Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Stakeholder Meeting on the Implementation of the Fitness for Duty Rule (SECY-00-0159)

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Wednesday, March 21, 2001

Work Order No.: NRC-119 Pages 304-537

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005

(202) 234-4433

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
+ + + + +
STAKEHOLDER MEETING ON THE IMPLEMENTATION
OF THE FITNESS FOR DUTY RULE
(SECY-00-0159)
+ + + + +
WEDNESDAY,
MARCH 21, 2001
+ + + + +
ROCKVILLE, MARYLAND
+ + + + +

The meeting was held at 9:00 a.m. in the Nuclear Regulatory Commission's Auditorium, Two White Flint North, 11545 Rockville Pike, Mr. Garmon West of the Office of Nuclear Reactor Regulation, moderating.

PRESENT:

GARMON WEST	NRR
NANCY DURBIN	MPD Consulting
A. BRUCE EARNEST	Region III
EDWARD JOHANNEMANN	NMSS
GEARY MIZUND	OGC
GARY PIRTLE	Region III
GREG SMITH	Region I

ALSO PRESENT:

BRAD BAXTER
JERRY BEBB
SHARON BLUE
BRETT BOISMENU
T. SCOTT BRAZIL
RICHARD BUCHER
KATHY BURKETT
MICHAEL BURRELL
LOREN BUSH
JEFF CAMPBELL
PATRICIA CAMPBELL
RON CASEY
PEGGY CLARK
RANDY CLEVELAND
SHELLY CRAIG
PATRICIA DAVIS
PETE DEFLIPPI
NICK DiPIETRO
AL DYMOND
SHERRY ECKERT
RICH ENKEBOLL
RICH FITZSIMMONS
JOHN FLINN

PETER FOWLER

ALSO PRESENT: (continued)
SANDRA FRANCIS
NEIL HARRIS
PAT HARRISON
AMY HANSE
LYNN HAUCK
LORI HAYES
LORNA L. HEALEY
WALTER JOHANSEN
MARGARET JULIANO
ROBERT R. KELM
DARLENE KOPP
SUSAN LANOUETTE
LISA MATULA
EILEEN MOORE
JOHN MORIARTY
RANDY MUMME
JAMES NOEL
PAMELA O'CONNOR
CINDY PARENT
REBECA L. PATSY
MICHAEL PRIEBE
SHARON QUINN
RICHARD RIST
BILLIE ROOKS

ALSO PRESENT: (Continued)
TED SHULTS
ROBERT SOUTHWORTH
REBECCA STANFIELD
MARTHA TAYLOR
SUE TECHAV
JANET THIEL
FREDERICK WHITT
GLENN WILSON
MANCHESTER WOODARD-HALL

I-N-D-E-X

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

(9:01 a.m.)

MODERATOR WEST: Good morning to everyone. I'd like to get started, please.

I know there was a little bit of slowness, probably yesterday morning in getting through the guard's station due to the fact that we didn't, some of the names that we had in advance, but hopefully we got that straightened out. Still not straightened out? Well, we'll just have to continue to work on that, at least for the ones of you who will be here tomorrow.

I want to mention on the schedule for today we've -- which I've been aware of, we've encountered a little bit of double booking for this auditorium. It's only a minor issue in that there's a group that has to be in here, we're scheduled up through 5 o'clock, but there's a group that has to be in here after 5, but you can probably tell from all of the arrangements they've made for us over the last couple of days, it takes a little bit to get everything set up and so forth and what I'm going to say is that we're going to go no longer than 4 today and that will give us a chance to -- I know you all are very disappointed because of that, but that will give us a chance to get a few of our things that we still need for tomorrow secured and probably a little bit of talking at the end so you won't be super rushed to get out. So that will be the only change to the schedule.

I continue to encourage you to use the sign-in sheets, particularly for those that are here that weren't here yesterday and I'd like to start today with just a few points that I wanted to make.

We talked yesterday about whether or not the history of substance abuse had been addressed in the proposed rule. I would agree if you look at the proposed rule that was published in the Federal Register in 1996, you won't, in fact, find in a subsection similar to what you have in the new rule, you won't find in a subsection labeled definitions and the proposed definition for history of substance abuse.

But what I would like to point out is that we did, in fact, mention that under the definition section which is admittedly general, we did mention that we were proposing to clarify definitions of some terms and especially those terms that would relate to other areas that would be changed and then one other

point in the rule making package itself, the proposed rule making package.

Under the proposed section for 26.23 which we discussed yesterday having to do with contractors referring individuals to the -- to a licensee with a known history of -- a history of substance abuse, we did mention that. So I'm just trying to indicate there was some sense of using that particular terminology in there, although it wasn't explicitly laid out with a definition.

And then lastly and then I won't belabor this point, lastly, there is a discussion in the rule making package for the new rule where we're -- it's in the attachment to the rule making package that deals with response to public comments and it indicates that we received a few and actually precisely there were two commenters that mentioned the need to have a definition for history of substance abuse and that's in Attachment D which is the one that deals with response to public comments in SEC-00-0159. And it's precisely, because it's a rather large document, it's in the subsection 6.5.3 that talks about history of substance abuse.

Today, what we will do, we'll just continue on. We'll go through the remaining sections of the rule, continue to use the same format. I'll pick up where I left off with Section 26.27 and I would ask you, we don't have a lot of remaining slides in that area, but I would ask you and I'll start with page or slide 73, but I would ask you to since, especially since we don't have a lot of remaining slides, to just wait for any questions or comments you have until after I've presented the slides and then we do, in fact, have some questions related to that particular section and then any questions or comments you have we can certainly get into those.

This continues with some of the questions that we received in this section and the question was if an individual who was terminated due to a confirmed positive drug or alcohol test returns after the mandatory 3-year period, must the licensee place the individual on a mandatory 3-year follow-up testing program?

And the answer we provided is as follows. Yes, as stated in 26.27(b)(5), persons removed for periods of 3 years or more under the provisions -- and there's some other of the language there -- before an individual is permitted to be returned or assigned to perform activities within the scope of this part, the

individual must be determined to be fit to safely and competently perform these activities by an appropriate manager and licensed position -- terminology we've used previously, certainly is management and medical determination of fitness -- qualified to make the medical determination of fitness.

Further, a return-to-duty test under 26.24(a)(5) must be conducted before the individual may be assigned to duties and follow-up testing under 26.24(a)(4) must be conducted to verified continued abstinence from the abuse of substances.

And the next question which has two bullets, what obligation does the licensee have to track the duration of follow-up testing at another licensee's facilities?

And secondly, for reinstatement of unescorted access after a violation of a policy under 10 CFR part 26, is a management and medical determination of fitness required?

And for the first item the answer is none with some further explanation. The licensee has the obligation to assure that individuals with a history of substance abuse have completed appropriate follow-up testing prior to gaining access to the protected area. For individuals being reinstated after having been suspended under 26.27(b)(3) or removed under 26.27(b)(3), (b)(4) or (c), this follow-up testing must meet the requirements of 26.24(a)(4).

The licensee has no obligation to track follow-up testing at another licensee's facility unless the licensee wants to credit the individual for completing a program at another facility. For example, an employee is detailed or loaned to another site. If the licensee does not verify that appropriate follow-up testing has been completed elsewhere, then the licensee would need to (a) complete the follow-up testing at the licensee's facility, or (b) determine that the individual has not completed the follow-up testing and must be denied unescorted access.

And for the second bullet, much shorter. The answer is yes.

The next question, 26.27(6)(i), this is the reference point here, does this include individuals who are suspended for 14 days on their first Fitness-for-duty violation and subsequently returned to work or only those individuals who were removed for a period of 3 years following their second

FFD violation for 5 years following the use, sale or possession?

And our answer is neither. And we refer you to Section 26.27(6)(ii) which states that temporary access provisions of 73.56 do not apply and cannot be utilized for these individuals.

The next question under 26.27, can unescorted access be granted up to 72 hours pending completion of a suitable inquiry on an individual transferring from another licensee?

The answer is no, with some explanation. This is only for licensee employees with unescorted access who have been absent from the program for 60 or more days. If a licensee determines that it will take more than 72 hours to complete a suitable inquiry for the individual, then the individual should not be granted unescorted access until 72 hours before the suitable inquiry will be completed.

I'm sure we'll get some discussion on that one.

(Laughter.)

I'll try to explain the intent a little bit later. So the overall answer is no for this particular question. This is only -- I'll repeat the question -- well, you can see the question. This is only for licensee employees with unescorted access who have been absent from the program for 60 or more days. If a licensee determines that it will take more than 72 hours to complete a suitable inquiry for the individual, then the individual should not be granted unescorted access until 72 hours before the suitable inquiry will be completed.

Next question, when unescorted access is granted with a pending suitable inquiry, does the suitable inquiry have to be initiated before access can be granted? And the second part of the question, is the 72 hours to complete the suitable inquiry taken literally, that is, does the clock start the minute the person gains access?

Our response to the first item is yes. Further, the suitable inquiry is initiated only after all previous employers have been contacted. The suitable inquiry is not initiated by only contacting one or two employers unless one or two is the total of all previous employers.

And for the second item, the answer is also yes. And we refer back to the response to question 75 which is also related to 72 hours, the one

that I mentioned we probably would have a lot of discussion on.

The next set of questions, how are initiations of suitable inquiries documented? What constitutes a best effort for suitable inquiries? Who decides when seeking information becomes too burdensome?

And the answer to the first question is as follows. A suitable inquiry is initiated with all required requests for the FFD information when all those requests have been sent to the individual's previous employers during the required period. This is documented by a written record of the request.

And for the second item the response is as follows. Best efforts include activities such as documented attempts to contact previous employers, obtaining verification by telephone, letter or some other means. The decision on too burdensome is left to the discretion of the licensee.

Next, does an applicant for unescorted access who lists a DUI always require a management and medical determination of fitness and follow-up testing, or must this report also raise a concern about the person's history of alcohol or drug use?

And our answer to this question is as follows. The history of substance abuse must raise a concern about the person's history of alcohol or drug use and therefore fitness. The NRC expects that in addition to all individuals who are seeking reinstatement after having been removed under 26.27(b)(3), (b)(4) or (c), other individuals with a history of substance abuse would be carefully evaluated with regard to whether a management and medical determination of fitness is required. The NRC understands that a DUI occurring many years ago followed by a treatment program of some type and no additional incidents in the intervening years may not need such follow-up testing.

Next question. Is a management and medical determination of fitness only required for new applicants or the first time a worker applies for unescorted access after a violation?

Our answer is all applicants who have a history of substance abuse that raises a concern about the person's history of alcohol and drug use must have a medical and management determination of fitness. Licensees may use a previous management and medical evaluation of a returning individual to help assess

whether there is a concern regarding the history of alcohol and drug use.

And the next question, if an individual has a history of drug abuse, must they have a medical determination of fitness and be put in a follow-up program?

And we answered in this fashion. If an individual has a history of drug abuse, that raises a concern about the person's use of alcohol and drugs. The individual must have a medical and management determination of fitness. An example of a history of drug abuse that may not raise a concern could be the one time use of a spouse's prescription medication. This evaluation will determine whether a follow-up program is appropriate.

In all cases of individuals being reinstated after having been suspended under 26.27(b)(3) or removed under 26.27(b)(3), (b)(4) or (c), follow-up testing is appropriate and required.

Next, we have this question. In areas where there are requirements for restoring access after absence of more than 60 days from the possibility of being tested, when was the unescorted access suspended?

And we answered, unescorted access has not necessarily been suspended, but the individual has not been covered by a Fitness-for-duty program for more than 60 days. Individuals in the employ of the licensee who have unescorted access are required to be under a Fitness-for-duty program.

If the individual has been removed from the possibility of being tested for more than 60 days, then the individual has not actually been covered by a Fitness-for-duty program and should no longer be granted unescorted access. The individual may continue to have access with a return-to-duty test or if selected for random testing during the absence, a random test and a suitable inquiry about the period of absence that is completed within 72 hours.

I only have a few more questions in this section.

What are the expectations for individuals put on suspension? For example, 30 days without pay referred to EAP for treatment, under what conditions must they still be covered by behavioral observations, chemical testing and sanctions for violations?

The statement in 26.27(b)(3) addresses this question. If the individual is in a 30-days without pay status and at home, it is not expected

that behavioral observation would be applicable. If the individual is still working for the licensee, for example, in an area outside the protected area such as training and the licensee anticipates restoring access after the period of suspension, then the individual should continue to be covered by the program.

This would mean that if the individual had a follow-up test, a random test or a for cause test, and had a confirmed positive test result, then the individual would have a second confirmed positive test result and be denied access for a minimum of 3 years.

That's the last question that we received in the section for 26.27.

Are there any particular ones that I covered that you might want to go back to?

(Laughter.)

MS. DURBIN: Before we start, can I clarify something on this last question? Because of the section that the question was asking about, the assumption is that they are suspended because of a first confirmed positive test result. And the rule states that if they're in a work status, they should continue to be covered by the program, so that was the reason that a second -- that if while they were under the program they got tested a second time, it would be a second positive.

I don't think if you're coming to this question without it in context, I didn't realize that until I kind of looked at it without the context, so the context is this is a suspension because of a first positive confirmed test result. Just clarifies the answer a little bit.

MODERATOR WEST: Thank you for the clarification.

MR. BURRELL: Good morning, Garmon.

MODERATOR WEST: Good morning.

MR. BURRELL: I'd like to go back to 6(i) and (ii).

(Pause.)

As well as 7. I'd like to look at these collectively, if we can, with the following foundation. Under the current rule, the grandson won unescorted access temporarily. We are required to complete suitable inquiries for the most recent year. And following that we have 180 days to complete the remaining suitable inquiries for 5 years best effort, 3 years certain.

Under the current standard applicable in this rule, under (i), we will now be required to

initiate and given your definition, initiated means that they've been sent and a written record is established, we'll be required to initiate suitables for the entire 5 years prior to the granting of a temporary clearance. Is that the intent? It seems to be what this says.

MODERATOR WEST: I think you're correct that you would have had to have initiated in terms of at least contacting the previous employers. I think that is correct.

MR. BURRELL: The entire 5-year window prior to granting unescorted access?

MODERATOR WEST: Well, there wold be instances where you could, under certain conditions, you could grant the unescorted access after looking at the first year for previous employers and then you would have initiated -- and if they didn't have any previous history of substance abuse, then you would be allowed to grant unescorted access, after initiating the remaining 4.

MR. EARNEST: This is very similar to what you had on the access authorization rule. In other words, you've got a -- for the temporary unescorted access, you clear them for a year, boom and then you go with -- you've initiated the full background, well, the same thing here. You're initiating the full 5-year -- the other 4 years --

MR. BURRELL: No, see, that's not the case. And that's where the real rub comes in.

MR. EARNEST: I understand. I just wanted to clarify it, what the difference is that you're talking about here.

MR. BURRELL: Okay, the requirement today is that we complete the suitables for the most recent year prior to the granting of unescorted access.

MR. EARNEST: Right.

MR. BURRELL: In other words, the word complete is important. We complete the suitables for the most current year prior to granting a temporary clearance. Okay.

Then we have 180 days.

MR. EARNEST: Right.

MR. BURRELL: To complete the remaining suitable inquiries for 5 years' best effort, 3 year absolute.

This new standard will now require us to initiate all the suitable inquiries for that 5 year window prior to the granting of a temporary clearance

which is distinctively different than what the rule requires us to do today.

MS. DURBIN: Could you show me where in the current rule it says that you can grant temporary unescorted access?

MR. BURRELL: Sure can.

MS. DURBIN: I'm sorry, I'm having trouble finding it right now.

MR. BURRELL: I don't have it right on the top of my head, but I can point it to you during a break.

MS. DURBIN: Sure. That would be great. Thanks.

MR. EARNEST: I'm confused too.

MR. BURRELL: The language is temporary access notwithstanding the provisions. It comes -- I'll be glad to point it out to you during a break.

MS. DURBIN: I just found it.

MR. BURRELL: Okay, thank you.

MS. DURBIN: It says for purposes of this discussion, the temporary access provisions are not affected by this part if the prospective worker passes a chemical test conducted according to -- etcetera.

MR. BURRELL: That's correct. All we need is the passing of a chemical test.

MS. DURBIN: Right.

MR. BURRELL: Okay. And the current year's suitable completed.

There's no requirement to initiate all the suitables for a 5-year window prior to the granting of a temporary clearance. So there's a distinctive difference in what exists today and what this proposed rule suggests we have to do. And that certainly gives us some concern.

Under item 7, I heard you say during your discussion that this applies itself only to licensee employees gone from the licensee for more than 60 days.

MODERATOR WEST: Correct.

MR. BURRELL: Okay, the problematic language here is that the last sentence of item 7 is precisely the same as the last sentence in item 6 and that suggests that the suitable inquiries are expected to take place with someone other than the licensee employee outside the licensee employee.

Now if indeed this person is a licensee employee, there are no other employers with which to contact for additional information. There are no

employers to contact if this indeed is intended to be for a licensee employee.

As Nick brought up yesterday, we would -- it seems as though the expectation would be to ask of the licensee employee, the litany of questions applicable to suitable inquiry and if that's where we are intending to stop, this last sentence is inappropriate in this paragraph because this last sentence drives one to go beyond the licensee employee and indeed seek out employers that don't exist.

MODERATOR WEST: Your point is well taken. The intent is, in fact, to address this particular requirement to licensee personnel.

MR. BURRELL: Okay.

MODERATOR WEST: And not other individuals. And I think we can address that through some clarification.

MR. BURRELL: Okay, because again the word, using the word individual seems to cover the broad scope of every person returning to a licensee utility.

MODERATOR WEST: I understand. Thank you.

MR. BURRELL: Thank you.

MR. ENKEBOLL: Rich Enkeboll, NEI. Following what Mike has said, it's not clear to me what's broken that you're trying to fix with this.

We've been doing this for 10 years, as Mike described, and now it looks like you're going to put a stick in the wheel to keep us from getting people into the plant and starting an outage and we just don't understand that.

Could you -- could somebody explain what's going on?

MODERATOR WEST: Are you speaking of the initial --

MR. ENKEBOLL: You can't grant temporary unescorted access until you've initiated a suitable inquiry for the total 5 years after the first year. That's a stick in the wheel. It's not been done and now there's something -- we don't understand why that's happening.

(Unmiked audience members shouting comments.)

MR. EARNEST: Well, let me ask a question here. I want to make sure I understand this.

Like I say, I'm sitting here kind of comparing this to the access authorization rule and I may be completely off base here, but I want to make sure.

As long as you show that you have initiated something, you have a record. Now for example, at your plant, Wool Creek, when you initiate suitable inquiry do you all do that work yourself or do you give that to your subcontractor or how does that work?

Russell?

MR. SEARS: The way that we do it now, we initiate the background investigation by sending it to the investigative agency.

MR. EARNEST: Right.

MR. SEARS: They return a temporary background to us with the completed 1-year suitable inquiry on all employments or unemployment periods covered in that temporary.

The initiation that we're taking credit for now is the fact that the background has been initiated. There is absolutely no expectation that the background agency is going to have a record that each of those employers has been contacted before we grant temporary unescorted access.

The remaining 3 or 2 years if it's a 3-year background or 5 years total, the initiating process is the fact that we have gotten the information off the security questionnaire from the applicant, put that in the hands with the release of the BI agency and they have returned a temporary to us. We grant unescorted access based on the temporary and the completed chemical test. Those two elements are put together and the individual is granted temporary unescorted access for 180 days.

MR. EARNEST: Right. Now explain though how you do the inquiry here, as far as Fitness-for-duty?

MR. SEARS: Well, the suitable inquiry is initiated based on our current practice by handing it to the background agency and they will contact all previous employers. For the first year, all those contacts are made, are documented and that is in-house before we grant temporary access. The initiation part for the remaining portion, applicable portion of the background investigation for the full or the up date is what they have in-house and they may have contacted 2 of the 20 employers. They may have contacted 19 of the 20 employers.

But we have absolutely no documentation or expectation at this point that they would have initiated by this current definition and have documentation in hand that every employer had been

contacted because that's what our -- the benefit of the 180-day temp period is for.

MR. EARNEST: Again, the rule says you're going to do that for one year. You're going to get that completed.

MR. SEARS: In-house.

MR. EARNEST: Right.

MR. SEARS: Documented.

MR. EARNEST: Then you're going to turn that over to someone else to do the rest of the 3 to 5. When you initiated it, as far as I'm concerned on the first one -- I guess I'm misunderstanding --

MR. SEARS: By our definition, initiated is having it in the hands of the background --

MR. EARNEST: I tend to agree with what you're saying.

MR. SEARS: As I just explained, we had to have documentation that those suitable inquiries have been initiated by contact with those employers. And if you've got 20 additional employers in that remaining scope, that is not currently happening and that would definitely close the process down.

MR. EARNEST: Thanks.

MR. MIZUNO: I guess I have two things. One is I don't, again, because this is a long time ago now, I'm not sure whether comments that suggested that the initiation proposal which was in the proposed rule was going to represent a burden, but I guess that's beside the point. You guys have now identified that as a concern.

Is Loren Bush in the audience?

MODERATOR WEST: Good morning, Loren.

MR. MIZUNO: My recollection, okay, and this was almost a -- I don't think we considered it an important issue, but I do recall Loren Bush saying to me at one point that he wanted to have the initiation start because he didn't want licensees to abuse the provision of completing the remaining 5 year, 4 of the 5 years of the suitable inquiry on a best-effort basis, that the best-effort basis would be truncated because they didn't initiate the inquiry until 5 days or a week before the 180 day period.

MR. SEARS: If you were a practitioner, you'd know that is not a place that you could get yourself. There's absolutely no way you can initiate 5 days before the 180 days.

MR. MIZUNO: Okay, well, you wanted to know what was the rationale. That was my recollection of the rationale.

MR. SEARS: Our 10-year track history of how we have implemented this, the way it's been inspected and audited showed that we were in agreement with initiation because initiation was what I just explained.

To redefine initiation as what Garmon explained earlier is complete changing of the process.

MR. MIZUNO: Okay, I think we will get back and we'll see -- I mean the word "initiation" is obviously susceptible of quite a number of meaning and we will take your comments and ultimately you'll get some kind of response.

MR. SEARS: One final note on this, I think if you had an opportunity to look at the actual implementation of this practice, as background agencies gather the information over that 180-day period, if anything derogatory is identified, they notify the licensees immediately. We don't wait until the last minute to get information, so it's acted on in a prompt manner.

MODERATOR WEST: I would just underscore what Geary has said. We can certainly take a look, another look at the definition we provided for initiation. And we'll do that.

MR. EARNEST: Basically, Garmon, on a suitable inquiry, I mean if you're going to require that they have paperwork to initiate every single person, more like he said, perhaps 20 of them, you know, I mean if you've made that initiated contact, you probably got the answer you wanted right then anyway and you completed it. So initiate doesn't really -- you know, and you're going to have to show that you've already contacted all of these people.

Initiate really isn't the right term to use if you're going to do that because initiating is just initiating the entire action as it goes just like Russell is explaining there and that's the way we've inspected it and that has been the standard by which at least some regional inspections have been conducted.

That's why I was having a little bit of trouble understanding it, based on the earlier comment because initiate to me was, hey, once you have shown me some records that I have initiated this BI or this suitable inquiry, you've initiated it and if you don't finish it, then I have a right to come in and audit you and tell you that you didn't do a good job of finishing it and that you're -- your best effort really wasn't a best effort if you waited 3 days

before the 180 days or whatever time frame it is runs out and you didn't really do a best effort if you only spent that much time doing it.

So I was a little bit concerned that we were misunderstanding what initiated meant here because we're creating a whole new methodology of initiate here and that's the reason for their concern and mine too. I just wasn't quite sure what I understood.

MODERATOR WEST: Thank you, Bruce. We'll certainly take all of that into account. Please.

MR. DiPIETRO: Nick DePietro with First Energy Nuclear Operating Company.

Just another point on initiation and I agree with what Russell says. When he sends his backgrounds to his background agency, that's initiating the background investigation and then the background company will start the 1-year suitables and then follow up with the 5-years. But that may not be true in all cases.

At my site, at least right now, we do the majority of the background investigations ourselves, so there is no initiation when we're sending that out to a background agency, because we're conducting them all in-house. We've been using the same standard. We have temporary access requirement. We'll complete the suitable inquiries for the first year, grant the temporary access and then at some subsequent time complete the full 3 or 5 years, whatever we can get on the background. So we don't have an initiation process by just sending that background to a background screening agency.

MODERATOR WEST: I see. Thank you. Your comment, please?

MR. BOISMENU: Brett Boismenu. Nine Mile Point Nuclear.

My question has to do with medical determination. Presently, if somebody has a violation, we have them go to an agency outside of Nuclear, get a substance abuse evaluation. That information is brought into the MRO. The MRO reviews it.

Under the proposed rule change, really that's not going to be an option because if we have to have all the different agencies in our pool as the change read up from the scope, we'll have to have the MRO reviewing all these medical determinations?

These MRO will be loving it. They'll have more business than they'll know what to do with.

Does the NRC have any guidance on having the assessment or the clinical evaluation performed outside by somebody else and then having the MRO review that to cut down on our costs?

MODERATOR WEST: Let me see if I fully understand what you're asking. It seems to me you're saying that under the current rule you would have some outside physician do some part of the MRO's functions --

MR. BOISMENU: Not only a physician, because most of the substance abuse agencies, they may have a master's -- all it really requires is a substance abuse evaluation.

MODERATOR WEST: It's an interim step and then eventually that information is funneled to the MRO?

MR. BOISMENU: Correct.

MODERATOR WEST: And you're anticipating, as I understand it, that under the new rule you wouldn't be able to do that?

MR. BOISMENU: They don't meet the definitions of a medical determination. You have to have a physician and it has to be a face-to-face interview.

MODERATOR WEST: I guess the point I'm trying to sort through my own mind is that ultimately even under the new rule, you would still have the Medical Review Officer making the determination, just using information from another source that he or she didn't originate.

MR. BOISMENU: Correct.

MODERATOR WEST: So I guess and I'd be interested in Geary's view on this, I don't see that as a fundamental problem in and of itself.

I think the central thing here would be that the Medical Review Officer would, in fact, make the determination.

MR. BOISMENU: But the Medical Review Officer will have to sit down with each DWI which every person with a substance abuse or history of substance abuse, do a face-to-face clinical evaluation which before they could pick up a piece of paper, contact an agency and say did this person fulfill their obligation based on this evaluation? And if they were satisfied, they'd give the green light to give access.

Now they're going to be responsible for the whole thing.

MODERATOR WEST: I guess what I'm missing here is how do you justify it in your own mind even under the current rule, that you're essentially doing the same thing or you propose to do the same thing under the new rule. But how do you justify the MRO making that medical determination under the current rule?

MR. BOISMENU: The evaluation could take -- a proper substance abuse evaluation could take two to three hours, okay? They have to contact spouses and representatives. If we're going to need the MRO to do that, it's going to delay the process tremendously and raise our costs.

What we're doing is basically telling the individual they need to go to a substance abuse clinic which they pay for their own evaluation and then they come in with a piece of paper. We don't have the burden of the financial cost, but now if we have to pay our MROs to do this, our costs will go way up.

MODERATOR WEST: But the individual would pay for their own evaluation and bring the results of that evaluation?

MR. BOISMENU: Correct.

MODERATOR WEST: To the MRO and then ultimately under the way you're doing business now, the MRO would make the determination?

MR. BOISMENU: Correct, without seeing the individual by just looking at the paperwork.

MS. TECHAV: Garmon, this is Sue Techav from Exelon.

What he's stating is we do the exact same practice. We require the individual to do a CAC from a Certified Addiction Counselor. We get a copy of that. We get a copy that they've enrolled in treatment. That goes to our MRO. They review it. There's no face-to-face exam and interview. It is a paperwork trail that they review and come back to us and say whether or not the individual is acceptable for unescorted access, if they need to be put in a follow-up program, etcetera, etcetera. And it's based on their expertise of substance abuse. But it's not a face-to-face.

MODERATOR WEST: Is it 100 percent that you never have this face-to-face interaction between --

MS. TECHAV: Absolutely.

MS. DURBIN: Even if the person is in violation of the Fitness-for-duty policy?

MS. TECHAV: Yes.

MS. DURBIN: Okay, under the current rule, I believe there has to be a face-to-face evaluation so --

AUDIENCE: No.

MS. DURBIN: No? For opiates? For opiates only. Okay.

MR. BOISMENU: I guess my question is does the NRC have any guidance how we can reduce the financial burden in putting the MRO -- basically, I believe a lot of us don't have an MRO on campus, on-site. He comes and goes maybe half a day a week. If we have to get into something like this, we're going to have to have a regular routine of either the individual going to the MRO's office or staffing a full-time MRO.

MODERATOR WEST: Let me throw this out -- excuse me, go ahead.

MR. MIZUNO: Because I'm still trying to work out the answer in my mind so that I can respond to you, but are we -- so that I'm not mistakenly going down the wrong path, are you asking about in the new rule 26.27(b)(1) which is the return-to-duty requirement for --

MS. TECHAV: Actually, it's in the definition of medical termination of fitness.

MR. MIZUNO: Right, but we're talking about that provision where it refers back to the medical determination of fitness. Is that what we're talking about here?

MR. BOISMENU: Actually, Geary, I think it's all throughout 27 and not specifically in one certain area, but if we determine that there's a history of substance abuse and a medical determination is necessary which is going to be quite a few we were talking yesterday --

MR. MIZUNO: I guess my response, now that you got that, okay, and since we're focusing on the medical determination of fitness, I guess I'm just looking at the definition under the final rule and it says that it means a process whereby the licensed physician who made be the Medical Review Officer, so the regulation doesn't specifically require that the medical determination of fitness be made by the MRO, but rather it focuses on the fact that the physician who is going to make the determination has "is qualified to make that determination."

That person examines and interviews the individual and reviews any appropriate and relevant medical records in accordance with the standard

clinical procedures. And so I guess my answer would be that I don't think that the rule, the proposed -- the final rule requires that the MRO itself, himself, make that determination in that I think that it is appropriate to have a situation where the MRO and the licensee's procedures regularize a practice whereby the actual interviews and relevant medical evaluations are done by a qualified physician and that the MRO on site reviews it as necessary. So I'm not sure that the proposed rule would prevent you or would significantly alter or prevent you from doing the practice that you are describing.

MR. BOISMENU: Geary, I agree with you --

MR. MIZUNO: Except --

MODERATOR WEST: It does say licensed physician.

MR. BOISMENU: But not only that, if you look under the scope it says people that need to be covered under the program which need the background checks and in the pool and one of the first things of people making medical and management determinations for fitness so that would mean that any physician that could perform this task for us would have to be in our program. So therefore, it would have to be the MRO.

MR. MIZUNO: I don't think that that's where you have to go, okay? I think that if the concern is that you want to use a nonphysician to make the medical determination of fitness I think that there's where the Commission, where the staff was pretty clear that they did not want a non-physician to make the medical determination of fitness.

So to the extent that your existing program relies upon a nonphysician to do the interview and all that sort of thing, I think that yes, it is going to adversely impact your program. But I don't think that if you accept the position that says that a licensed physician who's otherwise qualified does this stuff, that you couldn't modify your existing FFD procedures to regularize the practice of having someone other than the MRO actually conduct the interviews and do all that sort of stuff.

MR. BOISMENU: So if I understand you, we could have, have the individual, tell the individual it's their responsibility to see a licensed physician that can make this determination, bring --

MR. MIZUNO: And they can pay for it themselves --

MR. BOISMENU: -- it to us, they have the cost and then have our MRO review that and that would be acceptable?

MR. MIZUNO: Yes. I think the rule would permit that.

MR. BOISMENU: Sounds good to me.

MODERATOR WEST: If the individual was a licensed physician.

MR. MIZUNO: I believe that this is still not going to help you.

MS. TECHAV: Pardon? That is what we currently practice.

MODERATOR WEST: Well, it could help you with some modification of your program.

MR. MIZUNO: Yes, as long -- again, as I said, as long as the determination, the interview and the review of the records is done by a licensed physician who is qualified, I think that the staff was pretty clear in the proposed ruling and throughout the deliberations, that they wanted to make sure that it was a qualified physician that had expertise in this area.

That was something that I recall being discussed over and over again internally, that that was the crucial part. And it wasn't important -- I don't think that it was all relevant in our mind as to whether it was actually the MRO, whether he delegated that out in the program to someone else. And we certainly didn't care whether the licensee paid for it or the employee who is the subject of the review pays for it. That's not our concern.

MS. TECHAV: I need to make a clarification to my statement. We do receive documentation, but it may be from a Certified Addiction Counselor which is not a licensed physician, so there will be a problem in how a lot of us are because it's not a licensed physician. It's a person who is an expert in the field for substance abuse which could make a better determination than a licensed physician in these cases.

MR. BOISMENU: Would a family doctor have the expertise? If we tell them to go see their family doctor, so they have the expertise to make that determination?

MR. MIZUNO: Yes, I think that again the staff had a lot of discussion internally and also it was a discussion with the industry on that because I know that there were licensees who felt that why couldn't the physician, any physician make that and

the staff's position was pretty clear that no, they felt that it had to be physician that had the qualifications.

I will say that I don't recall the industry raising this issue about a Certified Addiction Counselor being, having qualifications that were as good as or possibly even better to make a determination of fitness than a physician who's qualified in the area of addiction or effects of drugs. I don't recall that being raised. But I think that that is a significant point. I'm not sure we're going to be able to interpret our way out of it although we'll see what we can do. Perhaps -- I'm not sure we can do that. If that's going to be a big hang up then again, that's something that the NRC managers and ultimately I guess the Commission are going to have to deal with as to whether they want to again pull back the rule and modify it to permit the medical determination of fitness to be made by a Certified Addiction Counselor.

MODERATOR WEST: I see we have some additional comments.

MR. DiPIETRO: Just one question. When were we supposed to raise that issue?

MR. MIZUNO: I believe that --

MODERATOR WEST: During the public comment period?

MR. MIZUNO: During the public comment period --

MODERATOR WEST: On the proposed rule.

MR. MIZUNO: On the proposed rule.

MR. DiPIETRO: Which was when?

MODERATOR WEST: That would have been in the 1996 time frame.

MR. DiPIETRO: I had nothing to do with fitness for duty in 1996. A lot of people in this room haven't had anything to do with fitness for duty in 1996.

MR. MIZUNO: That may be true, but the companies that you represent and employ you had the responsibility.

MR. DiPIETRO: The company that I work for is not even in the nuclear business any more in 1996. I work for a whole new company now.

MR. MIZUNO: The issue of who is to perform the medical determination of fitness was an issue. I distinctly recall it being raised.

MODERATOR WEST: I think the essential point here though and we can certainly check to see if it was or wasn't --

MR. MIZUNO: But that's sort of irrelevant, as I said. I mean we are going to reconsider the issue and see if we cannot interpret our way of it and if the Commission feels that it's appropriate, it could change -- they'll do whatever they feel is necessary. I mean generally speaking. You're raising the issues now. We'll have to address them and to the extent that we've -- all I can say is that there is a history -- this is not a new issue, at least internally within the staff.

MODERATOR WEST: I think what Geary is saying is that you originally raised the question with perhaps not as much leeway as perhaps you thought. I think certainly we can address some part of that and the remaining portion in terms of the licensed physician aspects of it. It doesn't look that great for being able to address that, but we'll look at it.

MS. DURBIN: I have one more minor comment which is that there may be differences in how it can be addressed with regard to people who have a violation of the Fitness-for-duty policy as opposed to people who have some history of substance abuse that may be of concern.

If you're talking about people who have some history of substance abuse that may be a concern, the way you determine whether you have a concern or not could go through a number of steps before it ended up requiring a medical determination of fitness. So there's a lot more leeway there than there may be with regard to people who have violated the program in the past.

Just in my recollection of the rule, there's a lot more about what you have to do if somebody has violated the rule.

MR. BOISMENU: So you're saying there's different levels to a medical evaluation?

MS. DURBIN: The requirements for a medical determination of fitness, I believe, are firmer with regard to people who have a violation than they are with regard to people who have some history. You have a lot of flexibility with regard to determining whether the history constitutes a concern up to the point if they have a violation it has to constitute a concern, so that's the difference there.

MS. TECHAV: I will agree with you that it was in the rule back in 1996 and the industry did

comment on it, but basically the comments were to my knowledge ignored.

And in Section 26.27(a)(6), the industry has -- the NRC has taken over a $2,600,000 credit that it's going to be a savings for the industry, which in fact, as we've been talking, it's going to be a burden.

Going back to even suitable inquiries to all employers, in 10 CFR 73.56, currently as it states to reinstate an individual for unescorted access, there really is no requirement to do anything as long as their unescorted access was terminated favorably.

The Fitness-for-duty rule is silent on suitable inquiry for reinstate. This new rule is going to cause a substantial burden to the industries because numerous times this morning I've heard the term that we need to do a suitable inquiry to each employer.

Now the industry has asked for clarification from the NRC about reinstatements for suitable inquiry and what to do and they kept on saying well, wait until the new rule comes out, wait until the new rule comes out and we have waited and now we see this great burden that the interpretation is going to cause us to go to each employer even if it's a one day employment and currently the industry got together and said okay, we will take any employment greater than 30 days and do a suitable inquiry on that for a reinstatement and that has been a standard current practice in the industry.

But from the terminology that's been used today, it feels that we are all going to have to go back and do every single employer, even if it's a 1-day employment on a suitable inquiry to reinstate somebody. That is a substantial burden to the industry.

MODERATOR WEST: Am I incorrect on this point? It's my understanding that either the industry is looking at the possibility of reconsidering the suitable inquiry through your own guidance for 30 days or less with respect to perhaps considering?

MR. SMITH: That's in the access authorization proposal, Garmon.

MODERATOR WEST: I see.

MR. SMITH: And it's one employer in a 30-day period. It's not each employer.

MODERATOR WEST: I understand. But it is, in fact, in that direction?

MR. SMITH: Yes. And that will be an upgrade from the current practice which is if it's not 30 days, you don't verify it. So the proposal is for one employer, not each and every employer.

MS. TECHAV: Yes. The industry knows that we need to look at gaps of employment to make sure that there is not a 30-day gap and it all ties into the CBOP to make sure that the 30-day issue -- and we do that and we make sure that there are no 30-day gaps for suitable inquiry with employments, but the terminology that's being used today is every employer.

And I guess I need to go back to yesterday and say well, the definition of suitable inquiry is gone. It doesn't even say that we need to go to the employer any more. So there's a big disconnect within the two rules now on how we're supposed to get this completed.

And I guess I'd like some guidance on how we're supposed to implement this and function.

With the outages getting shorter and shorter and we're getting pressed to get people in quicker and quicker and you're causing more and more for us to do, it is causing a great burden to all the utilities throughout the United States.

MODERATOR WEST: Although we're still at the discussion stage, I would mention that with regard to looking at all employers, even under Part 26, we are discussing along the lines of what's good enough. And we haven't finalized that. But we're considering that.

MS. TECHAV: One of the previous questions, Garmon, that you answered --

MODERATOR WEST: Yes.

MS. TECHAV: The question was asked whether or not we could grant unescorted access on a reinstate by just initiating the reinstatements and you had come back and it wasn't the 72-hour with the licensee, it was the subsequent question and answer. You had mentioned that we had to complete the suitable inquiry prior to granting unescorted access and that went to apply to all contractors.

I mean a lot of utilities throughout the United States right now are not doing that. We're initiating. We get the information from the individual. We look at their suitable inquiry questions. We look at their past criminal history since their last unescorted access. We look at the employment, whether or not they've been fired, let go,

different causes. We get that in the process to initiate that and then we grant unescorted access.

But you were talking about completing which is another burden.

MODERATOR WEST: Is this in the context of the 72 hours?

MS. TECHAV: No. It was the subsequent question to that where you -- it was after the 72 hour question and you had mentioned your answer which led us to believe that all contractors have to be completed prior to granting unescorted access for all suitable inquiries to all employers.

MODERATOR WEST: Okay, the one on 72 hours, this was 77? But then the one after that to do with how our initiations of suitable inquiries document

--

MS. TECHAV: You're going through them so quick.

MODERATOR WEST: What constitutes a best effort?

MS. TECHAV: No.

MODERATOR WEST: Who decides what's burdensome?

MS. DURBIN: Is it 78? One more back.

MS. TECHAV: 77. The first bullet.

MODERATOR WEST: But you said it wasn't in the context of the 72-hours though.

MS. TECHAV: The question didn't talk about the 72 hours.

MODERATOR WEST: But is it the first bullet there, when unescorted access is granted.

MS. TECHAV: Maybe it's the first bullet. What was your response to that question?

MODERATOR WEST: When an unescorted access is granted with a pending suitable inquiry does the suitable inquiry have to be initiated before access can be granted and the answer was yes.

And the further explanation was that the suitable inquiry is initiated only after all previous employers have been contacted.

MS. TECHAV: Go back one more. There was something else. That's it right there. That was it.

MS. DURBIN: But this is the 72 hours for people who are employees checking their self-disclosure.

MS. TECHAV: They're not going to be transferring from another licensee.

MS. DURBIN: The answer was no, it's not somebody transferring from another licensee.

MS. TECHAV: Can you read your response, Garmon, please? 76.

MODERATOR WEST: Yes. I responded that it was neither and I referenced the fact that 26.27(6)(ii) states that that temporary access provisions of 73.56 do not apply and cannot be utilized for these individuals.

MS. DURBIN: No, it's 76.

MODERATOR WEST: I'm sorry. Can unescorted access be granted up to 72 hours pending completion of a suitable inquiry of an individual transferring from another licensee? Is that the one? And I had indicated no, and this was the explanation. This is only for licensee employees with unescorted access who have been absent from the program for 60 or more days. That's why I was asking whether it was related to the 72 hours.

MS. TECHAV: Continue with the rest of the response though.

MODERATOR WEST: Sure. If a licensee determines that it will take more than 72 hours to complete a suitable inquiry for the individual, then the individual should not be granted unescorted access until 72 hours before the suitable inquiry can be completed.

MS. TECHAV: But now you just took him that, that we have to -- if we can't get it done within 72 hours we can't grant, but that's not our current practice.

MODERATOR WEST: Yeah, the thinking here was that --

MS. TECHAV: Maybe I should ask the question of how do you expect us to reinstate a contractor?

MODERATOR WEST: I think the point here is that the 72 hours is intended to be applicable only to licensee employees. It wouldn't be applicable to all contractors.

MS. TECHAV: Okay, can you explain to us how we are to reinstate or transfer a contractor?

MS. DURBIN: As you mentioned, I think the rule is silent on reinstatement and transfer. It's my impression and I'm once again going out on a limb because I'm just a consultant, you know, what I say doesn't matter, but just my impression that the industry practice has been to say we can do transfers and reinstatements because the rule is silent on them.

The rule basically is silent on them and the other interpretation is that you still have to fulfill all of the requirements of pre-access and suitable inquiry for reinstatements and transfer. There's nothing to say that that wouldn't be required.

Now I'm not saying that it should be required, but under the current rule there is nothing that provides that burden reduction or whatever you want to call it. Under the new rule, the intent was to provide some burden reduction but with caveats. So basically your current practices are not really covered within either the original rule or the new rule.

And that, I think, is the difficulty and I think this is an excellent question because I think if we can address transfers and reinstatements in addressing questions, then we can come up with a way to make the current practice and the new rule makes sense. But the new rule is not going to make sense with the current practice because the new rule wasn't written with the understanding that transfers and reinstatements were appropriate actions under the original rule. This is my kind of -- the original rule doesn't speak to it.

The original rule says somebody comes to your plant. It doesn't say if it's within 365 days you don't have to give him a pre-access test or you don't have to do a suitable inquiry or you don't have -- you know. It simply says somebody comes in, they're going to be tested. They're going to have a suitable inquiry.

If transfers and reinstatements are acceptable practices, then some interpretation of both rules is necessary in order to say how they would -- I mean that would be my kind of take on this.

And so we need to address this question, but I don't think we can solve it by looking at either the current or the new rule because neither of them, as you pointed out speak to transfers and reinstatements.

As I said --

MODERATOR WEST: Would you agree, however, that there would be some benefit of addressing this question in a NUREG type question and answer document?

MS. TECHAV: I think it needs to be clarified at what our expectations are.

MR. SMITH: Garmon, what would the vehicle be for the licensees to provide input to the process so you can make sure you absolutely understand how it

works now so when you clarify it, it doesn't make it worse.

(Laughter.)

MODERATOR WEST: I hear exactly you're saying.

(Applause.)

MS. TECHAV: And I think I speak for the whole industry, we'd be more than happy to help.

MR. MIZUNO: Well, I think though that there are limits to what can be done. I do not believe with respect to transfers or reinstatements of contractor personnel as opposed to licensee personnel, that there is going to be much room for interpretation to codify or to accept the existing practice. I mean from my perspective, the way you've described your practice for contractor personnel and in fact, even for a licensee personnel under the existing rule is that it's not consistent with the requirements of the existing rule. That's my initial reaction to what you're describing and how it comports with the requirements of the existing rule.

MS. TECHAV: Then I guess our only avenue of approaches to then say well, the backfit rule and the Paper Reduction Act and the justifications that the NRC put into this document on the savings are not accurate.

MR. MIZUNO: There's no backfit. I mean if there's no backfit because if the expectation under existing rule was that all the requirements for pre-access testing apply regardless of whether it was a licensee personnel or a contractor personnel, and there was no --

MS. DURBIN: Transfer or reinstatement --

MR. MIZUNO: There were no provisions for doing anything other than what the rule requires for any person, the fact that the rule is now providing some aspect of relaxation and that's what I would call it, a relaxation for licensee personnel, okay, does not in any way implicated backfitting concerns with respect to the fact that your current practices are not in compliance with the requirements of the current rule.

MS. TECHAV: Well, I'd like to know where we're not in compliance. I think we have proven that there's a lot of burden that we've brought up and there's a lot of information that is in this rule that's been approved that was not in the 1996 rule, that we could not make comment on.

MR. MIZUNO: Okay, I keep hearing that, okay? I've kind of withhold my point. There were points that were raised that said there weren't these things. I mean for example, this concept of medical determination of fitness, that definition is almost identical to what was in the proposed rule.

MS. TECHAV: And I agree, that was in 1996, but the definition for history of a substance abuse was not and that is going to cause a great burden to us in processing people.

MR. MIZUNO: I was focusing on at this point -- the concept here, someone made the representation that you did not have a chance to comment on medical determination of fitness. That's what we were just talking about just half an hour ago and my response is no, that was there.

This concept of providing an alternative or a relaxation from our standing point for reinstatements or transfers of licensee personnel was also in the proposed rule. I have to dig it out. I mean and the concept -- the issues, going back to the issue about whether it has to be -- whether it can be a home physician or whether it has to be some physician who is qualified, those things were all discussed in the proposed rule. I know that even post-1996 proposed rule, there was a back and forth between the industry and the NRC with respect to that issue. This is not a new issue. These were vented.

The Commission, not just Geary Mizuno sitting up here, is well aware of those things and they ultimately decided to accept the requirement for a physician and many of these other things. What I'm hearing is -- I mean to the extent that I do not recall, that's why I said a comment that dealt with the issue of or a proposal that perhaps certify what is it a substance abuse counselor be considered an acceptable person for making a medical determination of fitness. Had that been made, I think that that kind of a comment been made, I think that the staff would have taken it seriously, but I don't recall that kind of comment being made.

We seriously go through these things and try and address the -- what is the contractor seeking and is it consistent with what the NRC is seeking. And I think in that case, had that comment been made, we would have probably addressed it and accepted that.

MS. TECHAV: But Geary, I guess that the point we're trying to make is that yes, the definition and the terminology for medical determination of

fitness was in there in 1996, I agree with you. I stated that earlier. The industry did comment on it. To my understanding, it was ignored.

MR. MIZUNO: It was not ignored.

MS. DURBIN: It's not ignored. It may not have been accepted. That's the difference.

MS. TECHAV: Okay, so our concerns were looked at. But --

MR. MIZUNO: They were more than looked at.

MS. TECHAV: No, but what you really need to understand is that the definition of history of substance abuse was not there, so the determination of medical fitness wasn't defined as much. We have to go in and do all these things based on this new definition that we didn't even know existed then. And so it's making us do all this other stuff to make the medical determination of fitness and that's the point.

MS. DURBIN: And, you know, the medical determination -- the history of substance abuse term was used throughout the rule as I recall. But it was not defined.

The comment from the industry was that if it wasn't defined, that it would be impossible to know how to implement the rule.

So the change that was made was that a definition was provided. So that's part of the comment response process. I can't --

MS. TECHAV: See, then we weren't able to comment on that though in 1996.

MS. DURBIN: Right, but that's part of --

MS. TECHAV: That's part of the problem because it just has added this great burden with defining what --

MS. DURBIN: But this doesn't get back to the issue that Geary has been going through and --

MR. MIZUNO: Which is --

MS. DURBIN: Going back to the major issue which is all of the cost reductions are based on an assumption that you're in compliance currently with the current rule which does not allow for not testing anyone. It basically was very prescriptive about everybody who comes to the site has to have a pre-access test and one of the things that was intended in the rule revision was to reduce some of that burden.

Now because it's been so long the industry has made some accommodations. I'm not -- and has this

policy for transferring reinstatement. I think the thing that has to be clear is that those policies are not blessed --

MS. HAYES: This is Lori Hayes from Progress Energy. Those policies are blessed in the fact that every one of these licensees have had inspections by the NRC and we're very much aware of the policies that are going on. I've done many inspections myself and those policies are blessed to the industry basically through their physical security plans that are there that bless off on NUMARC 8901 and Reg. Doc. 5.66, so those policies are blessed in that respect. And the transfer and reinstatement rule was back in 1991.

MS. DURBIN: I can't speak to that. What I can speak to is how the analysis was done on the Fitness-for-duty regulation and the analysis of the cost savings has to do with the one in the other --

MODERATOR WEST: Let me interject one point, if you will. It seems to me it's not that we don't want to hear your concerns even if they're out of the scope of the implementation of the rule. We're certainly more than willing to listen to those. But it seems to me that the focus of this workshop is indeed to focus on those aspects of implementation where there is some obvious window for doing something. The rule has been approved. The Commission has made a decision to approve the rule and the next window for the rule making process is the OMB clearance package.

I don't see that it serves us well if we continue -- not to say that we don't talk about whatever your concerns are, even if it's out of the scope of precisely the implementation. But if we continue to go back to the proposed rule on each and every item, I don't see that that's going to be productive for us.

Please.

MR. ENKEBOLL: Not leaving a statement made that I disagree with --

MODERATOR WEST: Certainly.

MR. ENKEBOLL: The Council here has stated that after the comments in on 1996 that there was discussion with the industry. NEI represents the industry in this business and there was no discussion. There has been zero discussion with the industry on that subject.

MR. MIZUNO: On which subject?

MODERATOR WEST: Which subject, sir?

MR. ENKEBOLL: Comments to the Fitness-for-duty rule, 1996.

MODERATOR WEST: Thank you.

MS. HAYES: Garmon, I would agree, too, you're right, we shouldn't go back and try to resurrect things that are already going on, but just another comment is that you have to comply with 73.56 and the current practices and you have to comply with Part 26 and I think what we are saying as far as Lori Hayes' Progress Energy is to do that is going to put us in either conflict with one or the other and we're just trying to meet both is all that we're trying to do. So if you could hopefully look at Part 26 with respect to 73.56 and marry the two together and not necessarily pull the rule back, but make that some sort of way that those two would mix, we would greatly appreciate it.

MODERATOR WEST: I think that's feasible to do that.

MR. BRAZIL: From an implementation perspective, as requested -- Scott Brazil, Dominion -- I have a real problem on the whole with this in that I'm hearing here differently as what is said in your approved rule.

The scope says the rule applies to all persons granted unescorted access to nuclear power plant protected areas. It's everybody. It doesn't say whether you're a licensee employee, doesn't say whether you're a contractor, it doesn't say whether you're a vendor. It mentions other contractors and vendors with respect to the TSC and the EOF.

Throughout the rule we talk about individuals. Under 26.27(a)(1)(i) before assigning an individual -- and I think we'd agree that this section applies to all individuals, licensees, contractors, vendors, whoever, before we assign them to activities within the scope of this part. An individual.

We're trying to find out all this information about the individual. But I get down to two pages later under 6 and 7 -- where we talk about the individual has not been previously removed for violating a licensee's FFD policy. That's all individuals, again, whether he's a licensee, whether he's a contractor, whether he's a vendor, correct?

MODERATOR WEST: But there's some part of this that you --

MR. BRAZIL: But when you get down to 7 and we say if an individual is returning to a licensee after an absence of the possibility of being tested,

now you're telling me that that applies only to licensee employees.

MODERATOR WEST: Yes.

MR. BRAZIL: That's what we've heard here. It doesn't say that. It says an individual and throughout this regulation we mention the individual and it applies to everyone. Here, we're saying an individual has to be a licensee employee. I'm held to a pretty strict standard when it comes to verbatim compliance and I'm going to have a real hard time explaining that in this section an individual means anybody, but later on, the individual means only licensee employees.

MODERATOR WEST: I think the explanation is essentially because it's tied to the fact that the 72 hours is being referenced and the intent of that 72 hours was with respect to licensee employees.

MR. BRAZIL: But it doesn't say that.

MODERATOR WEST: And I hear that. And I guess the input that maybe we can have is from Geary to see if that's a difficulty.

MR. MIZUNO: I guess that's a potential way to try to resolve the industry's -- and interpret our way out. I'd say that that is a way of trying to accommodate the industry. I mean there is a potential for that without making a rule change.

MR. BRAZIL: My point is if it applies only to certain individuals it needs to say who those certain individuals are, otherwise we're all going to possibly implement it differently.

MODERATOR WEST: But if we said that in a NUREG type document, wouldn't that address your issue or not?

MR. BRAZIL: No, it wouldn't.

MODERATOR WEST: But why is that? That's what I'm trying to appreciate.

MR. BRAZIL: Because I've got -- before that NUREG comes out, I've got to implement this rule and --

MODERATOR WEST: Well, suppose the NUREG document came out before you had to implement the rule, would it address it then?

(Applause.)

MR. BUSH: This is Loren Bush. I want to state first of all that the intent of 7 was to cover not only licensee employees, but also contractors. It was specifically written that way because of concerns for contractors that were bouncing around, in fact, even had vice president of one utility contact me, a

consulting outfit. They were doing work two days a week at one site, another two days at another site and all that sort of stuff and this was an attempt to try to solve those kind of situations where you had people that were highly mobile.

As far as the earlier discussion about your program not being in compliance with the rule, I want to apologize to all of you here concerned because a number of years ago I was directed to have the inspectors go out and cite you for being in violation of the rule and I argued with management that I thought that that was inappropriate at that time because the rule was imminent and it would solve the problem, etcetera, etcetera, etcetera. So if there's anybody going to take any heat for your programs not being in current compliance, I'll take it, even though I'm retired.

(Laughter and applause.)

MODERATOR WEST: Thank you, Loren.

MR. ENKEBOLL: Garmon, could I get clarification on the last thing you said about publishing the NUREG prior to implementation? I want to make it clear that you mean prior to publishing the rule in the Federal Register because that's when these people have to start implementation.

MODERATOR WEST: I see your point. I didn't fully appreciate that level of detail and you're right, that wasn't what I was intending to say.

However, now that I have a better appreciation of what I actually said --

(Laughter.)

-- I think certainly that's something we could look at in terms of whether it's realistic to be able to do that.

MR. MIZUNO: You know, the Commission, I think, has a policy of -- I mean, generally the staff is supposed to develop and publish implementation guidance at the same time they publish a final rule and they're supposed to be together. I'm not sure why it sent out of sync here, but --

MODERATOR WEST: But again, even with that as the criterion, that's not to rule out the possibility of that.

MR. MIZUNO: Yes. That's exactly what I'm saying. I think the general rule of concept was that a rule doesn't go into place, I think the Commission has stated that a rule does not -- and rule which imposes or changes existing requirements should not go out there unless there's some implementing guidance

available at the same time. And we've done that before.

In fact, we've had situations where final rules have been published, but their effectiveness has been delayed until implementing guidance has been published. I think the maintenance rule is one of those and I mean that's certainly something that can be done here. I mean there are a lot of different ways that the Commission could have accommodate the -- what I consider to be the valid concern that says of not having specific implementation guidance in place when you have a major new regulatory regime being adopted by the Commission.

MR. EARNEST: Garmon, a question for you on the NUREG. If we can or if the Agency decides to put these out concurrently and we're going to have to pull all of these questions out of the transcript, we are going to give -- are we going or should we or I'll go on record and say hey, we should give the industry at least an opportunity to look at the questions and the answers in whatever draft NUREG it is to ensure that we have answered the question, that we have picked up every nuance in there that will affect their program.

Is there any chance of doing that?

MODERATOR WEST: I would agree and I would also add that we have considered that the first step in a process like that would be to initially let you take a look at, which wouldn't be hard to do, to let you take a look at what we consider the questions to be, similar to what we've done here today and we'll continue to do, but even taking the questions out of the transcript to offer those questions up for you to take a look at them to make sure we've captured the questions correctly and then certainly it would make sense to have some means of having you to look at the answers associated with all the questions that we anticipate putting in the NUREG-type document before it's going to be final.

MR. MIZUNO: That would be done in a public forum, whether we put it on the web or we actually publish a Federal Register notice. It would be available for everyone to see and to comment on.

MODERATOR WEST: Before it's final. It would seem to me that's doable.

It's about 10:30. I propose we take a break for 15 minutes. We'll convene at 10:45.

(Off the record.)

MODERATOR WEST: Okay, we're going to start up again, please.

I'll just mention this now and revisit it in more detail at the end of the day in the summary of what we've accomplished, hopefully, and where we have to go from here, but we'll get into some specific thoughts on the particulars of how we would consider addressing your concerns in various areas, whether it has to do with things we envision we could do in the NUREG-type document or even other issues that you've raised that fall outside of the -- any possibility of doing something in the NUREG type document.

I'll also get into the specifics of what schedule we think we might be able to accommodate and the particulars of the different ways that we feel we can address your concerns and just at this pause, if you will, and my apologies for the delay in getting things restarted again. But to just reassure you, we are hearing you and listening to your concerns and we'll do our best effort to address them.

The next section has to do with 26.28 concerning appeals and here we have applicants now are explicitly granted the right to appeal and that's a new addition with respect to applicants. And additional language has been added to make explicit that the appeals process must provide an opportunity for the individual to provide evidence and that it should be objective and impartial.

And then lastly, review must be conducted by persons not associated with the administration of the Fitness-for-duty program, here, trying to emphasize some independence of that review.

Previously, some applicants ended up with a record of a positive test result that made it difficult to obtain work in the nuclear industry, but had no recourse with regard to appeal.

Some appeals were processed in a pro forma manner by those who initially made the determination and with no opportunity for the individual to present any information. For example, a medical reason for the result, the test result that might bear on the case.

Also, there is a supporting change in the section on protection of information that assures individuals can readily get copies of all the information bearing on their case. And in this particular area, we didn't receive any advance questions.

Before I go into the section that I mentioned, protection of information, would there be any questions or comments in this area?

MR. BURRELL: Yes, Garmon. With respect to the next to the last sentence in 26.28, "the review must be conducted by persons not associated with the administration of Fitness-for-duty program", that necessarily mandate two or more people on what would be considered a review panel?

MR. MIZUNO: The answer is yes.

MR. BURRELL: Part of the foundation for my question is that we do have an appeals/review process for access authorization in place now with no requirement for numbers of persons to participate.

MODERATOR WEST: How do you decide, even though you don't have any requirements, how do you decide on those numbers?

MR. BURRELL: I have a person that listens to an appeal that's impartial.

MR. MIZUNO: Okay. I think that -- let me just say the rule was intended to use the plural so that if the licensee chose to use more than one person that -- I mean it's persons, but there's no requirement to use more than one person. If you have one person in your procedure that is responsible for having that appeal and that person is otherwise independent, not associated with the administration of the FFD program, it satisfies the requirement under 26.28. There's no requirement that you use more than one person.

MR. BURRELL: Thank you, Geary, that was what I was seeking. It looked as though we were required to have two or more.

MODERATOR WEST: I think the emphasis certainly is the independence.

MR. BURRELL: Okay, thank you very much.

MODERATOR WEST: As it has been for some other requirements in terms of testing of Fitness-for-duty program personnel.

MR. BURRELL: Thank you, Garmon.

MODERATOR WEST: Thank you for the question. Yes?

MR. NOEL: Garmon, would the MRO be disqualified for serving that role?

MR. MIZUNO: The answer is yes.

MR. NOEL: Thank you.

MR. MIZUNO: Because he is -- to be clear, so everyone understands. He is associated with the administration of the FFD program.

MR. NOEL: Thank you.

MODERATOR WEST: That's correct. Thank you. The next section deals with protection of information, 26.29. And here, contractors and vendors are now included in those who can get information with the release by the employee. And secondly, individuals have a right to copies of the documents related to the termination that they violated an FFD policy.

Regarding the first item, this is primarily a clarification to make sure an employer, for example, a contractor employing someone to work an outage to get records on FFD violations with the written release of the individual.

And with regard -- so that's the emphasis, with the individual's release of the contractor employing someone could in fact get the information, contractors and vendors now would be included.

And we didn't get any specific questions in this area. Would there be any comments or questions on this section?

MR. MIZUNO: I guess I just wanted to add to clarify that there's some -- if you look under 26.29(b) there are circumstances where a release from the individual is not necessary in order to disclose that. There are certain situations and I think to roughly characterize it as if the employee goes out and initiates a proceeding, then you don't have to get a release from them to disclose that information to the people who are directly associated with that like the presiding officer or a judge in a proceeding which the employee directly initiates.

That's just common sense.

MODERATOR WEST: Thank you, Geary. And 26.70 has received some clarifications. I'll just go on and mention those while we're waiting for the slide and we've clarified the licensee contractors and vendors shall permit NRC inspections with regard to documenting records and reports of FFD service contractors related to licensee contractor or vendor FFD programs. And then the specifics of that would have to do with HHS labs, MRO, MROs, EAPs and specimen collection of services. And we didn't receive any advance questions in that area.

Any comments or questions on that section?

(Pause.)

Next we go to recordkeeping requirements and here you'll find that records retained for 5 years or until completion of all legal proceedings related

to the violation or whichever is longer and you'll also find that program performance data reported once every 12 months now instead of every 6 months which is certainly a relaxation. And the addition of subversion attempts by type would now have to be reported.

And there were no questions submitted in that area.

(Pause.)

And the reporting requirements under 26.73, licensees must inform Commission by phone within 24 hours of significant events. Certainly there's nothing new about that. The wording has been expanded slightly such that it now includes not limited to, to give the -- to communicate that this is intended not to be an exhaustive list, that you'd only report the items that are listed in the -- that are listed there, but rather these are just examples. And there's quite a bit of discussion on that particular point in the statements of considerations.

I know there's been some questions about that over the years and even from the calls I receive on occasion.

And then further on the next slide, number 89, you get some of the further details on 26.73, particularly with what's been added.

And again, you see with the first bullet the inclusion of the emphasis on subversion and here again there is even with the second bullet, somewhat of an emphasis on subversion as well, trying to maintain the integrity of the Fitness-for-duty program. And then lastly, arrest of a worker for sale, distribution, use or possession of illegal drugs on or off-site. And we didn't receive any advance questions in that area.

MR. BURRELL: Garmon, with respect to item 4, we're talking about arrest of a worker for use or possession off-site and indicating that that arrest need be reported under this rule, rather than 73.71.

That seems to be somewhat inconsistent with Geary's perspective of arrest related to DUI, the discussion we had yesterday -- Geary, you didn't feel that an arrest was --

MR. MIZUNO: I'm not sure --

MR. BURRELL: -- part of establishing the foundation for --

MR. MIZUNO: No. I think the question about whether you report to the NRC about an event, okay, which raises a question with respect to either

that person's Fitness-for-duty, I guess in this case, to reporting since we'll just confine ourselves to that. I mean that's one issue which I think is, I mean the NRC has -- I mean we can argue, I guess, the Commission feels it has a legitimate need to know about that information in some timely fashion.

The point I was trying to make yesterday was that we need to -- if we are going to do a broad scope drug testing or a drug and alcohol testing, okay, as a for cause test, following a specific incident which deals with only a specific substance, okay, violation, we need to have a basis for doing that.

Now I think that the industry correctly pointed out that that's what our current regulations require. Having said that, I still think there's -- whatever infirmity that may exist in the current regulations, okay, continuing it under the -- into this new rule, I think still raises some concern, but yes, I think -- to do the broad scope testing is I think consistent with the current rule requirements, but so I think -- the issue about whether we can do a broad scope test based upon a narrow or a single violation, okay, to me is a separate issue from the question about what information the NRC wants me to have reported to it under the Fitness-for-duty requirements or under access authorization.

MR. BURRELL: Is it then the Commission's expectation that we only report this in tandem with the self-reporting that takes place under 73.56 or is there an expectation by the Commission that we more proactively determine those workers who might have been subject to an arrest for use or possession off site?

MODERATOR WEST: It seems to me the way the language is crafted here, it's specific to the area of the Fitness-for-duty rule. It's not necessarily tied to 73.56.

MR. BURRELL: Well, I guess that really doesn't answer my question, Garmon.

MR. MIZUNO: Are you asking -- with respect to your latter question, are you saying is it the NRC's expectation that you pick up the phone and call us about something you discover in the suitable inquiry that occurred two years ago or three years ago as opposed to something where the employee is on-site and he's working and you find out through whatever means that he was just arrested yesterday. Is that your issue?

MR. BURRELL: That's part of it. We're now going to be required to report to you an arrest of a worker for sale, distribution, use or possession of illegal drugs off-site?

Now we don't do that currently. If this occurs, then there has to be some vehicle for us obtaining the knowledge that this happens.

MODERATOR WEST: So how would you go about obtaining that knowledge, is that your --

MR. BURRELL: I'm curious what the expectation is.

MR. MIZUNO: Okay, so then there are two different things then. There are three now. One, the first two things and then the third issue which is do you have a positive obligation to go out and get that information about arrests and all that or whether you're simply a passive conduit, if you happen to find out about it. I mean if someone calls in an allegation and do you then have to verify it? Or if the police actually pick him up on-site, the bust occurs on-site, do you then have the obligation? I think -- so those are three things. I guess I'll leave that issue to the staff.

I will simply address the first part which is do you have an obligation to go back and report to us by phone of an incident that you discover in your suitable inquiry that occurred two or three years and my view is that that was not the intent of the rule and the rule -- I mean, again, it's subject to interpretation, I guess.

This is something we can clarify, but I don't see any reason for a telephone call at that point because the NRC's interest in finding about that information in a timely fashion, I don't think apply in the context of doing your suitable inquiry and finding out about an incident that occurred some time ago. I mean maybe the staff has to address and explain why it is we want to have this knowledge of current incidents because I think that really explains why it is that I don't think we need to have reporting of those things that you discover during the suitable inquiry.

MR. BURRELL: That really comes to the nexus of my question. Is the expectation an active or passive issue?

MODERATOR WEST: I think the expectation would be consistent with what we were expecting with the other items, even in the current rule. These would be, if I understand your question correctly,

these would be things that are brought to your attention as opposed to your going out to identify them.

MR. BUSH: This is Loren Bush. The expectation here was based on the fact that there were several cases where licensee employees and their spouses were manufacturing and distributing drugs off-site. There was concern as to whether that was happening on-site.

As we know, there's methamphetamines and etcetera, etcetera, etcetera being manufactured in these little shade-tree laboratories, if you want to call it that, all kinds of things happening. We figured some of that can flow over into the site and we wanted to know about these sort of things and be able to follow up in our regulatory responsibilities.

There was no intent for if you found out something through the suitable inquiry that happened several years ago to call it in. This is real time. There was no intent for you to go around and follow every employee, but we did have a fundamental expectation in the rule if you go back to 26.24 about having some kind of liaison with local law enforcement and I know you have that on the security side of the shop that some of these things, that if they're significant you would be informed of. I assume you stay aware of things that happen in the local community through reports in the newspaper or radio and so on.

But again, as Geary said, there's no expectation that you be aggressively proactive, if I can phrase it that way. But we expect a little bit of initiative and when you come across the information, that you initiate the proper actions on your part in addition to reporting to the NRC.

MODERATOR WEST: Thank you, Loren.

MS. HAYES: Lori Hayes, Progress Energy and I think Loren answered my question. I think if I'm understanding it clear, it's upon discovery of an arrest of a current worker in your facility or either through local law where you would normally take your normal actions anyway, than inquire from the employee and does that time clock start upon discovery?

MODERATOR WEST: I think the answer would be yes.

MS. HAYES: My second question is are you leaving cast doubt on honesty, integrity of the Fitness-for-duty program or personnel in the hands of

the licensee to define something in their procedures, what they consider would be reasonable in that area?

MODERATOR WEST: I think that's a reasonable expectation, yes.

MS. HAYES: Thank you.

MR. MIZUNO: Can I just add something?

MODERATOR WEST: Please.

MR. MIZUNO: Which is that I think -- I don't think that the NRC intended for you to run a drug smuggling or drug finding kind of program, okay?

And I don't think we intended for you to comb the newspapers or all this other sort of thing for interesting bits of trivia and stuff. But if yo do come across information through whatever means or just in your normal -- what you would normally do regardless of whether this was an NRC site or not, I know you have programs where you go out and do things and you discover information that deals with your employee that relates to a Fitness-for-duty matter.

I mean if you find out an employee or a contractor employee who has access to the site is busted off-site, okay, but deals with distribution of drugs, even if it doesn't deal with workers specifically, I would imagine that that would be the kind of thing that we'd like reported to us.

But again, I just want to emphasize, you're not under an obligation to run a little police operation.

MODERATOR WEST: Thank you, Geary.

MR. HARRIS: Good morning. Neil Harris, TXU Electric.

Under 26.73(2) we -- looks like there's an expansion on that part from -- for having the operator's license individuals or supervisors if events occur with those individuals. Now we're including all people that were subject to an FFD program?

MODERATOR WEST: Correct.

MR. HARRIS: All right.

MODERATOR WEST: And I think that goes back to the reference that's being referred to here, back over to 26.2.

MR. HARRIS: The other item I have is just a comment that in several places within this part it seems that we go in and reiterate and reiterate again about identifying when the use and sale or presence of alcohol, several different places such as in item 4 bullet or iii and back up again in 1, seems to be redundant throughout this section right here.

Thank you.

MODERATOR WEST: Thank you. Please.

MR. PRIEBE: Mike Priebe from Palo Verde. When I came here today I was asked by Palo Verde to carry two questions about this section. One of them concerns number 4 by adding this, the arrest reporting section.

The question that came from some of our QA people was how are we addressing employee confidentiality considering the fact that it's not a conviction, rather, it's just an arrest and it becomes part of the public record. I think they just really wanted to raise that as a comment that they were concerned, there may be some issues about confidentiality there.

MR. MIZUNO: I think that arrest records are public and so therefore there is no confidentiality, strictly speaking from a legal standpoint.

MR. PRIEBE: That was my answer to them too. Thank you.

MR. BUSH: We're not interested in a person's name.

MR. PRIEBE: That clearly addresses it. Thank you. And then the second one was just another comment concerning our performance indicators.

MODERATOR WEST: Yes.

MR. PRIEBE: And the fact that this, of course, as I understand it this then would impact our performance indicators and just a comment about whether that's really a true indication of the performance of a site if you have a contract employee who there for an outage and happens to get arrested under this section and then that shows itself as being a significant event for your Fitness-for-duty program. I'm not sure if I expressed it that well or not.

MODERATOR WEST: I think the thing to keep in mind in terms of the performance indicators and what I'll state is sort of in transition, if you will, because there is some current work going on between the NRC staff and stakeholders on performance indicators in this area as well as others.

But I think you would find in the industry guidance document relative to performance indicators and correct me if I'm wrong, the way it's framed now or worded, your performance indicator for the Fitness-for-duty area would only be affected with regard to things that went wrong in the program that weren't caught. It's somewhat of a Catch-22, if you will,

with respect to these would be the fish that got away. So it's somewhat hard to identify those occurrences. And that's part of what we're -- from the staff's perspective, trying to make some comments on with regard to maybe some other ways of looking at the performance indicator, specifically for a Fitness-for-duty.

I might add, one of the possibilities that we would suggest would be to take another look at the performance indicator guidance relative to what's going to be considered and what's not going to be considered. And if, in fact, it would go in the -- since I'm tasked to look at this and make some recommendations, if it will go in the direction that I'm proposing which I haven't been all that clear about as yet, certainly there might then be some implications with respect to additional items that have, in fact, been added to this particular section of the rule. We're certainly not there yet.

Next we'll go on to Section 26.80 under audits. And just to give you an idea where I'm headed here, I think we'll try to finish up these sections before Appendix A which will take us on through 26.90 or so, 26.91 and then I think we'll be -- it will be a natural break there. And we can stop and have lunch and then reconvene with Appendix A.

Under 26.80, there's one item here that speaks to a relaxation regarding audits where we've gone from audits to a period of 36 months as opposed to a year. This particular change also relates to a petition for rule making that we had received some years ago and that particular petition at the time had requested consideration of going to 24 months. So this certainly, this change has certainly bounded that petition and we do, in fact, use the rule as a way of dispositioning that petition.

We do, however, emphasize that licensees would be expected to increase that audit frequency if their program indicators suggested that it was necessary.

And third point is that audits must occur within 12 months for any area of significant change in the program.

And then lastly, contractor and vendor programs must be audited every 12 months.

And we did, in fact, get some questions in this area. The first one, what does FFD, Fitness-for-duty services include with respect to auditing services?

And our response was as follows: FFD services provided by personnel off-site or not under daily observation of licensee personnel, could include, for example, MRO services provided off-site and specimen collection services provided by contractor and we've certainly touched on some of this in our previous discussions today.

Vendors performing background checks and psychological evaluations of FFD program personnel are not covered by the auditing requirements since they are access authorization program elements rather than Fitness-for-duty program elements.

Further, the rule does not require licensees to audit manufacturers of blind performance specimens and reagents because these are commercially available supplies and not FFD services. However, the materials these vendors provided must be monitored to assure their accuracy and their reliability.

Yet another question under this section 26.80, if a licensee pays for a split specimen to be analyzed at a particular HHS certified laboratory and utilizes that laboratory only for split specimen re-analysis, does this obligate the licensee to perform an annual audit of that HHS certified laboratory?

And our answer was yes. The rule does not exclude HHS laboratories' testing split specimen from audits. Licensees may accept audits by other licensees. Licensees are not required to audit the laboratory that the individual chooses for testing the split specimen when the individual pays for the testing as stated in the statements of considerations of the rule.

Would there be any further questions on this particular section?

MR. ENKEBOLL: Rich Enkeboll, NEI. There was an OGC determination several years ago that said the rule did not require auditing HHS laboratories. Now you have rewritten the rule to require that and my question is why didn't it serve the purpose to have the HHS audit take care of that auditing? They're supposed to make sure their laboratories do things right. I don't see the purpose in having us double audit an agency. It takes a lot of time and effort and I don't think you've got any compelling reason to -- in your regulation that says licensees should, in fact, audit HHS laboratories.

I'd like to hear an explanation.

MODERATOR WEST: The only thing I could add would be that certainly we do above and beyond the

fact that these laboratories are certified by HHS. We do, in fact, still continue to get information with regard to errors that take place and other kinds of issues.

MR. ENKEBOLL: That's what licensees do when they find errors, they pull the string, but to go out and say -- there are always going to be errors and we can have three audits, we can have seven audits and you're still going to find errors. The point is why isn't HHS -- why aren't those audits sufficient that these laboratories are doing what they're supposed to do? This has been in business for at least 10 years. I don't see what's broken and I don't know why we have to add this requirement on and what you've explained hasn't helped me any.

MODERATOR WEST: Well, I think it's just another level of confidence that the laboratories are, in fact, doing what they're tasked to do.

MR. ENKEBOLL: Why doesn't the NRC go in and inspect them if you're worried about that?

MODERATOR WEST: Does anyone from the table have any further thoughts on this?

MS. DURBIN: There are several discussions of this. I was unaware that OCG had made such a determination. The one change in the rule that's relevant to this is that reviewing the HHS certification for the areas that HHS audits is specified in the new regulation as adequate for those aspects of the HHS laboratory.

Many of you have aspects of your programs such as testing at lower cut-off levels, testing for additional drugs that are not covered by HHS policies and procedures. So the intent is that for those areas, you would audit the laboratory to assure that their performance was adequate in the areas that HHS does not audit. For the areas that HHS does audit, a review of the audit findings from HHS would be adequate.

I don't know about the other issues. I can only speak to the changes in the rule with regard to that audit.

MODERATOR WEST: That's an excellent point. The intent wasn't to revisit each and every item that the HHS certified lab has already -- the certification process has already done. But rather to look at that certainly, but also to look at the delta that might be there, because of cut off levels and so on.

MR. ENKEBOLL: I understand your point there. My next question would pertain to do you have different requirements than HHS, for instance, opiate cut-offs which you are forcing these licensees to be out auditing something that they should not have to audit if you complied with the HHS guidelines on this subject and we have no compelling understanding of why you haven't taken the HHS cutoff level as being appropriate.

MODERATOR WEST: Yes, that is a fact. I might add though in response to that we have essentially maintained the current rule provision with respect to opiate levels and we did that. It was acknowledged in the proposed rule. We received comments on it and I might add too that we had support even from the comments on continuing with the cutoff level that we currently have in the current rule.

MR. ENKEBOLL: Not from the industry, you didn't.

MODERATOR WEST: I understand.

MS. THIEL: Garmon, if you would, please explain this to me again. I'm not sure I heard you correctly. On this question that is up here, the licensee pays for the split, we audit that lab.

MODERATOR WEST: Correct.

MS. THIEL: If the individual goes to a separate lab and pays for it himself at an HHS lab, we do not audit that lab?

MODERATOR WEST: Yeah, what I indicated was that licensees are not required to audit the laboratory that the individual chooses for testing the split specimen when the individual pays for the testing.

MS. THIEL: So what is the rationale for auditing this lab and not the other one? The split is going to be used the same for appeal purposes.

MODERATOR WEST: I think part of the rationale--

MR. MIZUNO: Can I provide at least one?

MODERATOR WEST: Please.

MR. MIZUNO: If an individual chooses to use a laboratory, I mean there are laboratories out there, I guess, and the licensee -- if the licensee were obligated to audit the laboratory that the individual chooses, a practical matter, they would have to audit every potential laboratory that is out there or rely upon -- assure themselves that perhaps there was another licensee who had audited that laboratory. It's just not a possible -- it's not

possible for the licensee to perform an audit or to impose an audit obligation upon an employee-chosen laboratory.

Now I guess it does raise the issue, I guess, why is it that we're willing to accept that kind of a laboratory without the audit and I guess we could have written the regulation to say no, you must -- split specimen testing must be done by -- solely by the licensee within the licensee's program. I guess we provided some additional flexibility there. But I mean do you understand?

If an employee chose X Laboratory, okay, not -- and if we required an audit requirement on a 12-month basis, you'd have to -- you would know ahead of time that that laboratory is going to be chosen by the employee, so the only way you could comply with that possibly is like I said, either audit all of the potential things or assure yourself that there was some other licensee that had audited that lab so that you ultimately ended up with some patchwork to assure yourself that everyone had been audited and that just wasn't a reasonable thing to impose upon the licensee. And so that's the reason why.

Can I go back to the issue about why have an audit requirement for the HHS laboratory? I think apart from the fact that it is true that the NRC has chosen to adopt cutoff levels which are different from the HHS guidelines, even if you are to assume that the NRC did accept the HHS guidelines in total for cutoff levels, as you well know, the rule provides flexibility for the licensee to adopt different, more stringent cutoff levels and yet, they're going to be treated as FFD findings within the scope of Part 26.

Well, if the licensee chooses to do that, and we have to assure ourselves, in part, that those things are -- I mean that there's some modicum of accuracy associated with that because the imprimatur of Part 26 is going to apply to that and I guess that's another reason, a separate reason for having the auditing of HHS laboratories apart from whatever HHS may do in order to certify.

MODERATOR WEST: Please.

MR. NETTLES: May I suggest then that if a licensee follows your regulation to the T with no additional features of his own, that he doesn't have to audit the laboratory?

MR. MIZUNO: I think that we will take that suggestion in, and we will see, first of all, if

the staff can accept that and if so, whether that can be accommodated under the rule language.

MODERATOR WEST: Thank you for the suggestion.

MS. TECHAV: Sue Techav, Exelon. In reference to FFD services, a lot of utilities, well, us in particular, for people for for-cause tests for backshifts, we typically do not have collection people on site. We do do the Breathalyzer on site by our security force, but we take them to a local hospital to do the collection. Are they going to have to be audited in response to this paragraph? If they provide FFD services by collecting the specimen. I need to know.

MR. MIZUNO: I'm sorry, what kind of service are they providing or what is the --

MS. TECHAV: They do the collection of the specimen for backshifts, for like a for-cause test when we do not have the people on site. We do the Breathalyzer on site, take the person off-site. We send a supervisor with them from our utility and they are there and watch the process. We send them our kits, our chain of custodies, all of our documentation with step-by-step on how it's to be conducted.

Do they need to be audited as part of FFD services under this 26.80 audit?

MODERATOR WEST: I think the general answer was this and I'll just repeat the beginning portion of it. FFD Services provided by personnel off-site or not under daily observation of licensee personnel would have to be audited.

MS. HAYES: This is Lori Hayes, Progress. I have the same situation, but in addition we also have collection of blood specimens for alcohol levels done by local hospitals after hours, so in addition to that it would be blood also.

MODERATOR WEST: I see.

MR. MIZUNO: Is there a -- I just wanted to clarify, is there a licensee FFD personnel there, in your situation, no.

MS. TECHAV: No, it's a supervisor of the licensee.

MS. HAYES: In ours, yes. We would have a collector with ours and we have a specific procedure outlined that the collector watches to make sure it's observed in accordance to our procedures.

MODERATOR WEST: How would you --

MR. MIZUNO: Is that licensee personnel?

MR. SMITH: That's someone certified to be a urine collector though. It's not a blood corrector, correct?

MS. HAYES: Well, actually, no. We do have nurses that are blood collectors. Not in every single case, but yes, we do.

MR. SMITH: Why wouldn't they just take the sample on site then?

MS. HAYES: Backshift.

MR. SMITH: But who is there observing the hospital taking the sample?

AUDIENCE MEMBER: We call a collector in or usually it's going to be authorized Fitness-for-duty supervisor will go in.

MS. HAYES: And you're right, Greg, it may not always be a nurse, but some of our collectors are nurses.

MR. MIZUNO: This is a preliminary answer, but I don't think there's an audit requirement there because it indicates and I think Garmon has mentioned it in his answer that the auditing requirement only applies where it's off-site or not under the direct daily supervision -- oh, I see -- or not under. I see. So if it's off-site, it doesn't matter, okay.

So I guess it would have to be audited because it is off-site, the way the regulation is written.

Even if you had a person watching, the way that it's written it says FFD services provide to the licensee provided by personnel who are off-site or not under the direct daily supervision, so even if there were other direct daily supervision, but they are off-site, I guess it would still have to be audited.

MR. BUSH: If I could interject here a minute, Loren Bush.

MODERATOR WEST: Please, Loren.

MR. BUSH: The change to the for-cause testing under 26.24(a)(3) says except under documented unusual circumstances, the for-cause testing must be conducted within no more than 2 hours for an alcohol test and 8 hours for specimen collection for a drug test. Those words were specifically added to cover the kind of situation --

AUDIENCE MEMBER: Eight hours won't cover that.

MR. BUSH: Yes. We debated that, but the -- going longer than that to collect the urine specimen we thought would not be acceptable. We felt

the 8 hours was as much as we could grant. We figured if somebody is on the backshift and obviously not fit for duty, you could arrange to have somebody come in like 15 minutes early from their normal early arrival and do the urine collection. At least that was the thinking.

As far as the other issues, does anybody up front have the backfit analysis?

Geary, I think there was a lengthy discussion on the reason for the auditing of the HH lab and by the way, Bob Fonnan when he wrote that paper that said that the rule did not require the auditing of the HHS lab was he said I know it was clearly your intent, but legally, I don't see the words in there that require it. He didn't say it didn't require. He said legally it doesn't require it. There's a little bit of a difference there.

MODERATOR WEST: Thank you.

MS. TECHAV: And in response to Loren's comment, I understand that we've got a longer time frame before we have to make the collection for the urine specimen, but we don't have people on-site every day of the week to do collection. Our security force that's on-site, I mean they do security. They're 10 CFR Part 55.

And that's what they're there to do. And with all of the different utilities going to the limited amount of people as is necessary to make them competitive in the industry, having those people available is not reasonable. And for us to call out a collector to do that, it's a $350 charge for something that wasn't scheduled. So I mean it's going to cost -- otherwise, we're going to have to audit all the hospitals that we send them to for all the different utilities. I've got 11 different utilities and --

MODERATOR WEST: I think we clearly hear your concern. Still, I would maintain the quick answer is that we do, in fact, believe it would require an audit, but we'll certainly take a look at it and see if there are any possibilities relative to the interpretation of it.

MS. TECHAV: Okay, thank you.

MODERATOR WEST: Certainly.

MS. HAYES: Lori Hayes, Progress Energy.

Just to expand on that and to maybe get the NRC's expectations, what about courier services and also what about EAP services? Would they be covered under this part for auditing?

MODERATOR WEST: Yes, I would suggest we'll just take those into account with the other examples.

MS. HAYES: Thank you, Garmon.

MODERATOR WEST: And give you some further clarification.

Thank you. Ted?

MR. SHULTS: One of the pieces of guidance that we give to MROs in administering split-specimen testing under the DOT program is really if you look carefully at the language of the DOT rule which comes out of the Omnibus Employee Testing Act, which guarantees a right to a split specimen, it says that the right to a split specimen, but that it doesn't dictate that the employee has the right to select what the laboratory is. You probably know that.

And the reason is that I've always felt uncomfortable with the idea of the employee selecting the laboratory of least competence or most favorable nation status and also, not only from an auditing perspective, but just from an accounting perspective. I also strongly advise employers to pony up the money for the retest only because they lose control of the specimen if they're going to allow the employee to do that.

Now that's just a policy decision that you can make, but I think there's a way of reconciling your requirements to certify this by selecting a couple of laboratories. One of the interesting things about the NRC industry is that they've pretty well identified the better laboratories within a good laboratory pool.

And if you can share the audits and basically find a list of three laboratories that would be acceptable for retesting, you'll be way ahead of the game, just from an administrative perspective and also avoiding having to do the random audit of some -- one of the other 70 laboratories that's out there.

This issue of controlling the retesting laboratory location is going to become more important as we start looking at adulterant testing. Clearly, you don't want to find yourself in a policy nit where you have said the employee can select the laboratory and they're selecting a laboratory that's incompetent for testing the adulterant that you're looking for. So a lot more control over this process is going to be in your benefit.

And I also don't discount the value of

-- I mean it's a privilege for me to work with a lot of the quality assurance programs that are out there, and it's a real asset to your industry. I will tell you although the HHS program takes a lot of pride in what they have done, the quality assurance programs and auditing that have been done under the NRC have identified some rather fascinating deficiencies in laboratories.

And to highlight some are the identification of false positives in amphetamines really originated from a utility quality assurance program. The decertification of at least two laboratories I know of and stopping work in three others were also from certified laboratories through your QA departments. And also, other than that, of those sort of highlights, what you find and what I have found is that laboratories don't get it. They don't get that the NRC rule is different than the DOT rule. No matter how much you may have put that in your contract, they apparently don't read those contracts.

So it really isn't until the quality assurance department and utility gets in there that you build this kind of relationship and have an understanding of what the expectations are. I think everybody in this process from my observation has come out as a beneficiary of it.

I also recognize the fact that you'd rather do it voluntarily than have to do it, but that's my two cents.

MR. BUSH: Loren Bush. I want to support what Ted said. When I had the pleasure of working at the NRC I had a number of occasions, quite a number of occasions where I'd be attending public meetings or visiting a lab or run into a lab director. These comments were from lab directors and they were very unanimous in complimenting the NRC licensees' audit programs.

A couple of times they said thank God for their audits because they found problems we didn't realize we have. We're much more efficient and accurate and so on. And they basically thought that the audits that you guys were doing were much better than those from HHS and you are to be complimented for that.

MS. MATULA: Lisa Matula, STP Nuclear Operating Company.

MODERATOR WEST: Please.

MS. MATULA: Back to -- I understand that you all are going to go back on the audit of the off-site, but I just wanted to make sure you understood that because the blood draw and the blood is still left in the FFD rule, most of our collectors are not medical personnel that can do that.

On backshift and these for-cause, a lot of us have to go with them, just like they said earlier, to the hospital, so that they can get that blood draw. And the hour limit just ruins that as a thing. I just wanted you all to think about it.

MS. DURBIN: Not to address that specific thing, but to the earlier question about this question, what does FFD services include, one of the things that I believe and of course, we'd need a legal reading of exactly what the rule says, but I don't think there was any intention that additional FFD services be added to those things that were audited.

The audit requirements were every 12 months for those things, those parts of the program implemented by contractors and vendors before and this was to specify that you still continued every 12 months for things outside, basically outside of your immediate control and you went to 36 months for those things within your program.

So I don't think there was any intent to add to the FFD services that would be included under the audit requirements, so it may be that we need to clarify even under the original rule what that meant. But this language was not intended to increase the audit requirement for FFD services, but only to maintain the yearly audits for those things that were off-site, not under direct supervision.

So that's, I think, something that, as I said, we need to do a careful review. The question seemed to be related to adding things, and I don't think that was ever the intention.

MS. MATULA: And I guess when you say direct supervision, we included that to be --

AUDIENCE MEMBER: Daily.

MS. MATULA: Oh, because we send the FFD collector with all the stuff with them, paperwork, everything. Nothing is left there. We just have a nurse at the hospital draw the blood.

MODERATOR WEST: I see your point. We can certainly factor that into our response. Thank you for those insights.

MR. ENKEBOLL: In response to the FFD laboratory audits, I would wonder if the HHS certified

laboratories aren't very good how we can let them run samples on truck drivers and things like that. If they're incompetent, then maybe the NRC ought to certify laboratories. The fact that the federal government says these are certified and they're fine and they're audited, I still don't see what the fact that we can audit better requires us to audit. You haven't justified why these licensees must spend the time and effort to do that.

MR. EARNEST: Well, if I may, going back to what Ted was saying a while ago, there has been quite a bit of good findings out there by some excellent auditors. One of those having to do, for example, with the identification of blind samples by laboratories, the producers of the blind samples were using a Social Security Number to be included with that sample when it went to the HHS lab. Now, the middle two numbers of that Social Security Number identified exactly what the sample contained. As a consequence, a significant part of the program was seriously flawed and the auditor was able to conclude that every single tech there that was doing the samples knew exactly what was in there before they ever did it, based on the middle two numbers of that.

So to say there's not a need, the rule established -- the new rule establishes the need because we wanted to put it in there. We felt that there was a need to monitor these labs and audit these labs. The only thing that -- going back to what Geary was saying earlier, the only thing that the OGC memo said was that the rule did not legally require that you do it under the old rule. And all the new rule, as near as I can tell has done is to make that a legal requirement under the new rule.

MODERATOR WEST: Please.

MR. ENKEBOLL: The fact that I see some management in the audience, I wanted to re-ask a question that I asked earlier and that was your intention to publish the guidelines, call them NUREG or whatever, prior to publishing the rule.

MODERATOR WEST: Correct.

MR. ENKEBOLL: Thank you.

MODERATOR WEST: We'll end with -- which will be rather brief, with Sections 26.90 and 26.91. There were no changes and we received no questions in that.

I propose we have lunch now and reconvene to finish off with Appendix A and some thoughts on where we go from here.

(Whereupon, at 12:02 p.m., the workshop was recessed, to reconvene at 1:00 p.m., Wednesday, March 21, 2001.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:10 p.m.)

MODERATOR WEST: Okay, I'd like to get started again, please. I was just curious, how many are you going to be here for tomorrow's session? Wonderful.

I guess initially I was thinking that maybe there was just a certain number that might be interested in tomorrow's topic and certainly not only by your show of hands, but the ones that I've talked to seem to indicate there's a lot of interest even in the topic for tomorrow and that's great.

I'd like to begin by just clarifying a question that I was asked just before we took a break for lunch and it seems kind of obvious to me, but I'll just state it nevertheless.

I was asked with regard to issuance of the NUREG prior to the rule being implemented and the point that I wanted to make is that that's a staff recommendation, but clearly, it will have to be considered by our management and then certainly the implication to not only the management review, but the issues of which is where I started even at the beginning of this workshop.

We go to ask for extensions on various things which we did in this case and we did, in fact, get one, but that's a Commission kind of decision. So those considerations will have to be factored in. I think the long and short of what I'm trying to clarify is that the staff will make such a recommendation and then we'll have to certainly factor in the fact that management will have to agree to it and ultimately the Commission with respect to when the rule will actually be implemented and the date that we're on the hook to do that. But again, we'll make that recommendation and hopefully it will be supported.

I'd like to begin with the Appendix A and work through that section. You'll note in Appendix A in the first section here, we didn't have any changes of any substantive kind so I'll go on to the next section which has to do with definitions and I might add before I get into all of the various slides under the heading for Appendix A, you'll find that some of them had a fair amount of detail in them, so we'll get to some of them where I don't have and in some cases I may even have a slide without a whole lot of, if any, information on it, just to give you the reference point and then I'll talk more from some notes that I've made and would have you to look at the --

particularly the redline and strikeout version of the rule changes, when those come up.

But in this particular section, you'll see now the definition for limit of detection, the lowest concentration of an analyte, that an analytical procedure can reliably detect which should be significantly lower and establish cut off levels. And we didn't have any questions on that particular section.

With regard to 1.3, this section was added and I would probably just comment that unlike the current rule when that rule was first implemented, there was a staff requirements memorandum and certainly we have that even with the new rule, but in the staff requirements memorandum for the initial rule there was language with respect to continuing to look at the program and so on and I think this is some equivalent of that.

Maybe not with the level of specifics that were in the actual staff's requirements memorandum for the initial rule. But here you'll find in order to adapt the rule to changes in the evolving disciplines related to substance abuse and employee fitness and ensure the full reliability and accuracy of programs conducted under Part 26, the Commission may make changes to these guidelines to reflect improvements with respect to science and technology and so on.

I think certainly the thing that's oft in the future somewhat has to do with the fact that certainly HHS will eventually have yet another set of guidelines similar to what we're even dealing with with the new rule in the 1994 context, whereas in some point forward probably within a few years, we'll have yet another opportunity to take another look at the updated guidelines for HHS and since we haven't even resolved the 1994 ones, it's probably premature to even speculate on how that will be done.

And then under Section 2.1 there are clarifications, a clarification that any substances suspected of being abused can be considered in a for-cause, return-to-duty, after removal or follow-up testing.

And 2.2 and here is one of the examples where we don't have a full indication of the perhaps all the changes that are in this section, but at least you get one of the notable ones there with regard to retaining custody and control forms. And there are other specifics there with regard to the blood

specimen which we've talked a little bit about with respect to appeal rights.

I think that particular item in that section does, in fact, help to clarify an area that I tend to get some, have gotten some questions on and does seem to come up on occasion with respect to whether the blood specimen is, in fact, intended to be a confirmation of the alcohol results and this clarification hopefully makes that clear, that in fact, does not.

And under 2.3, preventing subversion of testing, we have Fitness-for-duty personnel must be tested by -- and this gets back to the independence notion of trying to achieve that in testing the Fitness-for-duty personnel, it comes up in Section 2.3(b).

And 2.3(c) notes that background checks and psychological evaluations would be required for Fitness-for-duty program personnel within 5 years versus 3 years.

And then further under 2.3, we did get some questions under this heading. And the question reads as follows. If a licensee uses medical department personnel such as station nurse, independent of the administration of the FFD program, are they subject to the same background checks and psychological evaluations found in 2.3(c)?

And our answer is as follows. Individuals who perform one of these functions on an ad hoc basis, such as an emergency medical physician, are not FFD program personnel and therefore not included in the scope of the rule. In the case of the station nurse, the nature of the individual's relationships with the program, whether it is a routine and on-going responsibility or whether it is an occasional and unpredictable one would be part of the information required for determining whether the individual would be considered Fitness-for-duty personnel.

Another consideration would be whether the individual's actions would jeopardize the integrity of the Fitness-for-duty program. And further, background checks and psychological evaluations are specified for FFD program personnel in Section 26.2(a). The rule requires that provisions of licensees' FFD policy apply to FFD program personnel.

Individuals who have routine and/or on-going FFD program responsibilities of the type described in 26.24(a)(4)(i) through (iv) would be included under Fitness-for-duty program personnel.

It's just reiterating the expansion of who's covered under the scope of the rule.

And next under 2.4 we have these items that are included. A chain of custody requirements for couriers, specific requirements regarding validity testing --

MR. BRAZIL: Garmon, excuse me.

MODERATOR WEST: Certainly.

MR. BRAZIL: Previously slide, if you would.

MODERATOR WEST: Sure.

MR. BRAZIL: I'm not sure I understand the answer to the question. I understand routine versus ad hoc, if I'm going to have my station nurse designated only to collect Fitness-for-duty program personnel as defined, when they're selected for random testing or when they need for-cause testing, who's going to tell -- is it up to me to decide whether that is routine because they are going to be the ones responsible for that, or unpredictable and as you've said a minute ago because it's only going to happen when they get picked or there's a need determined.

MODERATOR WEST: Geary, were you pulling your mike because you wanted to jump in there?

MS. DURBIN: Can I clarify the question, first?

MODERATOR WEST: Go ahead.

MS. DURBIN: I just want to make sure I understand the question. Basically, what you're saying is your station nurse normally wouldn't be doing Fitness-for-duty, but will be doing the testing for your Fitness-for-duty personnel?

MR. BRAZIL: That is correct. My Fitness-for-duty personnel are not the medical staff or the station nurse. I need someone independent of the program, obviously, now to collect those people when there's a need to be collected.

MS. DURBIN: So you're basically, it's like how far back in the chain do we go for --

MR. BRAZIL: Exactly.

MS. DURBIN: Right.

MR. BRAZIL: Eventually, they become part of the program and then I've got to find someone else to collect them and well, now they're part of the program.

MS. DURBIN: I'm not sure that's how we interpreted this question, so I don't think the answer addresses that.

MR. BRAZIL: Okay.

MS. DURBIN: I don't know the answer to your question, but I thought that's what you were asking and I wanted to make sure we were clear on that. So it's kind of like you've designated somebody to test your Fitness-for-duty personnel --

MR. BRAZIL: Now are they designated program personnel and I've got to have someone else to do them.

MS. DURBIN: Thank you.

MODERATOR WEST: Your point is that's constantly changing with the nurse you are describing?

MR. BRAZIL: No. I have Fitness-for-duty staff who are not the nurse. The nurse would do not Fitness-for-duty related tasks other than collect the specimens as you've stated earlier from -- because Fitness-for-duty program personnel have to be collected by people independent of the program. Where am I going to draw that line? If I've designated the nurse as the person who is going to collect by Fitness-for-duty staff, does that make them part of those implementing the program? It grows and grows and grows and eventually everybody is program staff.

MODERATOR WEST: I see your point. Do you have any thoughts on that?

I think Nancy's response is certainly correct. We weren't necessarily thinking exactly of the question you've asked with this.

MS. DURBIN: Yes. I think that we're going to have to work through the wording and figure this out. I think we have to come up with a way that you don't have to test everybody ad infinitum, but since we haven't thought through the issue, I don't have an answer.

MODERATOR WEST: But we see your concern and we will attempt to address it.

MR. DiPIETRO: On that same line, some of us don't have a separate FFD staff and a separate medical staff. We have a very small staff and there is nobody else to do any independent testing. So I'm just going to put this out, I don't know, I might be in violation of the rule again --

(Laughter.)

-- the past practice that we had is that we have observed collections for Fitness-for-duty program personnel. Is that an acceptable means? It doesn't meet the words as in a rule, but is that acceptable or would that be acceptable or is that something that could be taken under consideration?

MODERATOR WEST: We'll certainly take it under consideration. I think -- and we can answer that when we get perhaps a modified version of the response we have, but I think it would certainly be appropriate to consider it relative to when practicable.

MR. DiPIETRO: Thanks.

MODERATOR WEST: Certainly.

MS. TECHAV: And on the same lines, can you also take into consideration contract people that do the collection? It's another category, not just nurses, but the contractor people that we contract to do all the collections. They're in our program and everything, but it was added in the front that people that do collection even would be part of your program.

MODERATOR WEST: Now with those individuals, would it be a distinction there with the contractors whether it would be frequent or on a routine basis with the same individuals?

MS. TECHAV: The same individuals are hired by our company to do collection routinely.

MODERATOR WEST: Any thoughts?

MR. MIZUNO: No, no thoughts. I just wanted to be -- I just wanted to understand what you were saying. We have two different situations here. I mean one, the situation is -- or the one that was problematic, I think, was the one where you -- if you have a nurse or someone that was designated who was not normally -- not considered to be part of the FFD program, but has to administer the test to the FFD program personnel and is considered independent, does that then make them part of the program personnel. I mean that was the sort of that circular spinning out of control thing.

I understand that issue, but I'm not sure what you are asking is the same thing. Your question seems to be more -- is a contractor personnel performing the same test, administering the test here to the FFD persons as part of this or are you talking about just a contract personnel who is administering the test to normal employees?

MS. TECHAV: I'll give you an example.

MR. MIZUNO: Okay.

MS. TECHAV: We have someone like myself who administers the FFD program come up in a random program. They do the collection for me. They come up, they're in our random pool already. They come up and they're covered under our program. They come up on the random test. We may have a site nurse. We may

have one of our people collect them. Is that going to be acceptable?

MR. MIZUNO: To the extent that the -- let me understand this here.

MS. DURBIN: I think -- I hope that we have a clear understanding in the transcript of what you described. I think we're going to have to work through it. But it's very good for us to have some examples to think through and so if other people either today or through sending an e-mail to Garmon want to give -- you don't even have to say this is what we do. You can say "if this what we do" --

(Laughter.)

-- would this be okay? Hypothetically.

MS. TECHAV: Those work.

MS. DURBIN: Yes, these are all hypothetical because hypothetical examples that are indicative of what makes sense in terms of practice, give us a much better idea of what the issues are.

MR. MIZUNO: I think one thing I can say is that under the final rule, you as a Fitness-for-duty program personnel cannot be tested by another FFD program personnel and meet the requirements of the rule. But I think the issue of spinning out of control is where you are being tested by a contractor who is not considered to be part -- you have not considered them to be part of the Fitness-for-duty personnel because the only task that they may have with respect to FFD is to test you and other people like you who are otherwise Fitness-for-duty personnel.

MODERATOR WEST: But certainly through the examples I think we can attempt to put some --

MR. MIZUNO: Is that correct?

MS. TECHAV: Well, they do -- they do all of our on-site collection and testing of our whole random program, our pre-access.

MR. MIZUNO: See, that takes them out of the -- they are no longer independent of the FFD program. If they have substantive FFD program responsibilities, i.e., collection, not of just the FFD personnel, to deal with this section here, okay, they have substantive responsibility in the administering the Fitness-for-duty program. They can no longer be considered to be independent of the administration of the Fitness-for-duty program, okay? So it couldn't be acceptable for testing you, but --

MS. TECHAV: So where does the cycle end?

MR. MIZUNO: That's what we have to deal with, okay?

MS. TECHAV: Okay.

MR. MIZUNO: But I mean I can give you examples where it would clearly, in my mind, okay, if the contractor had no responsibility in FFD other than to test you, okay, and FFD program personnel, to me that would be a situation where those people would not have to then be tested because they just don't have any responsibility for Fitness-for-duty administration. The only responsibility that they have is testing you and other Fitness-for-duty personnel for purposes of compliance with this provision and that's it. That's the way I would --

MS. TECHAV: They don't generate the random list. We still administer that aspect of it. They just do the collection and testing.

MR. MIZUNO: But that's still --

MS. TECHAV: I know what the new definition there included now.

MS. DURBIN: They report to you, however, is that --

MS. TECHAV: Well, they're contractors. They're under contract with us, yes.

MS. DURBIN: Under the Fitness-for-duty program?

MS. TECHAV: Absolutely.

MS. DURBIN: So you would need a contractor that wasn't under --

MS. TECHAV: Absolutely.

MS. DURBIN: Yes.

MR. MIZUNO: If I had to just go out on a limb now, I would say that you stop the spinning out of control in the situation of where it's your own licensee personnel. If that station nurse had no Fitness-for-duty responsibilities other than again collecting and/or testing the Fitness-for-duty personnel and that's it, they had no substantive responsibility for implementation of the Fitness-for-duty program generally for all employees, I don't think that that fitness for duty --

[Sound interruption.]

MS. TECHAV: Now with the independence issue which has always been there, it lends an issue that says that even though we're testing you, we're background screening you or psychologically screening you, over and above continuing the observation, we still are not credible enough to do our own collection

of our own personnel. It's just a comment that I feel is not appropriate.

In practicality, many people have multi-sites, so do you have to independently assign a person at each site to do collections, bring in program personnel who is already held to a higher standard to do that collection? It's not practical. It's just a comment.

MODERATOR WEST: Thank you for your comment. Yes?

MR. HARRIS: Neil Harris, TXU Electric.

I'd like to digress for a moment to 2.1(b). This gets into going back to testing. It says licensees may test for any illegal drug or any other substance suspected of having been abused.

My question is what kind of detectable limits will we be using and what type of procedures and what type of substances should we be looking for? This is a very nebulous statement and can include anything up to and including nicotine. You people who have smoked or used tobacco at one time, try using it again after about 5 or 7 years. Again, is that an abuse? I'm kind of taking that and stretching it a little bit, but this is very nebulous. How many things do we have to check for? What types of things and what levels of detectable should we use?

MR. EARNEST: You don't have to, if you choose not to. It says "may test."

MR. HARRIS: May test. Thank you. That's a fine enough answer for me.

MR. MIZUNO: That was put there at the request of licensees to allow you the flexibility to test for other things and nonetheless be under the imprimatur of Fitness-for-duty program.

But we are not designating what drugs, if any, that you have to test for, nor are we establishing what those cutoffs will be, but having said that, I will say that you -- any testing that you do under that and if you take -- if you follow actions under the Fitness-for-duty program, everything would have to be subject to the same requirements in terms of the trustworthiness of the test and the audits and --

MR. HARRIS: I understand.

MR. MIZUNO: But we're not requiring you to do anything in that area. If you choose not to test for anything else and just comply strictly with the requirements and look only at the things that we designate and you use our cut-off levels, establishing

the rule, you would be in complete compliance and that's all we ask.

MR. HARRIS: Thank you. The second part which Bruce led into for me, the use of the word "may". I would like to have again a clarification from my question yesterday where we said that "must" has basically taken the part of the word "shall."

MODERATOR WEST: I don't think you were here at the time.

MR. HARRIS: Is the word "must" now either a requirement or an expectation?

MR. EARNEST: It is a requirement. Thou shalt.

MR. HARRIS: So the intermingling of the words "must" and "shall" within this document are still a requirement?

MR. MIZUNO: Yes. I think that grammatically, I'm told, by our -- the people who deal with the language, that both the words "shall" and "must" are both - -they're not interchangeable, they both impose a regulatory requirement, but when you use "must", I believe it is for where the object is inanimate, whereas "shall" the -- it's applicable to an individual, that the object for which the obligation is being imposed upon is an individual or an entity as opposed to, for example, a paper -- your form must contain something. It's a regulatory requirement, but the object of the requirement is the inanimate object, the form.

MR. HARRIS: I just need clarification because I know our procedure writers will be looking at things like that.

MR. MIZUNO: Yes. Regardless of whether you see the word "must" or "shall", you can safely assume or you can safely rest assured that there is a regulatory requirement to do that thing.

MODERATOR WEST: Thank you for the question.

MR. BUSH: Loren Bush. I wanted to make a clarification to the earlier discussion on 2.1(b).

MODERATOR WEST: Yes.

MR. BUSH: The words there were chosen to give the licensees flexibility to do whatever they needed to do to find out what was the cause for this person being impaired or not fit for duty. Now we had several cases where licensees would apply the mandatory five and they'd test and retest and they'd examine this guy and they keep coming back positive, impaired, but they couldn't find out what the problem

was because they were stuck in this blinders on rut. And they lacked the initiative, if you would, to say let's look for methamphetamines or let's look for designer drugs that can cause the same problem. Okay? So this is supposed to give you a little bit of flexibility.

MS. TECHAV: And then Loren, along those lines, how does (d) apply to that because it talks about the specimen collected under the NRC regulations requiring compliance, with this part may only be designated for approved testing as ascribed in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

So if we're going to go and start testing for all these other things, how do we do that if we haven't had the permission ahead of time?

MR. BUSH: But you get that permission from the individual when he signs off on your collection, right?

MS. TECHAV: To test for only those certain things.

MR. MIZUNO: I guess my -- I think Loren was heading down that approach which was that you would have a blanket authorization when they first come on for employment that says we are going to test you for whatever, okay?

MS. DURBIN: One of the things it limits you from doing is for, example, testing for pregnancy or various kinds of diseases and I think that's the primary intent of that, whether or not it restricts you in other ways will have to be considered, but the intent of that was to prevent health kinds of intrusions on people's privacy.

MS. TECHAV: Yes, and I think -- I don't have the document with me, but I think with our Union we've got agreements on what we'll test for --

MR. MIZUNO: But we're not going to get into that. We, as NRC, have no place in dealing with that.

MS. TECHAV: I understand.

MR. MIZUNO: Right? Okay, but by the same token, I just want to emphasize that we're not -- the requirements there with respect to (d) only means that you tell -- basically, you tell the individual ahead of time that you're going to be subject to potential testing for whatever substances that fall within the scope of the Fitness-for-duty program.

In other words, if you've designated certain drugs as being indicators of you not being fit for duty, okay, then you identify it and you get that blanket approval, okay? What it also means it that all we're doing is saying it's only those things that are relevant to a Fitness-for-duty determination and the things that Nancy was talking about clearly have no place there, so we have nothing to say with respect to that. We're not authorizing you to do anything in that area.

MS. TECHAV: I understand. Can I go back to before our lunch break real quick to 26.80 for audits?

MODERATOR WEST: Sure.

MS. TECHAV: I just wanted a clarification on the first sentence. It says each licensee subject to this part shall completely -- and the word completely needs to be underlined here, audit the FFD program.

What is the expectation of completely audit?

MR. EARNEST: Good question.

MODERATOR WEST: I guess that's certainly something we haven't fully addressed, otherwise, you wouldn't be asking the question, I'm sure. We'll have to take --

MR. EARNEST: From an inspector's point of view, okay, I'll give you a for instance, okay?

When I look at your audit say of your physical security program at your plant, I don't expect to see that you've covered every possible portion of that program, every procedure. When I do that inspection I expect you to sample the procedures.

I expect you to sample some portions of that program. And when it says "completely" here, to me that would mean that the requirements of this rule which are the major aspects of that program, that at least you would sample portions of each of those, that to me is a complete audit.

In other words, where you're covering a sample of all aspects of the program, but not everything that happened. I don't expect you to audit the results of every test that was given or anything like that. Now that's basically what I've learned about audits during the thing -- but I would expect some portion of each part, a major portion of the program to be audited.

And here's Loren up here to go make a liar out of me.

MR. BUSH: No, Bruce, you're right on.
MR. EARNEST: Okay.
MR. BUSH: The intent was to indicate that the Fitness-for-duty program has a number of subelements, if you will. And that over a 36-month period we expected all of those elements to be looked at, that the audit to be complete.
MODERATOR WEST: Thank you.
MS. TECHAV: And then I just need to make one more comment and I really don't need a response, I just wanted to make a comment. On 26.27(a)(6)(i-ii), (7), when it talks about suitable inquiries. I guess it's basically (7) when it talks about suitable inquiries on reinstatements?
MODERATOR WEST: Yes.
MS. TECHAV: We did a study within the industry on how many reinstatements were completed within a year and we came up with about 16,000 that were completed and this was only five or six different utilities that we pulled. We only had two that we would have denied, based on the information on a reinstatement from a suitable inquiry information, so I just wanted that -- those types of statistics out there, so you guys could evaluate that along with everything else that you're doing with that.
MODERATOR WEST: Thank you.
MS. DURBIN: If I can make a quick response. Anyone else who has data of this kind that would be relevant and would like to provide it to Garmon via the website, it would be highly appreciated.
MR. EARNEST: Yes, one of the things that I've been doing while I've been sitting here for about a day and a half now is making up my own list of questions which I intend to give to Garmon and to put through the program because you're looking at how do I implement this? I'm looking at this how do I regulate it? How do I inspect it? What am I expected to come back from your site with? How do I know if you're doing it right?
And unless I can answer that, I have to answer the same questions that you're asking for the simple reason that if I don't understand it, I can't give you a fair review. So one of the questions about this that -- it kind of struck me and I'd like your help on it. And one of the changes that you're talking about here was to allow you if a person had not been tested, had been tested at another plant in the last few days and these have gone from there to

here and I'm beginning to understand that a little bit better, but some of the comments that were made this morning and some yesterday, maybe made me wonder if I'd been holding my plants to a higher standard than I had a right to hold them to.

Now I talked to some of my erstwhile people from my licensees out there and they assured me that I wasn't out of line, but I want to make sure that I'm at least consistent with the other regions. And one of the things -- if a person is transferring to your plant now. I'm talking about under the old rule, okay? If a person is transferring in there for an outage, he was just down the road at another plant two weeks ago or a week ago and now he's reporting in your plant and requesting unescorted access, are you giving him the pre-access screen every time?

AUDIENCE: No.

MR. EARNEST: All right. Now, I want to make sure, he has not been out from under a program less than 30 days. What about over 30 days, but under 60, you're giving it to him?

AUDIENCE: Yes.

MR. EARNEST: Everybody is giving it to him?

MR. SMITH: No, everyone is not.

MR. EARNEST: I'm sorry.

MS. DURBIN: I think you need a show of hands.

MR. EARNEST: Yes. Give me a show of hands of those who are not. I don't need to know where you're from. I just need to get a feel for this, okay?

If we have a problem with the way the rule is being interpreted now, then that question should be clarified if we're going to come out before -- before we ever come out with the new rule. So I've got a problem with both the old and the new here, so give me a feel for this so I can go back to Garmon's boss and tell Vonna, hey, wait a minute, we haven't resolved the old problems.

Let's not start some new ones here, okay? So please, if you would, I don't care where you're from, what region, what plant, give me a raise of hands, just of those who are not doing it if that's less than 60, but more than 30?

MR. SMITH: Anybody understand his question at all?

(Laughter.)

MODERATOR WEST: Why don't you repeat the question. Who's doing 30 and who's doing 60 is what I think he wants to know.

MR. FITZSIMMONS: Rich Fitzsimmons. I think one thing that needs to be considered, we also looked to see when the last time they had a drug test. If they've had a random within 60 days, then we don't give them any test because that would suffice for the pre-access test.

MR. EARNEST: If a random --

MR. FITZSIMMONS: At another utility, within 60 days, we will not go and drug test.

MR. EARNEST: Any drug screen within 60 days -- all right, anything over 60, you test them?

MR. FITZSIMMONS: Yes.

AUDIENCE: Yes.

MR. EARNEST: Everybody does that, am I correct?

AUDIENCE: Yes.

MR. EARNEST: Sixty to 30? Only if they haven't received a drug screen in that 30-day period?

AUDIENCE: Sixty days.

MR. EARNEST: Sixty days prior to arriving at your site?

AUDIENCE: Right.

MR. EARNEST: And it doesn't matter what kind it was? As long as it was negative.

That answers my question. Thank you very much.

MS. DURBIN: Now I want to ask some questions because I'm not sure of what Bruce's questions meant. So I just want to make sure that I've got it clear. Barring people who have had a test within the last 60 days, those people are -- we're just not going to think about those. How many of you are testing someone who comes to your site within 30 days of leaving another site? They're moving within 30 days. So you're testing everyone who comes to your site as long as they haven't had a test within the last 60 days?

AUDIENCE: Right.

MS. DURBIN: So that's the way to put it. How many of you are testing everyone who comes to your site who hasn't had a test within the last 60 days, regardless of where they were 30 days ago?

Let me try again. How many of you are doing a pre-access test on all of your applicants for unescorted access, either yourself or they've had another test within the past 60 days? No?

MR. SMITH: Take the test out. Now who's doing the test in 30 days and who's doing the test at 60 days, eliminate the random.

MS. DURBIN: Did I say random?

MR. SMITH: How many people are using the 30-day cutoff?

Okay, how many people are using the 60-day cutoff? Thank you.

MS. DURBIN: How many people are using no cutoff?

MR. SMITH: One guy back there, two guys.

(Laughter.)

MS. DURBIN: If they've had no test within 60 days?

MS. TECHAV: If they are covered under a random testing program and a CBOP within the last 30 days, we do not test them. When you go beyond that 30 days that's when they need a test.

MS. DURBIN: Okay, so some are doing 30 and some are doing 60.

AUDIENCE: Yes.

MODERATOR WEST: Thank you for that.

MR. MORIARTY: John Moriarty from Vermont Yankee.

We have kind of done it all of those ways over the years and the 30 days came from -- more from the CBOP than it did from the testing. Sixty days, the only thing it said about 60 days was how long you could use a pre-access drug screen before granting access. So this wasn't rule-based, it kind of evolved over the years.

MR. EARNEST: Exactly.

MR. MORIARTY: And we're all at the 30-day -- most of us at the 30-day point. But just a little history there.

MODERATOR WEST: Thank you. Let's move on to 2.4, please.

That's Slide 101. Here we have some of the changes within this section. Chain of custody for requirements for couriers, specific requirements regarding validity testing. An individual shall not be required to list prescription drugs. Changes in quantity requirements for urine specimens. Requirements for testing under direct observation and alcohol testing changes. And I'll just mention some of the specifics with regard to the changes in quantity requirements for urine specimens.

It notes that there are specifics for the -- generally speaking for the licensee is required to

do along these lines, a minimum of at least 30 milliliters. It would be more if additional drugs are being tested and at least 15 for splits and more if on-site testing is being conducted.

And then the priority of whatever the total amount would be would be along these lines. First, what has to be sent away to the HHS lab, a second would be splits and then the third would be on-site. And then the difference with respect to the current rule, partial specimens would have to be retained separately.

(Off the record.)

MODERATOR WEST: We'll continue on with Appendix A, Section 2.4 and we'll start with the first question that we're going to consider.

Could we go to Slide 102? Thank you. The question is as follows. Must each individual provide a single specimen that meets the volume requirements or can several collected specimens be used to meet the volume requirement?

I have somewhat of a long-winded response here, but I'll get into it and maybe some of the earlier part of it will answer the question. This is our response. With respect to the combining of partial specimens, the NRC now believes that the partial specimens should not be combined and no partial specimen should be discarded.

Instead, specimens of less than 30 milliliters should be sent, along with any subsequent specimens collected during that collection process for testing at the HHS certified laboratory and each specimen should be analyzed separately.

The rule has been changed accordingly and there is a discussion of this particular point in the SECY, the rulemaking package, SECY 00-0159. And it's located in attachment D in Section 9.5.1 and the subheading there is other chemical testing procedures.

Again, Bob mentioned it before, but the SECY is in fact available on the web, but just to continue on, the requirement is that each licensee predetermines a quantity of urine that it will require of all people submitting specimens in its testing program. This quantity should take into account all analyses and re-analyses provided in the licensee's FFD policy which I've certainly mentioned previously. And then the answer goes on to give some of the specifics with respect to at least 30 milliliters and so on, and what I touched on earlier, in terms of on-site testing, consideration of that.

In cases where an employee produces a specimen of smaller quantity than that predetermined by the licensee, the specimen should be used to the extent possible to meet the testing requirements in the following priority which I mentioned previously. I won't reiterate that.

I will note the example, however, which reads as follows and that is, if the licensee conducts on-site screening testing and for example, an employee can produce a specimen of only 30 to 35 milliliters, the licensee should not test that specimen on site, but instead should send the specimen to the HHS certified laboratory, given the minimum or the priority of how the specimen that is collected should be used.

In this example, there would be no split specimen for the donor to challenge the results of the primary specimen.

MS. TAYLOR: Garmon, Martha Taylor, Progress Energy.

I've got a question.

MODERATOR WEST: Sure.

MS. TAYLOR: What is the amount of urine you have to have in order for it to be processed? For example, sometimes I have people that give specimens that might be like 10 milliliters. It's not even enough to register that it's a valid specimen because there's not enough there to even get a temperature off of it. Do I now package that up and send it to the lab? And if I did do that, would there be enough there for them to even analyze it?

So I guess for those specimens like the volume is not even enough to get a temperature on.

MODERATOR WEST: I believe the answer is that we haven't specified a minimum and that's not to say we shouldn't consider that, but we haven't specified a minimum.

MS. TAYLOR: So you're saying we should package it and send it to the lab even if they came back and said hey, there's not enough here for us to analyze?

MODERATOR WEST: Well, that's my initial response, yes. The fact is we haven't specified a minimum.

We've specified a minimum in terms of not on the low end, but in terms of a minimum that you're trying to get.

MR. FITZSIMMONS: Rich Fitzsimmons, DTE Energy.

My understanding is, at least with my lab, HHS requires them to have to have a minimum of 25 milliliters.

MODERATOR WEST: I see.

MR. FITZSIMMONS: To go and process a specimen that allows for a number of retests and analytical testing.

MODERATOR WEST: That ties in --

MR. FITZSIMMONS: So anything else, they would refuse to test it because it's an insufficient quantity and it would come back. If any of us have had a leaker, we know what an insufficient quantity is that's sent out to an HHS certified laboratory.

MODERATOR WEST: Sure.

MR. FITZSIMMONS: So if we cannot combine, if an individual that provides us 10 milliliters in each specimen at no time would be able to get a valid test at the lab.

MODERATOR WEST: I think that's certainly a valid comment for us to take into account.

MS. TAYLOR: Would we get charged for that too?

AUDIENCE: Yes.

MODERATOR WEST: Thank you. Loren?

MR. BUSH: Loren Bush. My understanding is that the labs can do a test for a particular drug or metabolite with like only 3 milligrams which is obviously not a very large quantity. But more importantly, my understanding is on the partial specimens, this is based on conversations with HHS and the lab folks several years ago, they can do whatever tests they need to to determine, to assure themselves that these specimens are provided from the same individual.

One of the problems of people providing partial specimens to avoid testing and so on and then the laboratory could determine whether or not they would combine those partial specimens during the testing process.

But we figured it was appropriate to collect these specimens and send them to the lab for the specific reason that I just mentioned and that is a technique that the drug culture was advocating was submitting partial specimens so that you would not be tested.

MR. SMITH: I have a question, if you don't have enough of a specimen to get a temperature, how can you --

AUDIENCE: We throw it away.

MR. SMITH: Okay, it wouldn't be a valid specimen. You wouldn't send that off to a lab, would you?

MR. EARNEST: We're not there yet, but under (g)(11) it clearly states how much you must collect, how you collect.

MS. TAYLOR: That's what we're saying, if they don't give that much.

MR. EARNEST: It says here that you must and that you'll --

MS. TAYLOR: You tell that person that he must give you a --

MR. EARNEST: Yeah, you give him an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces. That's pretty specific. And again, I don't know what to tell you, if he can't, he can't.

MS. TAYLOR: We have people that can't.

MR. EARNEST: Trust me, I know.

MODERATOR WEST: I think also there was some discussion in the statement considerations for instances where they can't for some medical type reason.

MS. TECHAV: And something that must be brought out is that bringing up this whole issue is back in 1996, the words in there said that the specimens must be combined. That's been removed since 1996.

MR. EARNEST: Right, and it's supposed to be separately now.

MS. TECHAV: And we have not been able to comment on that.

MS. DURBIN: That was changed basically in response to comments that that was a really bad idea. So not just to say that was -- the change was actually a response to comments we got about the problems that were created by combining specimens. So -- and that's discussed in the comment response document, just a --

MODERATOR WEST: But your comment is certainly noted. Thank you.

The next question, I believe it's a question, still with regard to this section, what are the acceptable results for oral temperature of participants?

Our response is as follows. The individual's oral temperature is taken at the individual's request if the specimen submitted is outside the acceptable temperature range of 90.5 to 99.8 degrees Fahrenheit or another range, another more

stringent range specified by the licensee only in that we're aware that some licensees may, in fact, use more stringent ranges.

The reason for taking the oral temperature to give the individual an opportunity to provide evidence that his or her oral temperature provides an explanation of a specimen temperature that is out of the acceptable range, instructions in 2.4(4)(2)(ii) note that a specimen with an unacceptable temperature when the individual's oral temperature varies by 1.8 degrees Fahrenheit or more from the specimen temperature requires a second specimen collection under observation. The licensee should assure that under these circumstances the collection personnel are aware of oral temperatures that are outside the range that would indicate a healthy person.

And under -- still under 2.4, must an individual be present when an on-site screening is performed since the person has to be present when preparing a specimen for shipment to the HHS lab?

Our general response to this question is no with this explanation. The person must be present only when the specimen is split for various testing purposes and each aliquot is labeled, and prepared for shipment, including the aliquot to be sent to the HHS laboratory. Finally, once the labels and other documents have been completed and the container is sealed, the individual can depart.

Yes?

MR. BRAZIL: If we could tie what you just said to -- I apologize.

MODERATOR WEST: NO problem.

MR. BRAZIL: I should know this by heart by now, 2.4(g)(21). The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

If you flip to the next page, look at (h), specifically look at (i). Specimen preparation for transportation to laboratory or testing facility. If you take this word for word, and you go back to (g)(21) it says that the collection site person and the individual shall be present at the same time when I am performing step (i) and that specifically addresses packaging the specimen for shipment to the laboratory or testing facility.

I believe I submitted this question because I'm being questioned on that particular issue.

MODERATOR WEST: Right.

MR. BRAZIL: I do on-site screening and if I do this word for word, then I've got to have the person come back to my facility after I've performed that on-site screening and determine that it's a presumptive positive and I need to send it off to the off-site laboratory. I would -- granted, these words are in the current rule and they are untouched in the new rule. However, I don't see any way to implement this as it's written.

MR. EARNEST: That was never changed anyway.

MR. BRAZIL: Correct.

MODERATOR WEST: He's acknowledged that. Do we have any thoughts on that from anyone at the table?

MR. BUSH: I'm sorry, I don't see the problem. Mike talks about the preparation of the specimen for transportation to the laboratory and addresses the paperwork and sealing of the specimen and so forth and putting it in boxes, shipping boxes--

MODERATOR WEST: Which is what we're referring to in terms of shipment.

MR. BUSH: Yes.

MR. BRAZIL: Well, if a testing facility is adjacent to my collection site, I don't have to package it other than collecting the bottle, sealing it, and putting it in a refrigerator or taking it directly over to my testing facility.

Word for word here, when I'm ready to send it to that laboratory, go back to (g)(21), it says the individual shall be present. So after I finish my on-site screening, if I'm going to package it up to send it to the laboratory, that person is supposed to be there.

MR. BUSH: You're interpreting (i) to mean your on-site testing facility.

MR. BRAZIL: No.

MODERATOR WEST: You're saying that once you ship it to the --

MR. BRAZIL: Once I've completed what I'm going to do with it on site and have determined there's a need to send it to my off-site laboratory, according to (g)(21) the person has to be present for me to do that. It should stop at (h). I understand the intent. I think I understand the intent, that the person is present with the collection site person as it's collected, as it's bottled, as it's sealed, as the chain of custody is transferred from the participant to the collector, but as this is written,

it's telling me that that person has got to be there if and when I have to package it to send it to an off-site laboratory.

MODERATOR WEST: And in your case, the example you're giving is because you have this extra step as a result of the on-site testing.

MR. BRAZIL: Because I do on-site testing. That person is not going to be there if and when I determine I have to send it off-site.

MR. BUSH: Okay, that shouldn't be in there.

MR. BRAZIL: No, it shouldn't.

MODERATOR WEST: We can certainly, I think, address that.

MR. BRAZIL: Please do. Thank you.

MODERATOR WEST: Thank you.

MS. KOPP: Hi, Darlene Kopp from First Energy. I just wanted to go back to 2.4(d) on chain of custody and I'd like to just get some clarity on one of the statements. Custody and accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier or Postal Service. Is there some form of tracking system or bar coding that you would expect the laboratory to have for the specimens to be tracked in their system?

Right now what we do in our plant, as we collect our specimens individually and put them into one large container with a manifest, more or less, a chain of custody that we create, our collector signs that with the number of specimens that are in there and it's sealed and the lab courier actually picks that up, takes that to the lab for processing. The lab opens that. The manifest is removed. We get faxed a copy of that clarifying and saying that that many specimens are in that particular bag.

We really have no sophisticated tracking system and I think that my counterparts would like that answer to say is our manifest adequate?

MS. DURBIN: My recollection when we were working on this and Loren may have a different opinion, under the current rule it could be implied that you were supposed to take every, that the courier was supposed to sign every chain of custody and we wanted to make sure that was not the case. What we wanted was a system that sounds very much like what you're suggesting and it doesn't have to be a sophisticated tracking system, it's just a tracking system so you know that it got there.

Almost all couriers have some tracking system to assure you that the thing arrived and that somebody signs off that they got it and that it was sealed when they got it. So I can't answer your question specifically. It will have to be answered, but just to give you my recollection of the intent, it sounds like you're meeting the intent of this change.

MS. KOPP: Then that's what I wanted to know. Thank you.

MODERATOR WEST: And I think certainly the concern is that the integrity of the chain of custody is maintained, as opposed to trying to prescribe exactly what methods you used to do that.

Ted?

MR. SHULTS: Garmon, thanks. I just wanted to mention the fact that one of the big issues that DHHS is currently struggling with is the issue that was just discussed in terms of on-site testing and the process, the relationship between the collector and the donor. And the issue is it's a generic issue, is if you're going to do on-site testing, whether it's instrument based or non-instrumental, what is the procedure? Should you prepare that specimen for sending to the laboratory even though 95 or 98 percent of these are going to be negative, and I just think you should be aware that they're struggling with this issue and will be coming out with some guidelines and probably for consistency sake there may be some merit to looking at how they've addressed that issue.

MODERATOR WEST: That's an excellent point. I'm reminded that I served, not as an official member of the Drug Testing Advisory Board, that HHS has the lead on and clearly this is, in fact, as Ted has indicated, an issue that they're looking at and they're also looking, because they're certainly aware that the NRC is making changes with respect to Part 26 and other agencies as well, a change in their regulations in this area. So they're looking to us with respect to where we're headed and we're also, as Ted has implied or said explicitly, looking to them in terms of how they're going to come out on this issue and other agencies.

MR. BUSH: Loren Bush. I feel compelled to just make a comment. I want to make sure people don't go spinning off into the wild blue yonder.

Under (h) the collection control, the specimen that would eventually be shipped to the laboratory would be sealed and initialed and all that

sort of thing. It's the (i) requirement where it goes into a separate shipping container or bag or what have you that the individual need not be present for. Okay?

MODERATOR WEST: Thank you for that clarification.

MR. EARNEST: You know, in our own NRC testing program which I was very lucky to get checked on last week. I came up on a random, first time in about 4 or 5 years, and the lab that comes in that contracts with us and comes in, sealed it as I'm sure most of you do, we initialed it and then it goes into the shipping container that goes to the lab right there and it is sealed right in front of us, so there is some correlation to what's happening out there with some of the programs. I'm not sure whether (i) means to that extent or not. It's outside of my area of expertise, but it's a good question.

MS. THIEL: The problem with that is when you have 100 or 200 a day, you can't put them each in a shipping container. You have to put them in one big container at the end of the day.

MR. EARNEST: I understand and I guess it doesn't say that you got to seal up the container. It just says that you've got to put it in a shipping container in this.

MODERATOR WEST: Yes.

MR. BRAZIL: I'd like to ask Mr. Bush a question about what he just implied.

You're saying that I'm going to have one bottle that I'm going to be able to open on site, to do my on-site screening and a second bottle that's going to be sealed and ready for shipment to the off-site laboratory, if a need is determined to do so?

MR. BUSH: If you're going to meet forensic standards, you collect the specimen, you have a relatively large container, hopefully with a lot of urine in it.

(Laughter.)

And you decide that you're going to do on-site testing. You might want to split specimen and so forth. So you pour off basically three aliquots is what you end up with, three different containers of urine, correct, in my example? No?

MR. BRAZIL: Keep going.

MR. BUSH: Okay, then you put each a label and seal on each of those bottles because you're going to maintain your forensic chain of custody, right?

MR. BRAZIL: Sure.

MR. BUSH: Okay. What's wrong with that?
MR. BRAZIL: Where's the third container?
MR. BUSH: You have a split specimen, you have the specimen that's going to the lab and you have the specimen that you're going to do your on-site testing on.
You're not going to take the specimen after the individual's walked off and start pouring, opening it up and pouring things around and all that kind of stuff. You've ruined the chain of custody.
MR. BRAZIL: Your technician is already subject to a higher standard and --
MR. BUSH: It doesn't make any difference. You're going to go to court and argue that he opened up this bottle and then we sent it on to the lab for testing?
MR. BRAZIL: First of all, there's no requirement to split, correct?
MR. BUSH: No.
MR. BRAZIL: It may be split at the licensee's discretion.
MR. BUSH: Correct.
MR. BRAZIL: I just tried to do what you just described which is to have a bottle that I'm going to use on-site, a second bottle that I'm going to send off if it is determined that that first bottle is positive on-site. I was informed that that was splitting specimens. I had a primary and a split.
MR. BUSH: No. A split specimen is the -- a way of looking at it is that it is the specimen that is "owned" -- quotes around owned -- by the donor in case he questions the results from the lab. He can then say I want to test my split.
MODERATOR WEST: And the HHS is owned by the licensee. Do you have any further comments?
MR. BUSH: In other words, you have a retest of the specimen you sent to the lab. It's the licensee's specimen. The split specimen, as the rule is written, is the specimen that belongs to the individual. The individual decides whether he wants to challenge the test result. Okay?
On top of that, you have the specimen, the aliquot to be correct, that you're going to use for your on-site testing. What I'm saying is the rule is structure and good forensic practices, the individual is there when each of those specimen bottles are labeled and initialed. So if there's any challenge at any time in the future, you can go right to it and say

this specimen or aliquot was collected from you on this date. These are the test results.

MR. MIZUNO: And there's your John Hancock on the seal and you were there. So there's a chain of custody for every one of those things, including his split.

MR. BRAZIL: I understand where you're coming from. I know what I've been audited to and inspected to in the past and I'll sit down now.

(Laughter.)

MODERATOR WEST: Please, do you have a comment?

MR. BOISMENU: Brett Boismenu, Fitness-for-duty at Niagara Mohawk.

My question has to do with Bruce, you just said you went to -- and you got randomly tested. We've run into some cases in the past, we have the individual initial the seals prior to presenting the sample and putting it on the bottle. Is that recognized as being acceptable because once the bottle is filled and the seals are put on it sometimes it's hard to write on those bottles, so we have the individual come out, keep their eye on the specimen, we pour off what we need for the two or three specimens and then put the appropriate seals on them.

MR. EARNEST: In my case, I didn't go into the detail of how they did that. They split the sample right there in front of me. They take my main sample, they split it. They seal both and then they put it into the small box that has the spot for the two samples in it, the containers to be in it and then they seal the box and I sign the box.

MR. BOISMENU: I guess my question to the Panel is is it acceptable to put the initials --

MODERATOR WEST: Before you seal it?

MR. BOISMENU: Before -- correct.

MODERATOR WEST: My response would be yes.

MR. BOISMENU: Thank you. Thank you for your question.

MR. EARNEST: Courageous stand.

MS. PATSY: Rebecca Patsy, ConEdison.

MODERATOR WEST: Please.

MS. PATSY: If the technician in the on-site testing, if the technician continues the chain of custody by signing it and then when it's determined it needs to go out, again continuing the chain of custody by signing it to the courier, is that not continuing the chain of custody?

MODERATOR WEST: I'm sorry, one more time.

MS. PATSY: That would be in lieu of collecting that other sample, other than the split. We call the A, B and then the C for the on-site testing. So if you're taking from on-site testing, if you're taking out of the A, the technician is continuing the chain of custody by signing on that chain of custody and then signing off again when it needs to be sent out to the courier. So they are continuing the chain of custody.

MODERATOR WEST: I guess I'm missing the question. You're saying that with -- you're taking a specimen and you're taking from the original specimen or specimen A and taking a split?

MS. PATSY: Would that be sufficient? If they sign that chain of custody, they opened A. They signed that chain of custody and when it needed to be sent out, they continued the chain of custody by then sealing it again --

MODERATOR WEST: Sealing it again and then signing it again?

MS. PATSY: And signing it. The technician would sign it.

MODERATOR WEST: Well, again --

MS. PATSY: And he wrote right on that chain of custody that they were the ones that opened it.

MODERATOR WEST: As opposed to the individual?

MS. PATSY: Correct.

MR. EARNEST: Going back to my cop days, that wouldn't be sufficient under certain circumstances. One, if the technician takes that and she or he is the only person that has access to that sample, she doesn't leave the room, doesn't leave it, there's no way anybody else can get to that sample. You could probably make your case in court.

But if there is any chance of that specimen being contaminated by anyone, then her signature means nothing.

MS. PATSY: Other than the technician?

MR. EARNEST: Even by the -- well, I don't know by the technician, but again, if anyone else, anyone, any other technician, anybody in a program, anybody else could have access to that sample for any period of time if they even leave it in one room, if they get out of site of it, you've lost chain of custody.

It must be secured in such a way that it can't -- that the custody, chain of custody isn't

lost. And that that can't be done with locking it up in certain instances, but chain of custody means different things and under different circumstances. When you start talking about forensic custody as Loren is talking about, you're talking about a whole new ball of wax. Chain of custody for something that is inanimate, for example, and cannot be -- the basic structure of it can't be changed is one thing, like possession of a fire arm. But the chain of custody as far as a urine sample, that can be changed so easily as we all know.

So the forensic chain of custody here is a little tougher proof when it comes to a court.

MODERATOR WEST: I might add as a footnote and this is sort of back pedaling and I do want to move forward and we'll get to the remaining comments. That was somewhat my concern with the previous example that was given. If you're signing prior to it being sealed and let's say something of a distraction occurs and then you have the period there where you at least are vulnerable, so that was the thought that I had on that one.

Shall we take a comment over here and then we'll come to you, Loren.

MS. BURKETT: If Loren's is related to this topic, go ahead and take it.

MODERATOR WEST: Okay, please.

MR. BUSH: I'm leaving.

(Laughter.)

MODERATOR WEST: That's related.

MR. BUSH: The practice of opening, as was suggested, the specimen, the aliquot, bottle A or B, whatever in HHS vernacular, that's going to the certified lab for testing, to open that up on site I think you're playing with fire. You are seriously endangering yourself to compromising chain of custody, integrity of the specimen and all that sort of thing.

I would strongly recommend that if you're going to do on-site testing, you pour off an aliquot, have it witnessed and separately sealed and all that sort of thing like I talked about just a few minutes ago.

Anything other than that, you're looking for court cases, a lot of money trying to defend yourself and so on.

MODERATOR WEST: Thank you, Loren. I would second that.

MS. BURKETT: Go ahead.

MR. BRAZIL: I'd refer to Section K where it does not mention three containers if you're doing on-site screening. It only mentions two. Urine specimens may be split at the licensee's discretion into two parts. And this is the revised -- one part of each specimen hereafter called the primary specimen, formerly called the aliquot, must be analyzed by the licensee's testing facility. I've still got two containers here. I've got the one that I'm going to analyze on-site, the primary sample. Must be analyzed by the licensee's testing facility or the HHS certified laboratory. The other part hereafter called the split specimen may be withheld from transfer to the laboratory. I will go down into -- if the primary specimen, which is the first bottle that I have opened on-site for testing --

MODERATOR WEST: Are you at 2.4?

MR. BRAZIL: Yes. 2.7, I'm sorry.

(Pause.)

Page 51, if you've got the copy that everyone got here.

Okay, I'm being told here that that first bottle has to be opened on-site. I have to open it on-site to do on-site screening.

The other part is withheld. The split specimen is withheld for -- must be analyzed by the licensee's testing facility or the HHS certified laboratory. Okay?

I'm analyzing it at my licensee's testing facility.

MODERATOR WEST: Okay.

MR. BRAZIL: Drop down to the middle of the paragraph -- if the primary specimen is determined to be negative and free of any evidence of subversion, the split may be destroyed. If the presumptive positive screening test of a primary specimen has been confirmed, how am I going to confirm that primary specimen that I've already opened on-site for on-site screening without sending it to the HHS lab?

Are you with me so far?

MR. MIZUNO: No. Well, I know what you're saying. I know exactly what he's saying. I can tell you what Loren is saying is absolutely correct. If you don't have that third bottle there, okay, you are going to be subject to a claim that --

MR. BRAZIL: Geary, I'm sorry, I know where you're going. I just heard Loren say it and I heard you guys say it and I agree. I agree. What I'm saying though is if you want three bottles and I need

to have three bottles, this needs to say use three bottles. Because as it's written right now, it tells me to open the primary specimen on-site to perform my on-site testing and you guys are telling me I can't do that.

MODERATOR WEST: You see this is something we could clarify in the NUREG document, Geary?

MS. DURBIN: I think we can clarify this. That section is about split specimens. It's not about on-site testing and I think that's the difficulty.

MODERATOR WEST: That's a good point.

MS. DURBIN: But --

MR. BRAZIL: There's nothing else in here though about --

MS. DURBIN: We need to clarify it and the clarification can be provided elsewhere. I don't think we're going to clarify it here. And I appreciate you bringing up the lack of clarity because this is something that needs to be clarified.

MR. MIZUNO: Well, I'm not going to concede lack of clarity until I actually read the thing, okay? Really. It's been a long time since -- we have to go back to this thing. I'm not going to concede anything. I think that there may be, if there's a lack of clarity, then we will deal with it. Certainly, the questions, if necessary, in order to make it clear in the rule, we'll consider that as well, okay?

MODERATOR WEST: That's very well stated.

MR. MIZUNO: We understand that language that you pointed us to. Thank you very much. That's good. We can see where you may have an ambiguity there and a lack of clarity.

MR. BRAZIL: Absolutely.

MODERATOR WEST: Thank you for your comment. Please. I know you've been patient.

MS. BURKETT: Kathy Burkett, American Electric Power. I apologize for doing this to everybody, but I have to go back and revisit something and I just want to comment on it.

MODERATOR WEST: Sure.

MS. BURKETT: When we talked earlier about the 30-day, 60-day drug testing and the people moving through the industry and it appeared that you felt that the industry had made their own decision on how they were going to implement that and we possibly were not following the rule.

The rule never addressed reinstatements or transfers. The rule was silent.

We as an industry --

MODERATOR WEST: And we acknowledge that. You're certainly right.

MS. BURKETT: And we went back and repeated occasion and in 1995, I was present at a region meeting and Mr. Bush was asked what the intent of this was. We, at that time, said some of us are doing testing 30 days, some of us are doing 60 days.

He indicated at that time he did not -- his intent of that short period of time that a worker could go from site to site in NUREG 13857.1, that he had not intended that to be a 60-day window at that time. He meant 30. However, if any of the licensees had written 60 days into their program, it was not necessary for them to go back and rewrite their program until the rule was revised. And I just wanted to make it on the record that everybody knew that was not the industry making their own decision.

MODERATOR WEST: Was it transcribed?

MS. BURKETT: Would you like to have it transcribed?

MODERATOR WEST: Your comment is note.

MR. EARNEST: Aren't you glad you came, Loren?

MR. BUSH: I'll answer that question in the negative. I can barely remember all the meetings I went to, certainly, not all of the things that were discussed. But I was reminded during the break of this particular conversation and so I agreed to come up here and say something along the line of yes, I do remember the discussion and so on.

I do know that this issue of how do you handle people who are wandering from site to site and part-time under the licensee's programs has been an issue from the day the rule was issued. And I'm not sure that it's ever been fully satisfactorily addressed by anyone to everybody's satisfaction at this particular point.

I hope that the changes to the current rule or the current changes, who knows if they're going to be current or not, will address this situation, put it to bed once and for all.

MODERATOR WEST: Thank you for your comment.

MR. EARNEST: Thank you, Loren.

MODERATOR WEST: And I might add too, at the end of this session today, I'll revisit this particular point about the raising of the hands and so forth and hopefully that will be of some help as well.

Please.
MS. LANOUETTE: Susan Lanouette from North Atlantic.
I just need to go back to 2.4(g)(11). I just want to clarify, we do not do splits. We do one sample. In here, you're telling us that a partial specimen less than 30 milliliters should be retained and sent with any subsequent selected specimen or specimens? And further down, you're also telling us that each specimen must be sent separately for analysis?
Can you explain that?
MODERATOR WEST: So you're saying --
MS. LANOUETTE: What are you telling me?
MR. MIZUNO: They want to know why we changed our mind with respect to combining partial samples, which was in the proposed rule and then we changed our mind and now said do not combine partials and now we're keeping them separate --
MODERATOR WEST: Is that close to what you're asking or not?
MS. LANOUETTE: Are you talking to him or to me?
MODERATOR WEST: I was talking to you but with respect to what he just characterized. Was that your question, what he just mentioned?
MR. MIZUNO: I mean the rule says I have to -- I think you're complaining or you're asking what is the basis for -- as I understand it, your question is what is the NRC's basis for requiring that each partial specimen that does not meet the minimum amount, less than 30 milliliters be (1) retained and (2) labeled separately, and (3) sent off to the lab for quote testing, even though, in fact, it may be in a level too small to even be tested by that lab.
I think that's what I --
MODERATOR WEST: Why not just get rid of that --
MS. LANOUETTE: Right, you're saying we have to send it separately.
MS. DURBIN: What you're asking is can it be in the same container?
MS. LANOUETTE: Can it be in the same bag with the same COC or does it have to be separate COC for each single specimen?
MODERATOR WEST: I don't think it has to be separately, no.
MS. LANOUETTE: Then how do I label it because I only two labels, one for primary and one for

split. How am I going to label it and have that individual sign it?

I'm going to have to have more labels.

MODERATOR WEST: Does anyone have any thoughts on that?

MS. TAYLOR: The custody is supposed to be referring to a particular specimen that's going on. If you're going to do it separately --

MODERATOR WEST: To maintain the chain of custody.

MS. LANOUETTE: And if you send them all separately, how do you notify the lab that that's all from one person and how do they determine that it's all from one person?

MODERATOR WEST: Can we pause here just a moment?

(Pause.)

MODERATOR WEST: I'm sorry, could you repeat your question again, please?

MS. LANOUETTE: The question here is partial specimens.

MODERATOR WEST: Yes.

MS. LANOUETTE: I have less than 30 mls. that I've collected. I have to collect another partial to get that 30 mls.

MODERATOR WEST: To come up to the 30 mls, okay.

MS. LANOUETTE: But you're also saying that I cannot combine them.

MODERATOR WEST: Yes, we're clearly saying that.

MS. LANOUETTE: I have to -- let's say I have 15 mls. I have to send that 15 mls. separately with the other 15 mls. that I collect separately.

AUDIENCE: No.

MODERATOR WEST: No wait, let me pause here. You collect 15 mls. You don't have the minimum of 30.

MS. LANOUETTE: Right.

MODERATOR WEST: So you collect another 15 mls.

MS. LANOUETTE: Right.

MODERATOR WEST: And you're assuming that you have to send them separately?

MS. LANOUETTE: Right, because that's what you're saying here.

MR. BUSH: Separately means don't combine them. It doesn't mean you can't put them in the same container.

MS. LANOUETTE: Right, but how can I put them in the same bag with the same COC if there's not enough labels --

MODERATOR WEST: But why wouldn't you just take each one individually and send them off?

MS. LANOUETTE: And how am I going to label that? I'm going to put in my computer that I have three different specimens for one person, so I have three random separate tests? Uh-uh. I have one test. One specimen or actually one person, but three specimens?

MODERATOR WEST: I guess unless someone at the table or Loren has some further insights on that, we'll have to take that one up to give you some further guidance on that.

Let me make sure I understand the question before you leave, please. You have potentially two different specimens, each are less than the 30 minimum and you can't ship them both together.

MS. LANOUETTE: Right. Because I only have one label that says primary.

MODERATOR WEST: Because of your label.

MS. LANOUETTE: Right. So how do I label the second specimen?

MODERATOR WEST: We'll take that one as an action item.

Do you have anything on that, Ted?

MS. DURBIN: Does your question also include how you deal with chain of custody?

MS. LANOUETTE: Yes.

MODERATOR WEST: It's related, certainly, yes.

MR. SHULTS: This issue isn't without precedence. And in fact, under the current DOT regulations, there's an analogous situation and you know what it is or most of you know what it is. That's when you collect the specimen that's cold and it doesn't meet the temperature. Now under their regulations they say that you're supposed to capture that and send it in and collect a new specimen.

Now the only way I can conceptualize that is that really is capturing a separate urine specimen, it's a separate piece of evidence with its own chain of custody and if you do a split, it's split. If you don't do a split, it's not split. Under DOT, it's supposed to be split. Now the challenge in the DOT program as many of you can already anticipate is what oftentimes happens it that cold specimen is guess

what, negative, you know? And you get this negative report that comes in.

The MRO says negative and the guy is off flying an airplane. And then 3 days later a revolting development happens, you get another specimen with the same name on it, this time it's positive. So the way in which DOT's regulated companies deal with that is on the chain of custody for the first specimen they note that this is the first of two specimens that are going to be coming.

So you use that notation piece on the chain of custody. But this procedure is a little bit different. This is a different type of thing because now we're going to be capturing possibly two, three, four specimens and we're going to be doing some type of analysis on those specimens and we're going to have another set of complexities.

What happens if specimen 2 is positive for nitrite and specimen 3 is positive for cocaine and none of them have B bottles? So I think what probably would be worthwhile in looking at this is to look at it holistically in terms of again looking what the HHS is doing in this area and sort of giving sort of a protocol on how to deal with this and also to address, I think, what was also getting bungled up a little bit earlier is a distinction between the chain of custody issues and the integrity of the evidence in terms of what standard practices are for how on-site tests are done. Those are sort of separate issues.

They go essentially to the admissability and integrity of it, but they're two separate types of issues. But it is going to require a lot more infrastructure in how you manage your specimens and how you manage those -- with the laboratory. As you well know, when these laboratories start getting these specimens that are linked together, they will also have to develop the software to track it in-house and also have an understanding of how to report that to you.

MODERATOR WEST: Certainly that's relevant to the fact that we do indeed have a set of questions that we need to do some follow-up on that are relevant to talking to HHS and perhaps we can get some useful insights here.

Please?

MS. LANOUETTE: And to complicate it further, if you are doing on-site testing, you are supposed to first fulfill the A and then the B and

then the C which is the on-site testing, that sheet could be a very different sample. So you may be on-site testing a diluted sample than what you just sent down. You'd have to wait for everything to come back anyway.

If you sent a sample, the first sample down, that was say 15 mls.

MODERATOR WEST: Okay.

MS. LANOUETTE: And then you wanted to -- you couldn't on-site test at all, you would lose that. Because even if you did receive a quantity enough to fulfill the other split and on-site, couldn't do anything with that result until that first sample is still out there.

So you might lose a lot of your ability to get your quick results with the on-site test.

MODERATOR WEST: Thank you for that comment. Yes?

MR. BUCHER: I'm Richard Bucher from Bensinger, DuPont. I have a question, really a clarification. For the initial collection for any test, what is the minimum quantity that the rule requires be collected, period? If I collect only 25 milliliters on the first collection, what happens to that specimen?

MODERATOR WEST: I think the answer to the minimum question is 30.

MR. BUCHER: And by implication this gets thrown?

MODERATOR WEST: No, not at all. I think I addressed that on a previous slide. First of all, unlike the current rule, we would not say in the new rule that anything could be destroyed. That's one point.

In the new rule, the minimum would be 30 and if you get 25, then you're still seeking that minimum of 30 through yet another collection. So the definition of specimen is whatever aggregate urine I'm able to provide. Is that correct? I don't understand it, so I'm just trying to understand --

MODERATOR WEST: Whatever single collection --

MR. BUCHER: Will you please go to 2.4(g)(11) --

MODERATOR WEST: Okay.

MR. BUCHER: If I read this right it says the predetermined quantity for any particular specimen -- now you just said that's a single void.

MR. MIZUNO: That's right.

MR. BUCHER: Must include at least 30 milliliters. What if I don't get 30 milliliters. I haven't made the requirement.

MR. MIZUNO: That's right. You haven't made the requirement.

MR. BUCHER: So now what do I do?

MR. MIZUNO: You go down, continue down and it says it's considered then to be a partial specimen, less than 30 milliliters. It must be retained. It must be kept in a separate container. You have to --

MODERATOR WEST: And with any subsequent collected specimen.

MR. MIZUNO: That's right. That partial specimen has to be inspected, sealed, labeled and so forth --

MODERATOR WEST: And sent on to the lab.

MR. MIZUNO: Sent to the lab.

MS. LANOUETTE: I think what he's asking is let's go back to the 15 mls. that I've collected.

MODERATOR WEST: Okay.

MR. MIZUNO: Okay.

MS. LANOUETTE: Do I now have to wait and collect another 15 mls. to equal 30 or do I have to collect 30 mls.?

MR. MIZUNO: You have to collect an additional 30. Forget about that 15. That 15 is a partial specimen. You have to collect 30.

MS. LANOUETTE: So no matter what, I have to have 30 mls. in one container?

MR. MIZUNO: That's correct. For one void.

MS. LANOUETTE: No matter if it looks like water or not? You're going to dilute it.

MR. MIZUNO: You have a question about dilution, I guess, is further down in 11 where it says individual may be given a reasonable amount of liquid, but normally 8 ounces every 30 minutes, but not to succeed a maximum of 24 ounces. That's to address the question about that, about dilution.

Yeah, it ultimately still comes down, you need to collect 30 milliliters in order to have a full specimen.

MODERATOR WEST: We have another comment, please?

MR. PRIEBE: Just further clarification, please. Mike Priebe, Palo Verde.

I do not have as much experience on this as most people here, but I'm told we have people that

just have a great deal of trouble providing that amount. I did hear somebody up at the table say earlier well, if you have documented medical reason or whatever, that might help with a problem like this, but if we have somebody who is in for the first time and we don't have any documented medical condition on this person and they give 15 and they wait and wait and two hours later they still have not given a single specimen of 30, and two hours later they still have not, at what point do we say what? Do we keep them overnight, do we keep them for the week? Do we keep them -- do we just tell them go away, you don't have a badge anymore?

(Laughter.)

Honestly, I'm not trying to be facetious. I really don't know.

MR. MIZUNO: That's a good question and under the final rule it says that to anticipate that situation, the last sentence of 11 says if the individual fails for any reason to provide a quantity of urine sufficient to fulfill all analysis and re-analysis requirements, the collection site person shall contact appropriate authority and I guess a minimum first up the chain and then presumably that person will contact the NRC to obtain guidance on the action to be taken.

I didn't say you were required to contact the NRC, but I'm saying that person contacts the next person up the chain and determines what it is.

MR. PRIEBE: At my site they're going to contact me and I have no clue what to tell them, so I'm really looking for some advice. So when they contact me I'll say --

MR. MIZUNO: Do you have any suggestions?

MR. PRIEBE: Do I? No.

MR. MIZUNO: Contact MRO. Do you have any suggestions as to what our guidance would say as to what would be an appropriate course of action in that situation? I mean that's -- we're looking for that.

MODERATOR WEST: Please.

MS. TAYLOR: Garmon, for this particular thing, when you all are doing your NUREG in question and answers, can you clarify how -- she brought up, like for example, if this is a random test and I end up sending like four or five specimens off and I'm going to get four or five results, can you clarify in there how we report this during our reporting period? Because like right now, I have a system that I count randoms, but I'm going to receive five different

results for one test. Do I count that as one test? Or like if four come back negative and one comes back positive, do I count that as five different -- do you see what I'm saying?

MODERATOR WEST: I understand exactly.

MS. TAYLOR: Could you clarify that for us, please?

MODERATOR WEST: I would also suggest for -- obviously, we're not giving you specific guidance in the rule on the question of what do you do. While I appreciate Geary's point, we say that you should contact your management, but it doesn't tell you precisely where you end up. I would suggest also that this one, in addition to us just thinking about it a little bit more for any additional thoughts we might have, might be yet another one that might be HHS has some guidance on.

I think that takes us to 2.5. We probably have about enough remaining to get through perhaps within the next hour. Would you like to have a short break now?

Let's reconvene in about 10 minutes, say a quarter after.

(Off the record.)

MODERATOR WEST: The next section is 2.5 and in this particular section we didn't have any particular questions. I guess the way that I would propose dealing with this, I'll just have you refer to the redline and strikeout version and see if there's any particular aspect of it, that you'd have any specific comments or questions about.

Most of the beginning portion of it, up through Section 7 and even to some extent 7(b) is largely editorial type changes. And then under (b), under 7(b) test validation, we've added certifying scientists as defined in Section 1.2 of the HHS Guidelines and some additional language there in that section and then some additional changes under (d), (e) and (f), the files, for example, the laboratory personnel files shall include, and there's some specifics on that. Back to (e), there's some additional language there on training, a laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

I'll go on to Section 2.6. And under this one, again, if you take a look at the redline and strikeout, we have some added language with respect to day to day management of operations. Any licensing

testing facility shall have an individual to be responsible for day to day operations and to supervise the testing of technicians. And the further addition, these individuals shall have at least a bachelor's degree in the chemical or biological science, medical technology or equivalent. He or she shall have training and experience in the theory of practice of the procedures used in the licensing, testing facility. Little more specifics there.

And then under 2.7, largely changes with regard -- conforming type changes with regard to the terminology for the chain of custody. That particular form.

And then under 2.7(a) -- actually, it's (b)(2)(c) under the short-term refrigerated shortage, specimens that do not receive screening testing and for appropriate or confirmatory test, there was some additional language there.

And then moving forward to subsection (e), there's certainly quite a bit that's been added with respect to greater emphasis on specimen validity. And you can see all the details of that.

Then in Section 2.8 --

MS. DURBIN: We had a pre-submitted question on 2.7.

MODERATOR WEST: I'll address the question. Section 2.7. What qualifications would a staff person need to review and sign negative test results?

I think we've had some discussion of this in the past. The MRO must review and sign negative test results as noted earlier. A staff can receive test results and prepare them for MRO review as well as scheduling interviews. The MRO should determine the need for an interview.

And then further under 2.7, the rule on split specimens states in part, the chain of custody and testing procedures to which the split specimen is subject must be the same as those used to test the primary specimen. However, HHS guidelines for retesting of split specimens prohibit rescreening by immunoassay, except for dilution information. Therefore, is it acceptable for split specimens to be tested by GC/MS only for purposes of substantiating the original result?

And the answer there is no. And we further note that screening by immunoassay is necessary for dilution information, but a negative screening in this case does not negate the GC/MS. I

think this is one of the ones that I had alluded to earlier where we have a set that we intend to have some follow-up discussions with HHS.

MR. HARRIS: Neil Harris, TXU Electric. Right here we talk about using GC/MS for testing. However, back a few pages on page 28, we struck basically the use, actual use of the word or term GC/MS. That's under -- let's see, future revisions where it begins "in order to adapt a rule for changes involving disciplines relating to substance abuse" we strike out the words "at this time gas chromatography and mass spec is the only authorized confirmatory method." We have stricken those words. I'm wondering why they're reappearing.

MS. DURBIN: They reappear somewhere else, I believe. I can't find it for you this minute.

MR. HARRIS: I'm just wondering why we're seeing a dichotomy here within the document.

MODERATOR WEST: That's just a function of how this redline and strikeout --

MR. HARRIS: Okay.

MS. DURBIN: But we'll look for it when we get your question on the transcript.

MR. HARRIS: Another item here is when we talk about shipping. We say that we will cool to 6 degrees Centigrade or 43 degrees Fahrenheit.

MODERATOR WEST: What's your reference point for that?

MR. HARRIS: It's back a few pages, I can't -- then we get to where we're talking about "then the sample must not be raised to a temperature any greater than 6 degrees" or I think it's 42.7 degrees. In other words, you have a disparity between your degrees in Fahrenheit in this and at the same time you give no leeway on a divergence of the temperature. You must cool down to 6 degrees and you must not raise above 6 degrees. So where do you get any type of capability of having a plus or minus on this?

I know it sounds like of trite. However, as being a supervisor of a laboratory for several years and writing multiple procedures for our own company, I know that a lot of times you have to have a range that you can work within and by cooling down to one temperature and saying that's absolute and then saying you cannot get above that, if I go in and audit your system and I find out that your temperature control is not absolute, then there's a potential for a hit on that. That's just a comment.

MODERATOR WEST: Okay, thank you for your comment.

Now the next question under 2.7, the laboratory shall retain the original custody and control form and must send only to the MRO certified true copies of the original custody and control form and the test report. Does this mean that HHS laboratories must send the certified true copies of the custody and control form to the licensee on negative drug tests?

And the answer here is yes, with this explanation. The rule hasn't changed with regard to the requirement to send custody and control forms on negative test results, only that the laboratory shall retain the original.

An additional question. HHS laboratories use two types of negative screening, control specimens, a drug-free control and a -25 percent of the cut-off negative control. Appendix A 2.7(e)(4) states in part, "the responses of questionable donor specimens must be compared to the acceptable range of negative screening control responses. Those specimens that have responses that are greater than the negative control responses must be subject to confirmation testing by GC/MS at the laboratory's limit of detection, LOD."

The question is, which negative screening control is expected to be utilized in this case?

And the answer that we provide, the drug-free control should be used in order to identify any detectable drugs in these questionable specimens. However, we will also discuss this particular item with HHS, just to ensure that it's a reasonable approach.

Another question under this section, confirmatory tests for amphetamines should be reported as amphetamine and methamphetamine. However, Appendix A 2.7(g)(5) states specimens that have a positive GC/MS result for amphetamines must be tested for d and l isomers. The question is would it not be more appropriate to state that specimens that have a positive test for methamphetamine must be tested for d and l isomers?

Our comment here is that, in response, is that believe the wording is actually correct. However, again, we'll also take this one up with HHS just as a confirmation.

And the next question has two parts to it. Why is there an extra day allowed for l and d isomer

testing, but not for 6 a.m. testing? The licensee is the -- second item -- the licensee is supposed to promptly notify the NRC in the case of a false positive test result. What is the definition of promptly in this case?

On the first one, we didn't necessarily believe it was an implementation question, but we crafted a response, nevertheless. There's been no change in the requirements for the laboratory to submit testing results for 6 a.m. The NRC followed the HHS technical advisory of March 11, 1991 in developing the requirements for l and d isomer testing.

And then with regard to the second item, this is an obviously existing requirement and no problems have been caused by the very few false positive results to date. Contacting the NRC FFD program manager within a day or two of the result has been acceptable. Follow-up with contact on information provided has been useful as has the written report made within 30 days in accordance with Appendix A, 2.8(f).

That was the last question we received in that section. Before going to the next section 2.8 are there any comments or questions on 2.7?

And here at 2.8 deals with quality control, quality assurance and quality control. And I'd ask you to turn to your redline and strikeout version.

MS. TECHAV: In reference to 2.7(d), the very last sentence says "the MRO shall report any adulteration or dilution evidence excluding hydration resulting from an acceptable reason to management immediately." Does that mean that they don't have to talk to the donor prior to this and are they declaring the test something?

MODERATOR WEST: I'm sorry, this is under 2.7?

MS. TECHAV: 2.7(d). The last sentence. I guess my question is does this mean the MRO does not speak to the donor and would this be considered an immediate violation?

MS. DURBIN: I would say that's a very useful question. My kind of thought on it which is not binding in any way on anyone is that the intent here is if it's not a questionable specimen, if it's totally, if it's adulterated or so dilute that it couldn't possibly be a normal urine specimen and we have ranges specified for that in the specimen

validity, then there would be an immediate report. If it's a questionable specimen, then it goes through the testing procedure that's specified for specimens that are questionable and then if the MRO determines that there is no detectable evidence, then it wouldn't be reported if they do determine that it was a violation.

Loren Bush seems to have additional comment on this.

MS. TECHAV: You snuck up on me.

MR. BUSH: This particular change was designed to provide management some flexibility to take action if they so desire to in the interest of public safety. In other words, you have this mess in your hand and you haven't gone through the legal process of assuring yourself that it is, in fact, what you are quite sure that it is, but NRC management was concerned that you have, in hand, evidence that somebody may be impaired, may be a threat to public health and safety and all that sort of thing. Management should be afforded the opportunity to shine and take whatever action they need to protect public health and safety, so that's what this is all about.

MODERATOR WEST: Thank you, Loren.

MR. MIZUNO: Did he address the part about --

MS. TECHAV: What are we going to do?

MR. MIZUNO: No notice to the individual?

MODERATOR WEST: Did you have any thoughts on that, Loren?

MR. MIZUNO: And while Loren is going there, I would just point out that my view is that 26.28 is a relevant requirement for notice to the individual and that my initial cut is that 2.7(d) does not address specifically the issue of whether notice to the individual is necessary at that point. I think what definitely controls is 26.28.

MR. BUSH: Thank you, Geary.

MODERATOR WEST: Thank you, Geary.

MR. SHULTS: Ted Shults, again. Back when this rule was conceptualized, there was no recognition of a need to have MRO oversight over specimen, what's called now specimen validity, adulterated or substituted specimens. And for those of you who have any dealings with DOT know that under their provided rule change at the end of this year, they've now asked for Medical Review Officers to oversee this process. At the same time, I think Loren's point is well taken, that under this program I can certainly see it acceptable to have a person removed from duty.

Now the reason I mention this is that this issue is still in play and that you need to be aware that there's been a great deal of controversy over the substituted specimen standard under DHHS and it's interesting to point out that one of the complaints that the unions have made concerning the way in which specimens were handled under the DOT program was that there was insufficient due process, that there was no oversight over -- and the idea that since management's sanctions were often more severe for adulterated specimens or substituted specimens, that that just didn't pass muster and in fact, so DOT responded by requiring the MRO to review that.

Now I should say that even given that consideration, there has now been a challenge, a legal challenge in the Ninth Circuit by the Delta union challenging DOT's regulations, again, being a violation of due process, not to have MRO over -- that even with MRO oversight, that somehow or another these rules are defective. So just be aware that that's currently out there.

From my perspective, your program is functionally different in the sense that DOT does not provide for an appeal process where you do and I think that it may be very appropriate that you may have that sort of oversight and due process through the appeals process and the MRO could be involved in terms of not being the decision maker in that, but also developing up the data that whoever is making that decision would be able to look at.

But anyway, I just wanted to share that sort of background with you.

MODERATOR WEST: Thank you. I appreciate that. Now under Section 2.8, quality assurance and quality control, some editorial type changes in the beginning portion of it. There is some addition there in Section b with respect to the results reported by the certified laboratory must be evaluated and appropriate corrective actions taken.

And several shalls to musts for sure.

And some additional changes under (d), actually it's (e), subitem (ii), specifying during the initial 90-day period of any contract with an HHS certified laboratory, not included in rewritten or renewed contracts. And the minimum, well, first of all the 50 percent has gone to 20 percent with respect to the total number of specimens submitted, up to a maximum now from 50 samples to 100 samples or 30 blind performance test specimens whichever is greater,

following the additional 90-day period, a minimum of 3 percent of specimens and from a maximum of 250 to 25 or 10 blind performance test specimens, whichever is greater must be submitted per quarter.

And further, licensees should make an attempt to submit blind performance test specimens during the initial 90-day period and per quarter, thereafter, at a frequency that corresponds with the submission of frequencies for other specimens so that they're not all stacked towards the end. And then further, under item 3, it's gone from 80 to 50 percent of the blind performance test specimens must be blank. And then in addition, 10 percent of the positive blind specimens must be appropriated adulterated or diluted and spiked between 60 percent and 80 percent of the screening cutoff values established in 2.7(f).

Then there's some additional language under (f)(i).

MS. DURBIN: I just have a question. Is anyone having difficulty getting -- has anyone tried to get adulterated specimens that were spiked at these levels and if so, is anyone having difficulty getting those blind performance test specimens?

MS. TAYLOR: I just found out yesterday because I've been trying to get those for a year and a half and I talked to Nancy yesterday and asked her who said in the rule that it was easy to get these and I found that in the comment section it said the toxicologist said there should be no reason why people cannot provide these. It wasn't -- so you know, anyway, I found out yesterday, I don't know who you all used.

We use you all solely, but our person has indicated they will provide these blinds at such time this regulation is out for implementation. But up until now I have not been able to get anybody to provide them for me because we started testing for nitrites like a year and a half ago and we've been trying to get blinds ever since to do it and we haven't been able to up until now.

MS. DURBIN: Thank you. I knew that question was pending and I wanted to make sure it was in the record, but now we have an answer. Thank you.

MODERATOR WEST: Thank you for the update. Then under (f)(l), the added language there with respect to testing errors or unsatisfactory performance discovered in blind performance testing. And then it ends with some additional editorial-type changes.

Under 2.9, reporting and review of results, there's some additional language in subsection (b) regarding the MRO shall not be an employee or agent or have any financial interest in a laboratory or contracted operator of an on-site testing facility whose drug test results the MRO is reviewing for the licensee. Similar to other agencies, some additional language with respect to conflict of interest.

And then towards the middle of that section, the MRO is also responsible for identifying issues associated with the collection and testing of specimens and advising and assisting management in the planning and oversight of the overall FFD program.

Subitem (c) is an addition with regard to the medical officer verification of FFD policy violations.

And then just the highlights, if you will, some additional language on presumptive positive screening test results is not to be reported as except as provided in 26.24(d).

I can probably skip over to subsection (f). And there's additional language there under -- concerning the MRO shall further evaluate the result and medical explanation to determine if there's a potential risk to public health and safety of the individual being impaired on duty from the substance or from the medical condition. If the MRO determines that such a risk exists, he or she shall conduct a medical determination of fitness and then it goes in through a list under (g) of the various forms of medical determination of fitness.

I won't go through all of those, but just to bring them to your attention.

Then under Section 3.1, I just have a couple more to conclude with, largely deleting portions of that current requirement and then lastly the use of HHS-certified laboratories. And that's been modified to some degree, only with respect to addresses and that sort of thing.

And then at the end of that section there's been an addition there, under subsection (b) as well as (c) has been added. Because the HHS national laboratories certification process does not cover practices outside the HHS guidelines such as using more stringent cutoff levels than set forth in the HHS guidelines or testing for additional substances, licensees and their contractors that choose to use practices outside the HHS guidelines

must take measures that are consistent with this part to assure that the reported test results are valid and defensible. And then lastly, all contracts related to this part between licensees and their contractors and laboratories must require implementation for all obligations of this appendix applicable to HHS certified laboratories.

Well, that ends the two very intense days we've had and I sincerely -- I'm sorry, go ahead, and I know Mr. Enkeboll would like to make some final comments and I have some final comments myself, but please, go right ahead.

MS. KOPP: I'd like to address 2.7(j), the retesting of specimens. I have a question relative to an adulterated sample and split specimen.

It says because some metabolites deteriorate or are lost during freezing and storage, etcetera, etcetera, quantification for a retest is not subject to a specific cutoff requirement, but must provide data sufficient to confirm the presence of a drug or metabolite.

Then we go on to say for the retesting of specimens that have been determined to have been adulterated or diluted the retest need only substantiate the information that the MRO used to make the initial determination.

Do we as a utility -- in the past, we have not offered a split specimen to the employee with an adulterated sample, only because we have found that the split has come back as a negative and did not prove an adulterant from the beginning. So it's kind of a touchy area and can we as a utility sanction the fact that if it comes back initially on the aliquot and the initial testing that it proved to be an adulterant, do we have to offer a split sample as part of the appeal?

MODERATOR WEST: I think the general answer and correct me if I'm wrong, Geary, the general answer to that is that the split specimen is at the discretion of the licensee.

Do you disagree?

MR. MIZUNO: No, we don't require --

MODERATOR WEST: That's my point.

MR. MIZUNO: Okay, I thought you were saying once you collected, whether it's actually going to be tested or not is at the option of the --

MS. KOPP: You see, at the utility we do offer, we do take a split and we do offer that split.

MR. MIZUNO: Right, but I believe whether the split gets tested, I believe is the option of the individual. I do not believe that -- I have to go back and look at it again, but I don't think the licensee can on his own volition --

MODERATOR WEST: Loren, are you going to help us out?

MR. BUSH: First of all, the collection or splitting a split sample away from the primary specimen is the discretion of the licensee. It's not required to split specimens.

If you do split specimens, then the individual has the option when he gets the test results back of using that specimen to challenge the results.

MR. MIZUNO: Correct.

MR. BUSH: The MRO is the principal person who decides whether or not the test results are questionable. It could be because of the data from the lab. It could be from his interview. He can decide whether or not he wants to retest the sample. That's what we're talking about here, the retesting of the specimen -- the MRO can make a decision that there's no need to retest.

MS. KOPP: Thank you.

MODERATOR WEST: Thank you for that clarification, Loren. Would you like to go next?

MR. HARRIS: Yes, please. Neil Harris, TXU Electric.

Two questions, in one of the sections here we talk about day to day management of operation of the testing facility. It says the individuals who are in control of these facilities shall have a bachelor's degree in chemical or biological sciences, etcetera, or the equivalent. Now what are we using to measure the "or equivalent" statement in here?

MODERATOR WEST: We haven't specified that in any other document that I have been able to identify, certainly not in 13.85. The question has come up and I think that would be certainly a good one for us to give some additional clarification on in the NUREG document.

MR. HARRIS: Thank you. The other question is on page 50 concerning records, is there retention at the laboratories. It says that the licensee's testing laboratory or facility shall maintain records for a minimum of two years. We require records of audits or records of positives to be kept from anywhere between 3 and 5 years, yet we

only require the laboratories to require their records to be maintained for 2 years. We feel this is adequate document control. That's just a statement. Thank you.

MODERATOR WEST: Thank you for the comment. Please.

MS. TECHAV: Okay, 2.9(c)(1), added that the MRO shall give the individual an opportunity to discuss the test results or other occurrence, any type of program violation with him or her. So if somebody refuses the test, they have to be afforded the opportunity to talk to the MRO. And then also, somebody who violates like the 5-hour rule, they also have to be afforded the opportunity to talk to the MRO? Section 2.9(c)(1).

MODERATOR WEST: It's page 57. I'll just read the portion again.

Before making a final decision to verify a laboratory confirmed positive test result, and additional language, of the occurrence that would constitute an FFD policy violation with the associated example, attempted subversion, the MRO shall give the individual an opportunity discuss the test result or other occurrence with him or her. And I believe you gave some --

MS. TECHAV: So somebody who refuses to test and somebody that violates like the 5-hour rule should be afforded the opportunity to talk to the MRO or must be?

MODERATOR WEST: I believe the answer to that in terms of someone that's refusing to test would be yes, given that -- under the new rule, it's my recollection that that's a violation of the licensee's Fitness-for-duty policy.

MS. TECHAV: Yes, it is.

MODERATOR WEST: So I think the answer on that one would be yes.

MR. MIZUNO: I concur.

MS. TECHAV: Okay, then 2.9(c)(ii).

MODERATOR WEST: Okay, your question?

MS. TECHAV: And for the 5-hour rule, did you say yes to both?

MODERATOR WEST: No, I didn't say yes to the 5-hour rule. Could you tell us a little bit about that?

MS. TECHAV: Somebody who admits to drinking 5 hours prior to their assigned work time. You have a for cause test and they're positive, any type of violation like that?

MODERATOR WEST: I think the answer to that one would also be yes. Would you agree, Geary? Given that they're supposed to abstain 5 hours prior to working on a shift.

We'll give you an initial yes on that one as well.

MR. FITZSIMMONS: I'd like some clarification on an individual who refuses to test. The individual gets up and walks out, leaves the facility. How do we get him to the MRO if he's not even going to test? If the individual leaves, he doesn't have the opportunity -- he's not going to talk to the MRO. Does that mean we do not constitute that as a failure to test or a Fitness-for-duty violation?

MODERATOR WEST: I think you would -- if I hear your question correctly, I think you would clearly count that as a violation of the licensee's Fitness-for-duty policy.

MR. FITZSIMMONS: Okay, but you just previously said that an individual who refuses a test must go and talk to the MRO. Isn't that what I heard.

MR. SMITH: Afforded the opportunity.

MODERATOR WEST: No, afforded the opportunity.

MR. FITZSIMMONS: Okay, so if he refuses that, okay. All right, thank you.

MODERATOR WEST: I think also the aspect of affording the opportunity is covered in a question in NUREG 1385 as well.

While I'm thinking of this, I think it would perhaps be appropriate to consider a revision 1 perhaps to NUREG 1385. It's clear that there's certain information there that continues to be relevant to the new rule and my further thinking on this, not that I've given a whole lot of thought to it, but it would essentially deal with an issue of not having two different documents that you'd have to go to. You'd essentially have the Rev. 1 that would supersede the other one, cleanly, but yet at the same time roll over any relevant information.

Yes?

MS. TECHAV: Okay, 2.9(c)(2)(ii). Page 58.

MODERATOR WEST: Yes.

MS. TECHAV: It talks about prior to making a final decision. The MRO, after making all reasonable efforts has been unable to contact the

individual within 14 days under which the MRO receives notice of the lab, confirmed positive test results.

Does this mean that the full 14 days need to pass before declaring a violation?

MODERATOR WEST: I think here again if I recall accurately, I think aspects of this may be covered in NUREG 13.85.

Does anyone at the table have any --

MR. MIZUNO: Okay, I just want to understand this; (c)(2) says MRO may verify a laboratory confirmed positive test result or otherwise make a determination of an FFD policy violation without having discussed the test result in these three circumstances. So yes, if you want to take advantage of (c)(2)(ii) and that provision only, you do have to wait under (c)(2)(ii) for 14 days to pass and make reasonable attempts to contact. But if you choose to go down some other route in order to -- for the MRO to declare a Fitness-for-duty violation, you don't have to wait 14 days.

MS. TECHAV: So the licensee can set different expectations, proceduralize-type?

MODERATOR WEST: Different than what?

MR. MIZUNO: So long as you --

MS. TECHAV: That's what he just said that we can --

MR. MIZUNO: So long as you -- if you choose to do some other way of attempting to contact the person and provide them the opportunity under either (1) or (3). I mean for example, if you have a situation, okay, of confirmed positive test result and then you contact the individual and they expressly decline the opportunity to discuss it, you can make your -- once you hang up that phone, you can make that determination that there is an FFD policy violation at that moment, because you're doing it under (c)(2)(i).

If you haven't been able to contact them, however, and you don't have (3), okay, I assume (3) doesn't apply, yes, then you do have to wait for 14 days to pass before you can declare the FFD policy violation.

MS. DURBIN: Okay, I think I can say something about what we expected here. If the individual is working on your site, the MRO should be able to contact them very rapidly and so this two week was someone who's left the site, isn't working for you, you can't get a hold of them, they don't get back to you in two weeks. You haven't been able to get a

hold of them. You can declare a confirmed and report it to other licensees as a confirmed.

MR. MIZUNO: Right, (3) is the one that talks about the -- Roman 3 is the one where the guy is on site. If he's on site and you've documented contact and we can argue about whether the contact is actually you have to talk to him as opposed to leaving him a notice in his locker, for example, and instructed him, if that notice says contact the MRO within 5 days and 5 days go by, you haven't heard from that person, okay.

MS. DURBIN: As I said, we're assuming that MRO, if they're working at the plant, that the MRO can contact them in a much shorter period, so it's -- these were for circumstances of difference absence categories and the 2 weeks was, as I said, specifically for somebody who has left the site. You can't get a hold of them and it was so that you're not stuck with an unconfirmed positive test result because -- or laboratory confirmed positive test result and you don't know what to say when they -- you can confirm it, it's a violation and they do have the right to appeal it and reopen.

MR. SHULTS: Can I make a comment about that before your next question? Because these again are rules that are derived from DOT's practices with the 5-day and the 14-day rule. They have changed that and reduced it in their new rule to being 5 days and 72 hours. But even with that, to some transportation concerns, it's been problematic.

For example, the concept of having somebody who is in your -- performing safety sensitive functions who knows they're positive and has been told to contact the MRO, it's just a sense of great uneasiness that an airline would have, for example, somebody out there who had 5 days to contact the MRO.

So the point I'd like to make is that what a lot of employers have done is they haven't vitiated their own management responsibilities. In other words, many employers will say to that individual who is in the DOT program call the MRO in two hours or else. And they can do that. Now it's not conforming with this regulation, but you don't -- don't forget you have your own sort of management prerogative in this area. And many -- that's exactly how a lot of DOT companies deal with that. They'll basically give them notice that they have to contact -- and if they don't do it, it's basically in subordination and they're removed from duty based upon insubordination.

MS. TECHAV: We cannot take any action on a presump. positive. We'll get a violation for doing just that.

MS. DURBIN: It's a laboratory confirmed positive test result, not a presump.

MS. TECHAV: But without them talking to the donor, we cannot take any action.

MR. MIZUNO: But he's not taking action on the basis of the laboratory test I think is his point.

MR. SHULTS: Right, exactly.

MR. MIZUNO: He's taking the basis on the subordination which is a non-FFD issue.

MR. SHULTS: Right, exactly. It's basically a directive that you're giving to contact the MRO. That's -- and if they fail to do that, it's the failure to follow that directive that's the violation that you are removing him for. Again, I understand how this has all gotten convoluted, but think it through.

MS. TECHAV: Well, and then 29(c)(2)(iii) kind of goes hand in hand with the previous one because there was an addition added that a licensee representative has successfully made documented contact with the individual and instructed him or her to contact the MRO and more than five days have passed since the date of that individual's contact. Since we can't take any action on uncovered positive, this allows the individual to continue to working in the plant for 5 days.

If we've got documented that they were told to contact the MRO, now we're going to have to sit there and say okay, did he call? Did he call? Did he call? Did he call? And administratively, make sure that that is happening and for five days he could be working in our plant with unsafe conditions.

MS. DURBIN: That wasn't the intent of this change, so we can look at that.

MODERATOR WEST: I was thinking if you -- I acknowledge what you were saying. It certainly wasn't the intent, but if you had some --

MS. TECHAV: I just want it documented so we can look at that.

MR. MIZUNO: I wouldn't say that. See, I have to go back and look at it. I think you have some independent authority to remove a person immediately on the basis of current information that shows they're unfit for duty, okay?

The problem is that a confirmed positive that occurred testing five, whatever days ago, no

longer provides you a basis for saying that they are at that point in time unfit for duty, but that authority to immediately remove somebody on a current basis for believing that they are unfit for duty exists, okay? So you always have the authority and indeed the responsibility to assure yourself that every person who comes on site, every time he comes on site and enters that protected area, that he is fit for duty. And if you have any -- if you have reasonable belief that he is not, you may immediately prevent that person from entering --

MODERATOR WEST: Through other parts of the regulation.

MR. MIZUNO: Yes, yes. The only thing we're dealing with here is when you have the positive HHS lab test.

MODERATOR WEST: Thank you.

MS. TECHAV: Okay, and 2.9(c)(3). It was added that the MRO can reopen a case that the individual can present to the MRO information documenting reasons why they did not contact him or her? I mean there's no time frame specified here, so a year later somebody comes back and gives them the information? We may have a reversal possibly and so how do we report that and document that? Well, we can document that, but how to report that?

MODERATOR WEST: The time frame for the MRO having that discretion?

MS. TECHAV: Well, in 2.9(c)(3) it says that the MRO can reopen the case if the person can give them information documenting reasons why they didn't contact the MRO.

So they didn't contact the MRO initially. The MRO declared it a positive test and now the guy is coming back and saying well, hey, I was in the hospital, I was unconscious, I was in a coma, I was whatever a year later and we had already had a positive test and now it's going to come back and be possibly a negative test?

MODERATOR WEST: The individual wouldn't still be in the employ of the MRO, excuse me, the licensee?

MS. TECHAV: Who knows? It doesn't matter. I just wanted some guidance on how to deal with that reporting.

MODERATOR WEST: We can take that one as an action item as well. Thank you for the question. We'll take a question or comment over there.

MR. BUCHER: This is just an issue of intent, 29(c)(1), the MRO has established that indeed there was an occurrence of violation and then the MRO to immediately notify the EAP and licensee management official. What is the intent of notifying the EAP consequent to the establishment of a violation?

MODERATOR WEST: Well, I guess -- is there something about this in terms of the new rule? I mean that's essentially what's in the current rule.

MR. BUCHER: I'm asking what is the intent of contacting the EAP at that point? If you've established the violation through the MRO, the MRO would more than likely notify management to take appropriate action. What's the intent of notifying EAP? And I realize that there's not a change, but I'm asking the intent question.

MODERATOR WEST: Does anyone at the table have any insight on that?

Is it possibly that the individual -- would you assume here that the individual is involved in some EAP program?

MR. BUCHER: That assumption is not merited.

MR. MIZUNO: Is the question why is there a requirement under (c)(1) to notify the EAP immediately or to notify the EAP at all?

Before Loren goes, let me just say --

MR. BUCHER: The point is you've got an FFD violation that's been established by the MRO.

MODERATOR WEST: I hear what you're saying.

MR. BUCHER: What is the EAP going to do that in a sense management would not dictate to the EAP and management, in turn, would take the appropriate action. If it's second violation, why notice via EAP, the person may have been terminated.

MS. DURBIN: I think it says, isn't this after it says "as provided by the licensee's policy?" I think -- so if the policy requires that you talk to the EAP, then you talk to the EAP. I guess.

MR. BUCHER: I don't read it that way. Let me hear from Loren then.

MODERATOR WEST: I think that's a reasonable
--

MR. BUSH: We wanted to make sure that the EAP was earning its money.

(Laughter.)

Actually, I think there's an assumption on our part that as described elsewhere in the rule in many locations that people who've tested positive have been sent part of their chain of actions to include being referred to EAP for counseling and follow-up treatment and all that sort of thing. There's a general assumption that there's not going to be too many second positives, so we don't write the rule to address those infrequent incidents. We wrote it address the more frequently occurring thing. It shouldn't be a problem, I wouldn't think. I would think the EAP would want to know there's one less person that they will have coming in for counseling.

(Laughter.)

MODERATOR WEST: Thank you, Loren. Yes?

MR. BOISMENU: Brett Boismenu, Nine Mile Point Nuclear.

Maybe there's a disconnect here and this has to do with the reporting of the results from the MRO. If you look at the strikeout page on page 14 it says "should the MRO review not be completed within 14 days of the collection of the specimen" and then when you go over to page 58 it says "14 days from the date of which the MRO received results."

Are they talking about the same thing?

MODERATOR WEST: And you're referring in 14 on page 14, under (f), should the MRO's review not be completed within 14 days of the collection of a specimen, licensee management must be advised of available test results, the status of the review, the reasons for the delay, so that one is saying --

MR. BOISMENU: They need to know within 14 days from collection.

MODERATOR WEST: So what's the -- is your question what's the reference point there?

MR. BOISMENU: Well, there's a disconnect. It's almost like they need to know within 14 days from collection here. As you go, on page 58, it says the MRO can take an additional two weeks from when he receives the results. Am I not reading it right, or is there a disconnect?

MS. DURBIN: Actually, I think this is useful to the earlier question. On page 14, regardless of whether it's been a confirmed positive test result, it says that you can notify licensee management after 14 days of the status which might be, we have a laboratory confirmed positive test result, but we haven't been able to contact the individual. So that's the 14 days from the date of the test.

The other one is 14 days after you've tried to contact the individual, if they haven't gotten back to you, then you've declared a confirmed positive test and it's done.

The first one is you notify management of the status at 14 days and the status may be that it's not yet confirmed because you have not yet contacted the individual. So what this is saying is that after 14 days you have to tell management what's going on, even if you haven't been able to contact the individual.

MR. MIZUNO: To put it another way, on page 14, the 14-day limit there was intended to assure that the MRO just doesn't sit around and management doesn't lose sight of what's going on. It kind of is a ticker that says MRO, I mean basically it's an MRO saying gee, if I have to tell my management that I'm 14 days on this, I better make sure that I've done everything possible to get this thing cleared out or else I have some valid reason for holding on it. But that really is separate than from the 14 days which is on page 58 and as I recall that was just arrived from the HHS guidelines as to a due process concern. It has nothing to do, whereas on F, on page 14, that's more an internal --

MR. BOISMENU: A status report?

MR. MIZUNO: A status report -- really, it was intended to assure that the process, internal process within the licensee proceed in the most expeditious fashion and that the MRO be required to explain why there is any delay beyond 14 days.

MODERATOR WEST: Does that answer your question? Thank you.

I wish to thank you, not only for the many insights, inputs, additional questions that you've given us, but also for your patience over the last couple of days.

I'd just like to take a few minutes to make some closing remarks and then we'll get Mr. Enkeboll a chance to also make some closing remarks. I think it's clear that beyond the questions that you've submitted to us in advance, there's certainly some additional ones that we need to be entertaining and working on as well and I might add that will certainly also allow you even if there are questions downstream of the workshop to provide any additional ones that come up and the way to do that would be I think the preferred way on my end at least would be to do it through the Fitness-for-duty web page and some

of you have asked me how do you get to the Fitness-for-duty web page.

If you are familiar with the external web page for the NRC, if you take that path and I can bring you the exact address tomorrow, what you would do would be to click on the external web page and then, in turn, you'll see the various icons. You select the ones, the one for the reactor icon and then, in turn, you'll have various -- an alphabetical listing, including the Fitness-for-duty web page. That's one route.

On that web page, you'd have the option of either the Fitness-for-duty mailbox which is one of the standard features up at the top or you'd have a comment box that's provided there under the question and answers or comment section. So that would be one possibility. Or you could just send it, even if you weren't on the web page, you could just send it directly to the Fitness-for-duty at nrc.gov. And coming to that particular mailbox certainly helps to sort of sort out my incoming, my other type of incoming e-mails versus the ones that are specific to your questions.

But I think generally speaking what we would propose to do would be to, as I've mentioned, throughout the workshop to ultimately have a NUREG type document that will capture the generic type questions and answers, but we would certainly start off with trying to capture all of them from the transcript. It takes about 7 days for us to get the transcript and we would expect to go through that transcript and identify all of your questions. And then make an additional cut on what the questions are available to you, so you can take a look at those to make sure we captured the questions properly.

And then there would be perhaps several methods that we could perhaps use for both the questions and the answers that we could have you to take a look at before we eventually publish the final NUREG and with the input of my management and certainly the Commission relative to the implementation date of the final rule, the staff recommendation at least would be to try to get the NUREG question and answer type document issued prior to the implementation and understand clearly what implementation means on your end when it actually goes in the Federal Register as has been explained.

Beyond that, I think big picture of what we're considering is collecting hopefully the totality

of what you've told us today, not simply the questions and the answers, focusing on that, but also some of your concerns about the rule itself and here again, one of the benefits of the transcription, it allows us to be able to go back and do that in some systematic way. But that will provide us with a means to brief management.

And by that I mean to make it known up the management chain. We would also propose to brief the Commission with respect to the technical assistance with regard to your concerns about the rule such that hopefully I'm conveying that it's not simply restricted to the questions and answers that you've raised, but some of the broader concerns you have about costs and so on.

So that's the overall plan and certainly there are some details of scheduling and so forth that we need to work out a little bit better. And again, I thank you for your taking the time to spend a couple of days and even an additional day, tomorrow, with us.

I'll let Mr. Enkeboll have an opportunity. After he finishes, I'll make a few brief comments on tomorrow.

Please.

MR. ENKEBOLL: Rich Enkeboll, NEI. On behalf of the Nuclear Energy Institute, we thank you for the opportunity to discuss our concerns with the new Fitness-for-duty rule. We think this should have been done a long time ago.

The industry Fitness-for-duty Task Force meets tomorrow at NEI to evaluate how to challenge the premise that since the Commission has approved the rule that it is a done deal. It will delay access. It will overturn 10 years of a process that has been working. It has been five years working without stakeholder evaluation, interaction. The rule is not risk-informed. It is not performance-based and not in concert with the direction the Agency is going in the other areas like regulatory oversight process. We will work directly with the Commission for those concerns.

That said, the industry will work with the staff as appropriate to provide comments for consideration in the impending NUREG or other clarification document. We would prefer that this be interactive, face-to-face, to avoid misunderstandings.

Any other comments from the industry?

MODERATOR WEST: Thank you for your comments. With respect to tomorrow, certainly a much

shorter day, we will get started here at the same area at 9 o'clock. We're scheduled to go until 10:30, however, we do, in fact, have the room for longer than that, just to emphasize the fact we're not going to get kicked out at 10:30. And the topic is separate from this larger rulemaking effort is a proposed amendment to Part 26 that would essentially amend Part 26 with regard to the scope of random testing and would redefine it simply in terms of random testing relative, instead of the protected area, would redefine it in terms of the vital area.

I just throw that out to give you sort of an overview of it and what we will do is hand out the handouts with respect to -- and this essentially tells you in a nutshell where the rulemaking effort is. We would provide you a copy of the rulemaking plan which is SECY 00-0022 and I think the way to view this is that it's an attempt, similar to this particular workshop over the last two days, but much earlier in the process if you will, to get your comments. We'll have to treat them as public comments relative to the proposed rule.

We're not quite there yet with regard to the proposed rule, but this would be viewed as a preliminary effort to get stakeholders' views on and we'll have to couch it in terms of the rulemaking plan, rather than -- because we can't talk from a predecisional perspective with regard to the proposed rule, but we thought since you were here, principally for the larger role it would certainly be advantageous to provide the opportunity to even give some limited time to consideration of the proposed amendment. So on that note unless anyone else has any from the table or elsewhere has additional closing remarks, I thank you again and look forward to seeing you tomorrow.

(Whereupon, at 4:23 p.m., the workshop was recessed to reconvene tomorrow, Thursday, March 22, 2001 at 9:00 a.m.)

1