your questions and feedback.

If at any point you cannot hear the meeting discussions, please let the operator know.

Next slide, please.

The agenda. This meeting is scheduled to last from approximately 9:00 until 10:00 a.m. today. Once the logistics and introductions are complete, NRC staff will discuss substantive changes to the final rule and the effective date of the final rule. The NRC staff will, then, open the meeting to take public feedback and questions. This will, then, be followed by the NRC staff's closing remarks and adjournment.

Next slide, please.

MR. ZALESKI: Stew, hold on one second. It's Brian Zaleski, NRC.

MR. SCHNEIDER: Yes?

MR. ZALESKI: The agenda, it's actually started at 10:00, just so people aren't confused. It's not nine o'clock right now. It's ten o'clock.

MR. SCHNEIDER: Oh, I'm sorry. Did I say 9:00?

MR. ZALESKI: It said nine o'clock on the slides, but I just wanted to make sure.

MR. SCHNEIDER: Oh, I'm sorry.

MR. ZALESKI: It's going to go from 10:00 to 11:00 a.m. Eastern Time.

MR. SCHNEIDER: Sorry about that.

MR. ZALESKI: Yes. Just to make sure everybody's aware of that.

MR. SCHNEIDER: Oh, okay.

Providing feedback. Public feedback on today's meeting will be captured as follows: first, as I have already stated, your feedback will be captured in the transcript of today's meeting, and second, you will also be able to provide your feedback after the close of the meeting. I will discuss later in the meeting how to do this.

Next slide, please.

Meeting purpose. The purpose of today's meeting is to discuss the proposed effective date of the final rule. This is the date on which the Office of The Federal Register considers the final regulations to be part of the Code of Federal Regulations, and that is when the rule is legally binding. Please note that the terms "effective date" and "implementation date" will be used interchangeably during the presentation. Thus, all affected licensees and other entities must implement or comply with the

revised requirements no later than the effective date published in The Federal Register notice for the final rule.

The meeting purpose is to also obtain public feedback on the effective date as it pertains to CER and to discuss the substantive changes to the final rule and their relationship to CER.

With respect to these changes, they're only being discussed today in order to give the public a better understanding of the overall final rule as it pertains to CER. Thus, again, the NRC will not be accepting formal comments on these or any previously proposed changes that are being discussed today. And again, NRC will not provide written responses to any comments made at this meeting.

Next slide, please.

Background/Schedule. At this point, I will briefly discuss the rulemaking background and the schedule going forward.

On September 16th, 2019, the proposed rule was published to align Part 26 with select drug testing provisions in the 2008 HHS Guidelines. Subsequently, on December 2nd, 2019, the public comment period closed. The NRC received a total of 22

public comment submissions on the proposed rule.

With respect to the schedule going forward, on September 15th, 2021, the NRC staff will be submitting the final rule package to the Commission to obtain Commission approval to the publish the final rule.

Next slide, please.

Cumulative effects of regulation. So, what exactly is the meaning of the term "cumulative effects of regulation," as used by the NRC? CER is a term used by the NRC to refer to the challenges that licensees and other entities face while implementing multiple regulatory actions within a limited implementation period and with limited available resources. Thus, this CER public meeting is intended to obtain feedback during the final rule development in order to inform the implementation schedule.

Next slide, please.

CER considerations. CER considerations cover the following three areas:

First, substantive changes to the final rule, as well as changes included with the proposed rule;

Two, NRC's expectations for the full

implementation date;

And three, public feedback on the implementation date.

At this point, I will turn the presentation over to Brian Zaleski, the NRC Technical Lead for this rulemaking activity. Brian will discuss the proposed rule changes, the substantive rule changes due to public comment, and the proposed implementation date.

Brian?

MR. ZALESKI: Good morning.

Stew, can you hear me?

MR. SCHNEIDER: Yes, I can.

MR. ZALESKI: Okay. Thank you.

Okay. Good morning, everybody.

So, first off, I'm going to go through the proposed rule changes, the high-level proposed rule changes.

One of the key changes that was proposed in this rule was to lower the testing cutoff levels for existing drugs that we already test for: amphetamine, methamphetamine, and cocaine metabolites.

In addition, there were two new amphetamine-based drugs proposed to be added to the

testing panel. This is methylenedioxymethamphetamine, or otherwise known as MDMA, and methylenedioxyamphetamine, MDA.

And third, revising the testing approach for 6-acetylmorphine. 6-acetylmorphine is a definitive metabolite of heroin use. Right now, licensees are required to test for 6-acetylmorphine only after a confirmatory positive result for morphine. The revised testing approach would no longer pair it to a morphine-positive result. It would be initial testing and confirmatory testing for 6-acetylmorphine.

That's slide 10 that I just discussed. Slide 11, please. Thank you.

Another core change or focus area of the proposed rule is to strengthen the subversion attempt detection provisions in Part 26.

One provision in Part 26 right now is that licensees and other entities have the option to conduct what's called special analysis testing, which means if a specimen has a dilute test result -- so, that's a validity test meaning that the creatine concentration in the urine specimen is low. It's still humanly possible to produce it, but low. When

you have a diluted specimen, that's one indication that someone might be consuming large quantities of fluids to reduce the concentration of drug in their specimen to avoid detection.

So, when we see that, currently, the rule allows a licensee to conduct what's called special analysis testing. So, in that instance, if a specimen is dilute, the licensee is allowed to lower the initial cutoff level. So, for example, if the drug had a 100-nanogram-per-millimeter initial cutoff level, and the specimen was a dilute, the licensee would be allowed to look at anything from 50, 50 nanograms, and that's 50 percent of the cutoff level. And if there was any drug concentration 50 up to that original cutoff level, confirmatory testing would be conducted at the lowest level that the laboratory can scientifically support, which is the limit of detection.

So, in the proposed rule, we mandate special analysis testing instead of providing the option. Almost every licensee currently does it. There's only two licensees that don't. So, mandating special analysis testing, and we would also lower the cutoff level. So, if a specimen was dilute -- and I

gave the example where it was 100 nanograms is the normal cutoff level and 50 was in the normal rule -- then the proposed rule would lower that to 40, so 40 percent of the cutoff level.

The second piece that we would change is we would go from the limit of detection to the limit of quantitation for the confirmatory testing when special analysis testing is conducted. And I will say that in many laboratories the limit of detection and the limit of quantitation is exactly the same measure. The limit of quantitation means that the specimen, that the quantity of the drug is scientifically supportable, it's physically supportable, and that the actual value is supportable. So, it's an added assurance that was proposed.

Okay. Next slide.

To improve the subversion attempt detection, the proposed rule proposed to expand the situations where special analysis testing would be conducted. And again, special analysis testing is just lowering the testing cutoff levels when there's an indication of a possible attempt to subvert the testing program. A subversion attempt is to cheat the testing program.

So, we just talked about mandating special analysis testing for dilute specimens. Now these are four additional criteria that would be permitted to use special analysis testing -- actually, mandated -- under the proposed rule.

One is if the donor provided a urine specimen with a substituted, adulterated, or invalid test result with no adequate medical explanation. The reality is -- and I've never seen the first two, substituted or adulterated -- but we do have instances where an invalid test result is reported back from the testing laboratory on the initial specimen collected from a donor. The MRO, the Medical Review Officer, is required to talk to that donor to understand if there's any legitimate medical explanation for that invalid result. Sometimes a medication used could result in an invalid test result.

If there is no legitimate medical explanation, a second specimen collection must be conducted. And right now, it's conducted under direct observation, which wasn't changed in the rule. So, it would be collected under direct observation.

So, under that circumstance, we would lower the cutoff levels again, as I described, based

on the special analysis criteria. So, you're going to have 40 percent of the initial cutoff level for any drug that's detected, and then, the limit of quantitation for confirmatory testing.

The next condition is, during the collection process, if a donor specimen is outside the acceptable temperature range of 90 to 100 degrees Fahrenheit, the second specimen collected from that donor under direct observation would be subject to special analysis testing. So, again, we're lowering the cutoff levels in the instances where there is evidence of a possible subversion attempt.

The majority of the subversion attempts that are identified in the NRC program -- and last year and the year before that, it was about 300 of, roughly, 1100 confirmed testing violations, drug and alcohol testing violations. About 300 of them were subversion attempts. The majority of the subversion attempts are identified by the initial specimen provided by the donor being out of temperature range.

The next condition would be if the donor's conduct indicates a possible subversion attempt. It is understandable that that would be the donor goes into a privacy enclosure to provide a specimen. The

collector hears unusual noises. A container drops. He doesn't hear the stream of urine going into the cup.

If there is unusual behavior such as that, or noises or sounds, or the characteristics of the specimen are different, or if the specimen doesn't look as it should, the collector can communicate that information to the Fitness for Duty Manager and make the determination of doing a second collection under direct observation. And in that situation, again, the special analysis testing provisions would apply. Lower cutoff level for the initial test and limit of quantitation for the confirmation testing.

And finally, the fourth condition would be if a specimen is unavailable for retesting. So, the only time that this would be occurring is if a donor had tested positive for a drug, confirmed positive. The MRO verified a positive test result or they were determined to have subverted the testing process through an adulterated or substituted test result that was reported by an HHS-certified laboratory and, again, verified by the MRO.

And then, in that instance, the donor -- this is the donor protection in our rule -- is allowed

to request either Bottle B, if the licensee collects two specimens or collects a specimen and splits it into two bottles, or a single specimen. And licensees are allowed to collect one specimen. They would take an aliquot of that and they would send it to an independent second laboratory to verify the test results from the first.

So, if a specimen was positive and the donor requested retesting in a second laboratory, and either the specimen was lost in transit or it leaked in transit and there was no available specimen, that testing event would be cancelled. And then, a second collection would be required, under our rule, under direct observation. And in that instance, again, the lowest cutoff level for special analysis testing would apply.

And what does lower cutoff levels mean? The lower cutoff levels mean that the detection of that substance, that metabolite or that drug, in an individual's body will be there longer because the concentration that we're looking at is lower.

Okay. That's slide 12. Next slide, please.

Shy-bladder process proposed rule change.

Currently, the rule requires that, if a donor cannot provide a specimen on the initial attempt, it's called a shy bladder. It means they cannot provide either any or not the minimum required quantity of urine to be tested in the laboratory. The collector will initiate the shy-bladder process, which is the donor is provided up to three hours and 40 ounces of fluid to hydrate to provide a specimen.

Under the current rule, that collector that initiated the process must remain with that donor for the entire period that they're hydrating. The proposed rule provided flexibility, allowing another member of the FFD program, another individual beyond the original collector, to observe that donor while they're sitting and hydrating, drinking water.

We received substantive comment on the proposal, and the NRC has decided to permit hydration monitors, which would be the individual, not the original specimen collector, a hydration monitor, not to be FFD program personnel. And the rationale for that was that there are other conditions currently in Part 26 that permit an individual that is not a trained collector under Part 26 requirements to observe certain elements of the collection process,

one of which is, if an individual must be subjected to an observed collection, and the same-gender collector is not available, an individual that is not a trained collector can observe that process.

Based on those public comments, the NRC has decided that we will proceed with permitting a licensee or other entity to use an individual that has been instructed on the activities that they must conduct and their responsibilities to observe a donor in hydration.

Next slide, please. That's slide 13 I just spoke about. Okay. Slide 14.

Questions in the proposed on which the NRC received substantive comments. There were two. There were more than two questions, but these are the two questions where we received substantive comments that are resulting in changes that we wanted to inform the public.

And when I say, "decided to change the rule," so these are the staff decisions that we will present to the Commission for their vote and approval or recommendations to modify.

So, the first question had to do with the 2017 HHS Guidelines. So, the original proposed rule

proposed to align the Part 26 minimum drug testing panel with the 2008 HHS Guidelines.

We also modified one element in our proposal, and that was for the ecstasy drugs. So, MDMA, MDA, and MDEA were originally in the 2008 HHS Guidelines. The 2017 Guidelines removed MDEA because of a low prevalence in the Federal Workplace Drug Testing Program.

So, NRC chose to adopt the standard in the 2017 HHS Guidelines with respect to the ecstasy drugs and only proposed to test for MDMA and MDA, and asked the question, should the NRC also include the other drugs that HHS added in the 2017 Guidelines? And those four drugs are prescription drugs, Schedule II prescription drugs: hydrocodone, hydromorphone, oxycodone, and oxymorphone. These are heavily prescribed painkillers that I'm sure the public is well aware of, these substances. These were added in the 2017 Guidelines. We received significant comment in support of adding these substances to the NRC's drug testing panel.

The second question where we received substantive comment on that was resulting in change to the rule is on direct observation of specimen

collection. So, I spoke about several of the conditions where directly observed collections would be taking place: an invalid test result on an initial specimen, coming back in to do second specimen collection; an individual during the collection process -- information that the collector is observing or hearing that suggests possible subversion attempts, and there will be an observed collection by an FFD manager at a site that's appropriate. They could also just stop the collection process.

So, in the instance of the direct observation, the donor must provide a specimen. They can refuse, but if they choose to move forward, they would provide a specimen where they need to reveal their clothing from the waist to their knees in front of an individual of the same gender.

The question in the rule asks, are there any effective alternatives to direct observations of collecting a urine specimen that would assist in preventing subversion of the direct testing process? We did receive one comment; actually, two comments supportive of possibly considering an oral fluid specimen in lieu of a urine specimen under direct observation.

HHS just published, just announced, in November of 2019, published 2019 HHS Guidelines. This is the first new specimen HHS has permitted for testing in the Federal Workplace Testing Program since the inception of the program.

So, with this comment that we received, the NRC is proposing to provide the option for licensees and other entities to collect an oral fluid specimen instead of a urine specimen under direct observation conditions. That's an option. It's not a requirement. Licensees can continue to collect urine specimens under direct observation. But the Agency's position is that these are equally effective methods of collecting a specimen from the donor.

An oral fluid specimen is collected in front of the collector. There is no going behind a closed door. So, therefore, all specimens provided on oral fluid collections are observed.

Next slide, please.

And again, I already spoke about the decisionmaking the NRC has decided to propose in the final rule to the Commission for review and vote:

Expanding the drug testing panel to include the four semisynthetic opioids: hydrocodone,

hydromorphone, oxycodone, and oxymorphone.

The second would be to provide the option for a licensee or other entity to collect an oral fluid specimen for direct observation conditions.

That's slide 15. Next slide, please. Slide 16.

Another one of the questions that was included in the proposed rule was to ask about the proposed effective date. The NRC proposed an effective date of 60 days after the final rule will be published. So, licensees and other entities would have a total of 60 days from the point that the final rule was published in the Federal Register to comply with the changes in the rulemaking.

We received two comments that are presented before you on this slide 16.

One commenter recommended that a 120 days be considered instead of the 60 days proposed. And the rationale was to understand and communicate changes to all departments and sections within the entity that they were representing.

Another commenter recommended one year. And the rationale they provided to support the one-year request was to implement the new program

utilizing established procedures, "and we'll need to evaluate a changed management plan of items, to include procedures, union labor contracts, computer systems, and training."

Those were the only two comments that the NRC received on the proposed effective date of the final rule.

Next slide, please.

NRC staff expectations. So, as a part of all rulemakings, we are required to conduct what's called a regulatory analysis, in which we evaluate the potential benefits and costs of a rule.

And this was a published document along with the proposed rule, the one that was issued before and reviewed by the public. There are many, many assumptions made in that document in terms of compliance with the rule.

The NRC staff's expectations in terms of the 60-day implementation period, it was based on an assessment of the proposed rule changes at the time and what licensees and other entities would need to do to come into compliance.

The rationale in terms of the 60-day implementation schedule is this: there are no other

pending Part 26 regulatory actions that would impact site professionals responsible for implementing the rule requirements. The changes to the FFD policy, procedures, contracts, and training are minimal. And the implementation guidance will be issued with the rule.

So, this is the opportunity now for the public to provide additional input to us in terms of the compliance date that was proposed of 60 days.

Stew, I'll turn this back over to you.

This was slide 17. Please turn to slide 18.

MR. SCHNEIDER: Well, thank you, Brian.

At this point, members of the public and stakeholders participating in today's meeting will be given the opportunity to provide feedback and questions on the NRC staff's presentation.

As a reminder, please state, first, your name and affiliation, and then, speak clearly.

Now, Operator, can you please check the bridge line to see who wants to provide feedback and/or a question?

OPERATOR: Thank you, Stewart. I sure can.

If you would like to ask a question, please press *1 at this time. Please unmute your phone and record your name clearly when prompted. Your name is required to introduce your question.

To cancel your request, you can press *2.

Again, if you would like to ask a question or make a comment, please press *1 at this time.

Speakers, give me a couple of moments for the questions to queue up.

(Pause.)

Speakers, our first question comes from Johnny Rogers.

Johnny, your line is open. You may proceed.

MR. ROGERS: Well, good morning. Thank you very much.

My name is Johnny Rogers. I'm a Senior Project Manager at NEI.

Just some feedback based on the presentation. And thank you, Brian Zaleski, for running down the new rule changes.

NEI appreciates the opportunity to speak on behalf of the industry, many of whom are present on this call this morning. The industry professionals

represented here today are supportive of the new fitness for duty rule changes. The new rule changes represent enhancements, efficiencies, improvements, and do nothing short of strengthening the FFD program.

Our members are concerned regarding the timing and the execution of the new rule, and we appreciate the opportunity to provide some feedback this morning.

First, let me say that there are always concerns with timing and schedules, and nothing impacts a program more in terms of timing than outages and major maintenance. Licensees are engaged in outage operations typically at two points during the period of the year -- springtime, of course, but, usually, it extends from February to May, and then, the fall of the year, August through November. And these periods vary slightly, depending on the outage scope.

Program personnel are fully engaged in processing workers that can range anywhere from 800 to 1200 workers. And again, that varies. But they have only a few weeks to screen these individuals and get them ready for a nuclear-work-ready environment. And then, you have that followed by weeks of outage

support, and then, the eventual time it takes to outprocess all of these personnel. It's an eight-week or more commitment at least once a year and sometimes twice a year.

Some sites impose training and system change blackout periods of two months prior to and through two months after outages. And this means that no training or no system changes are conducted during this period of time.

Outage duties, in short, are an all-hands activity and it requires the total commitment of access and fitness for duty staff.

And then, there's the time between outages. And that ranges from May to July for programs. And in that time, there are inspections and audits, self-assessments, departmental training, program improvement projects, and then, there's the conferences and trainings that programs have to get through.

Brian mentioned change management considerations. That's absolutely true. The new FFD rule will require what we believe to be significant change management efforts.

Site communications. We have to do that

in all-hands meetings, electronic newsletters, websites, shop meetings.

We have to train a program, fitness for duty staff.

Then, there are the NANTeL changes that have to take place. NANTeL, of course, is the National Training Database that all sites use. Changes to the NANTeL course are submitted only on two occasions during the year, the first window being usually in March, and then, the second window in November. If those windows are missed, then you have to -- or if the first window is missed, you have to defer to the second window. So, the salient point is those changes aren't made on the fly. They're made at certain times of the year.

We have to train our worker population, and then, there's stakeholder discussions with unions, for those programs that have unions; contract changes with laboratories, primary and secondary labs. Blind specimen providers will also need to be put on notice.

And then, we have the procedural changes to the FFD program that need to be changed. After we change the procedures, we'll have to talk about changes to house systems. External IT software

vendors are going to need to make changes based on these rule variances. Licensee house systems will require IT changes to accommodate the expanded panel that you heard Brian talking about. Fields to receive that expanded data, that expanded panel data, must be constructed, and then, the internal IT personnel must develop those test plans and test those changes.

And then, when the IT organization is done, they hand those off to program personnel to perform user acceptance testing before the changes can be implemented.

Some additional considerations include COVID. COVID has forced many organizations to work remotely, a condition that may continue on some level well into 2022; thus, potentially complicating notification and training efforts.

Personnel retirements within the industry have resulted in new personnel in key management positions, and that sort of complicates new rule implementation.

And then, over time, overall, if we're just talking across the organization, overall staffing levels and access in FFD organizations have declined.

And then, there are some cybersecurity

concerns with respect to additional reviews, as licensees consider transmitting laboratory data reports from the lab to the licensee.

In conclusion, the access-FFD community supports the proposed rule changes. For the reasons that I've highlighted, the industry is concerned about a 60-day implementation. Given the challenges with outages, changed management, and IT challenges, we feel that a 60-day implementation is not reasonable. And unless I'm mistaken, the 2008 rule was one year in implementation.

The Industry Task Force continues to hold that a one-year implementation period provides the necessary time to prepare and properly execute the changed management plans.

The industry and NEI are grateful for this opportunity to speak regarding these issues this morning, and we thank you.

End of comments.

MR. SCHNEIDER: Thank you, Johnny.

Brian, do you have any comment on that?

MR. ZALESKI: No. I appreciate the additional detail in terms of what you just mentioned. It's far more detail than what we received in the

public comments to help understand the impacts of the rule changes.

Fred, I don't know if you have any follow-up questions.

And I'm referring to Fred Schofer, who's the Regulatory Analyst.

MR. SCHOFER: I just had to unmute.

This is Fred Schofer, NRC.

Thank you, Mr. Rogers, for the breakdown of the steps required to implement the rule.

One thing that you brought up which was probably not fully developed was the impact on external IT software. What we're saying is that, within that one-year implementation period, all these steps can be taken, such that software can be revised, tested, and implemented, and installed, as well as your NANTeL training course database can also be revised and that training can be rolled out and implemented. Is that correct?

MR. SCHNEIDER: Johnny, if you're speaking we can't hear you. I don't know if you've been muted again or if you unmute yourself.

OPERATOR: Johnny, can you please press *1?

(Pause.)

MR. SCHNEIDER: Johnny, we're still unable to hear any response, if you are trying to communicate.

MR. ROGERS: Can you hear me now?

MR. SCHNEIDER: Yes, we can.

MR. ZALESKI: We can.

MR. ROGERS: No, I was just commenting -- and thank you for that; I was on mute. No, we believe that both of those elements, the IT software changes and the NANTeL course, can be adequately changed and modified within a one-year period.

The additional comment I have on the IT piece is, while our external vendors are fully engaged and supportive in helping programs develop the change, a lot of the challenge comes from the internal IT organizations. This is what I've learned from members of our Task Force and industry. So, all IT organizations have schedules, and getting them onboard and getting test plans made, and then, getting those vetted and tested is really where the most significant change happens. So, after the external vendors are completed or have completed those changes and turned them over to the licensee, then you've got the

internal IT organization you have to work with. So, I'll just add that for clarity.

MR. ZALESKI: And, Johnny, this is Brian Zaleski -- I do have one question -- NRC.

So, the changes would be specific to adding these additional substances in the actual systems to accommodate transfer from the laboratory and manage those results internally? Or does it go beyond that? I'm just curious.

MR. ROGERS: No, based on what our software vendors have told us, tables have to be built for the expanded panel, such that the information that's, then, transferred from the labs to the licensee can receive that data. And then, it's filtered into the house system. So, that requires a little architecture and a little work, and then, it has to be tested.

MR. ZALESKI: Which you need to, then, be able to report out test results to the NRC and the annual reports, correct?

MR. ROGERS: Absolutely correct.

MR. ZALESKI: As part of the tracking system. Okay.

MR. ROGERS: Yes. Yes, sir.

MR. ZALESKI: Thank you.

Brian, I don't think I have any other questions in terms of the information that NEI provided.

MR. SCHOFER: I have no further questions, either.

MR. SCHNEIDER: Operator, can you check to see if anyone else has a question or feedback to provide from today's meeting?

OPERATOR: Yes. Our next question comes from William Gross.

William, your line is open.

MR. GROSS: Thank you very much.

I didn't have a question. I wanted to fill in with Johnny, if he had dropped off, when he was trying to come up but on mute. So, I'm done. Thank you.

OPERATOR: And, Speakers, at this time, we have no additional questions or comments. Thank you.

MR. SCHNEIDER: Thank you very much, Operator.

I want to thank the participants on the bridge line who provided feedback and questions on the material presented at today's public meeting.

Now I will discuss how members of the public and stakeholders can find information on the final rule.

Next slide, please.

Where to find information. You can find information about this rulemaking activity on regulations.gov.

A summary of this public meeting and the transcript will be posted to this site within 30 calendar days after today's meeting.

Please note that the meeting summary will also include a list of today's attendees.

If you search for Docket ID NRC-2009-0225 on regulations.gov, you'll be able to find these and other documents related to this rulemaking, such documents being The Federal Register notice for the proposed rule, the 22 public comment submissions on the proposed rule, and the slide presentation for today's meeting.

Next slide, please.

How did we do? Your opinion on how this meeting went will help us to improve on future meetings. There are two ways for you to access the online NRC feedback form for today's meeting. One way

is to scan the QR code displayed on this slide. This will bring you directly to the feedback form. The second way is to go to the NRC's public website meeting schedule after today's meeting, then open the meeting notice, and you will see that it was updated to provide a link to the feedback form.

Please note that this slide includes an example of a notice from a previously held meeting to show you where the feedback form link will appear. And if you look at the picture that was screen-captured, you'll see it under the telephone. It says -- thank you -- "Meeting Feedback Form".

Please let us know if you were satisfied with today's public meeting or if you have any suggestions for how we could make it more effective.

Next slide, please.

NRC contacts. As a reminder, you can contact me, Stewart Schneider, if you have any questions related to the rulemaking process, and Mr. Brian Zaleski for any technical and regulatory-related matters.

Next slide, please.

Thank you. Thank you for attending today's meeting to discuss the Fitness for Duty Drug

Testing Requirements final rule and the cumulative effects of regulation.

Have a great day. And this concludes today's meeting.

Thank you.

(Whereupon, at 10:45 a.m., the meeting was concluded.)