

# 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

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1 UNITED STATES OF AMERICA  
 2 NUCLEAR REGULATORY COMMISSION  
 3 + + + + +  
 4 STAKEHOLDER MEETING ON THE IMPLEMENTATION  
 5 OF THE FITNESS FOR DUTY RULE  
 6 (SECY-00-0159)  
 7 + + + + +  
 8 WEDNESDAY,  
 9 MARCH 21, 2001  
 10 + + + + +  
 11 ROCKVILLE, MARYLAND  
 12 + + + + +

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

17 PRESENT:

18 GARMON WEST NRR  
 19 NANCY DURBIN MPD Consulting  
 20 A. BRUCE EARNEST Region III  
 21 EDWARD JOHANNEMANN NMSS  
 22 GEARY MIZUND OGC  
 23 GARY PIRTLE Region III  
 24 GREG SMITH Region I

25  
 26 ALSO PRESENT:

27 BRAD BAXTER  
 28 JERRY BEBB  
 29 SHARON BLUE  
 30 BRETT BOISMENU  
 31 T. SCOTT BRAZIL  
 32 RICHARD BUCHER  
 33 KATHY BURKETT  
 34 MICHAEL BURRELL  
 35 LOREN BUSH  
 36 JEFF CAMPBELL  
 37 PATRICIA CAMPBELL  
 38 RON CASEY  
 39 PEGGY CLARK  
 40 RANDY CLEVELAND  
 41 SHELLY CRAIG  
 42 PATRICIA DAVIS  
 43 PETE DEFLIPPI  
 44 NICK DiPIETRO  
 45 AL DYMOND  
 46 SHERRY ECKERT  
 47 RICH ENKEBOLL  
 48 RICH FITZSIMMONS  
 49 JOHN FLINN

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1 PETER FOWLER  
2  
3 ALSO PRESENT: (continued)  
4 SANDRA FRANCIS  
5 NEIL HARRIS  
6 PAT HARRISON  
7 AMY HANSE  
8 LYNN HAUCK  
9 LORI HAYES  
10 LORNA L. HEALEY  
11 WALTER JOHANSEN  
12 MARGARET JULIANO  
13 ROBERT R. KELM  
14 DARLENE KOPP  
15 SUSAN LANOUETTE  
16 LISA MATULA  
17 EILEEN MOORE  
18 JOHN MORIARTY  
19 RANDY MUMME  
20 JAMES NOEL  
21 PAMELA O'CONNOR  
22 CINDY PARENT  
23 REBECA L. PATSY  
24 MICHAEL PRIEBE  
25 SHARON QUINN  
26 RICHARD RIST  
27 BILLIE ROOKS  
28  
29 ALSO PRESENT: (Continued)  
30 TED SHULTS  
31 ROBERT SOUTHWORTH  
32 REBECCA STANFIELD  
33 MARTHA TAYLOR  
34 SUE TECHAV  
35 JANET THIEL  
36 FREDERICK WHITT  
37 GLENN WILSON  
38 MANCHESTER WOODARD-HALL  
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I-N-D-E-X

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

(9:01 a.m.)

1  
2  
3 MODERATOR WEST: Good morning to everyone.  
4 I'd like to get started, please.

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

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

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

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

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

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

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

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

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

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

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

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

7 Further, a return-to-duty test under  
8 26.24(a)(5) must be conducted before the individual  
9 may be assigned to duties and follow-up testing under  
10 26.24(a)(4) must be conducted to verified continued  
11 abstinence from the abuse of substances.

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

16 And secondly, for reinstatement of  
17 unescorted access after a violation of a policy under  
18 10 CFR part 26, is a management and medical  
19 determination of fitness required?

20 And for the first item the answer is none  
21 with some further explanation. The licensee has the  
22 obligation to assure that individuals with a history  
23 of substance abuse have completed appropriate follow-  
24 up testing prior to gaining access to the protected  
25 area. For individuals being reinstated after having  
26 been suspended under 26.27(b)(3) or removed under  
27 26.27(b)(3), (b)(4) or (c), this follow-up testing  
28 must meet the requirements of 26.24(a)(4).

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

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

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

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

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

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

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

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

21 (Laughter.)

22 I'll try to explain the intent a little  
23 bit later. So the overall answer is no for this  
24 particular question. This is only -- I'll repeat the  
25 question -- well, you can see the question. This is  
26 only for licensee employees with unescorted access who  
27 have been absent from the program for 60 or more days.  
28 If a licensee determines that it will take more than  
29 72 hours to complete a suitable inquiry for the  
30 individual, then the individual should not be granted  
31 unescorted access until 72 hours before the suitable  
32 inquiry will be completed.

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

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

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

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

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

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

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

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

25 And our answer to this question is as  
26 follows. The history of substance abuse must raise a  
27 concern about the person's history of alcohol or drug  
28 use and therefore fitness. The NRC expects that in  
29 addition to all individuals who are seeking  
30 reinstatement after having been removed under  
31 26.27(b)(3), (b)(4) or (c), other individuals with a  
32 history of substance abuse would be carefully  
33 evaluated with regard to whether a management and  
34 medical determination of fitness is required. The NRC  
35 understands that a DUI occurring many years ago  
36 followed by a treatment program of some type and no  
37 additional incidents in the intervening years may not  
38 need such follow-up testing.

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

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

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

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

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

16 In all cases of individuals being  
17 reinstated after having been suspended under  
18 26.27(b)(3) or removed under 26.27(b)(3), (b)(4) or  
19 (c), follow-up testing is appropriate and required.

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

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

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

40 I only have a few more questions in this  
41 section.

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

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

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

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

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

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

16 (Laughter.)

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

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

33 MODERATOR WEST: Thank you for the  
34 clarification.

35 MR. BURRELL: Good morning, Garmon.

36 MODERATOR WEST: Good morning.

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

39 (Pause.)

40 As well as 7. I'd like to look at these  
41 collectively, if we can, with the following  
42 foundation. Under the current rule, the grandson won  
43 unescorted access temporarily. We are required to  
44 complete suitable inquiries for the most recent year.  
45 And following that we have 180 days to complete the  
46 remaining suitable inquiries for 5 years best effort,  
47 3 years certain.

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

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

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

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

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

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

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

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

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

36 MR. EARNEST: Right.

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

41 Then we have 180 days.

42 MR. EARNEST: Right.

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

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

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

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

6 MR. BURRELL: Sure can.

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

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

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

14 MR. EARNEST: I'm confused too.

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

18 MS. DURBIN: I just found it.

19 MR. BURRELL: Okay, thank you.

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

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

26 MS. DURBIN: Right.

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

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

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

39 MODERATOR WEST: Correct.

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

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

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

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

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

14 MR. BURRELL: Okay.

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

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

22 MODERATOR WEST: I understand. Thank you.

23 MR. BURRELL: Thank you.

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

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

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

34 MODERATOR WEST: Are you speaking of the  
35 initial --

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

42 (Unmiked audience members shouting  
43 comments.)

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

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

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

7 Russell?

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

11 MR. EARNEST: Right.

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

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

22 The remaining 3 or 2 years if it's a  
23 3-year background or 5 years total, the initiating  
24 process is the fact that we have gotten the  
25 information off the security questionnaire from the  
26 applicant, put that in the hands with the release of  
27 the BI agency and they have returned a temporary to  
28 us. We grant unescorted access based on the temporary  
29 and the completed chemical test. Those two elements  
30 are put together and the individual is granted  
31 temporary unescorted access for 180 days.

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

35 MR. SEARS: Well, the suitable inquiry is  
36 initiated based on our current practice by handing it  
37 to the background agency and they will contact all  
38 previous employers. For the first year, all those  
39 contacts are made, are documented and that is in-house  
40 before we grant temporary access. The initiation part  
41 for the remaining portion, applicable portion of the  
42 background investigation for the full or the up date  
43 is what they have in-house and they may have contacted  
44 2 of the 20 employers. They may have contacted 19 of  
45 the 20 employers.

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

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

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

6 MR. SEARS: In-house.

7 MR. EARNEST: Right.

8 MR. SEARS: Documented.

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

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

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

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

23 MR. EARNEST: Thanks.

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

31 Is Loren Bush in the audience?

32 MODERATOR WEST: Good morning, Loren.

33 MR. MIZUNO: My recollection, okay, and  
34 this was almost a -- I don't think we considered it an  
35 important issue, but I do recall Loren Bush saying to  
36 me at one point that he wanted to have the initiation  
37 start because he didn't want licensees to abuse the  
38 provision of completing the remaining 5 year, 4 of the  
39 5 years of the suitable inquiry on a best-effort  
40 basis, that the best-effort basis would be truncated  
41 because they didn't initiate the inquiry until 5 days  
42 or a week before the 180 day period.

43 MR. SEARS: If you were a practitioner,  
44 you'd know that is not a place that you could get  
45 yourself. There's absolutely no way you can initiate  
46 5 days before the 180 days.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 MODERATOR WEST: Let me see if I fully  
6 understand what you're asking. It seems to me you're  
7 saying that under the current rule you would have some  
8 outside physician do some part of the MRO's functions  
9 --

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

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

17 MR. BOISMENU: Correct.

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

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

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

31 MR. BOISMENU: Correct.

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

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

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

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

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

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

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

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

23 MR. BOISMENU: Correct.

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

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

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

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

43 MODERATOR WEST: Is it 100 percent that  
44 you never have this face-to-face interaction between  
45 --

46 MS. TECHAV: Absolutely.

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

49 MS. TECHAV: Yes.

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1 MS. DURBIN: Okay, under the current rule,  
2 I believe there has to be a face-to-face evaluation so  
3 --

4 AUDIENCE: No.

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

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

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

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

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

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

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

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

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

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

13 MR. BOISMENU: Geary, I agree with you  
14 --

15 MR. MIZUNO: Except --

16 MODERATOR WEST: It does say licensed  
17 physician.

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

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

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

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

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

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

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

6 MR. BOISMENU: Sounds good to me.

7 MODERATOR WEST: If the individual was a  
8 licensed physician.

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

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

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

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

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

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

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

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

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

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

21 MODERATOR WEST: I see we have some  
22 additional comments.

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

25 MR. MIZUNO: I believe that --

26 MODERATOR WEST: During the public comment  
27 period?

28 MR. MIZUNO: During the public comment  
29 period --

30 MODERATOR WEST: On the proposed rule.

31 MR. MIZUNO: On the proposed rule.

32 MR. DiPIETRO: Which was when?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

44 MODERATOR WEST: I see.

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

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

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1 MR. SMITH: Yes. And that will be an  
2 upgrade from the current practice which is if it's not  
3 30 days, you don't verify it. So the proposal is for  
4 one employer, not each and every employer.

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

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

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

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

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

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

33 MODERATOR WEST: Yes.

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

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

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

3 But you were talking about completing  
4 which is another burden.

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

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

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

17 --

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

20 MODERATOR WEST: What constitutes a best  
21 effort?

22 MS. TECHAV: No.

23 MODERATOR WEST: Who decides what's  
24 burdensome?

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

26 MS. TECHAV: 77. The first bullet.

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

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

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

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

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

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

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

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

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

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

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

5 MODERATOR WEST: Yes. I responded that it  
6 was neither and I referenced the fact that  
7 26.27(6)(ii) states that that temporary access  
8 provisions of 73.56 do not apply and cannot be  
9 utilized for these individuals.

10 MS. DURBIN: No, it's 76.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

41 As I said --

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

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

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

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

3 (Laughter.)

4 MODERATOR WEST: I hear exactly you're  
5 saying.

6 (Applause.)

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

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

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

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

33 MS. DURBIN: Transfer or reinstatement  
34 --

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

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

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

7 MS. TECHAV: And I agree, that was in  
8 1996, but the definition for history of a substance  
9 abuse was not and that is going to cause a great  
10 burden to us in processing people.

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

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

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

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

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

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

4 MR. MIZUNO: It was not ignored.

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

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

9 MR. MIZUNO: They were more than looked  
10 at.

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

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

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

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

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

31 MS. DURBIN: Right, but that's part of  
32 --

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

36 MS. DURBIN: But this doesn't get back to  
37 the issue that Geary has been going through and  
38 --

39 MR. MIZUNO: Which is --

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

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

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

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

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

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

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

38 Please.

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

41 MODERATOR WEST: Certainly.

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

48 MR. MIZUNO: On which subject?

49 MODERATOR WEST: Which subject, sir?

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

3 MODERATOR WEST: Thank you.

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

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

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

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

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

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

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

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

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

3 MODERATOR WEST: Yes.

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

14 MODERATOR WEST: I think the explanation  
15 is essentially because it's tied to the fact that the  
16 72 hours is being referenced and the intent of that 72  
17 hours was with respect to licensee employees.

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

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

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

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

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

34 MR. BRAZIL: No, it wouldn't.

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

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

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

43 (Applause.)

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

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

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

18 (Laughter and applause.)

19 MODERATOR WEST: Thank you, Loren.

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

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

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

31 (Laughter.)

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

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

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

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

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

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

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

25 Is there any chance of doing that?

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

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

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

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

48 (Off the record.)

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

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

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

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

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

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

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

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

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

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

10                  MR. MIZUNO: The answer is yes.

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

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

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

20                  MR. MIZUNO: Okay. I think that -- let me  
21 just say the rule was intended to use the plural so  
22 that if the licensee chose to use more than one person  
23 that -- I mean it's persons, but there's no  
24 requirement to use more than one person. If you have  
25 one person in your procedure that is responsible for  
26 having that appeal and that person is otherwise  
27 independent, not associated with the administration of  
28 the FFD program, it satisfies the requirement under  
29 26.28. There's no requirement that you use more than  
30 one person.

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

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

36                  MR. BURRELL: Okay, thank you very much.

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

40                  MR. BURRELL: Thank you, Garmon.

41                  MODERATOR WEST: Thank you for the  
42 question. Yes?

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

45                  MR. MIZUNO: The answer is yes.

46                  MR. NOEL: Thank you.

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

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1 MR. NOEL: Thank you.

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

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

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

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

22 MR. MIZUNO: I guess I just wanted to add  
23 to clarify that there's some -- if you look under  
24 26.29(b) there are circumstances where a release from  
25 the individual is not necessary in order to disclose  
26 that. There are certain situations and I think to  
27 roughly characterize it as if the employee goes out  
28 and initiates a proceeding, then you don't have to get  
29 a release from them to disclose that information to  
30 the people who are directly associated with that like  
31 the presiding officer or a judge in a proceeding which  
32 the employee directly initiates.

33 That's just common sense.

34 MODERATOR WEST: Thank you, Geary. And  
35 26.70 has received some clarifications. I'll just go  
36 on and mention those while we're waiting for the slide  
37 and we've clarified the licensee contractors and  
38 vendors shall permit NRC inspections with regard to  
39 documenting records and reports of FFD service  
40 contractors related to licensee contractor or vendor  
41 FFD programs. And then the specifics of that would  
42 have to do with HHS labs, MRO, MROs, EAPs and specimen  
43 collection of services. And we didn't receive any  
44 advance questions in that area.

45 Any comments or questions on that section?  
46 (Pause.)

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

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

7 And there were no questions submitted in  
8 that area.

9 (Pause.)

10 And the reporting requirements under  
11 26.73, licensees must inform Commission by phone  
12 within 24 hours of significant events. Certainly  
13 there's nothing new about that. The wording has been  
14 expanded slightly such that it now includes not  
15 limited to, to give the -- to communicate that this is  
16 intended not to be an exhaustive list, that you'd only  
17 report the items that are listed in the -- that are  
18 listed there, but rather these are just examples. And  
19 there's quite a bit of discussion on that particular  
20 point in the statements of considerations.

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

24 And then further on the next slide, number  
25 89, you get some of the further details on 26.73,  
26 particularly with what's been added.

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

36 MR. BURRELL: Garmon, with respect to item  
37 4, we're talking about arrest of a worker for use or  
38 possession off-site and indicating that that arrest  
39 need be reported under this rule, rather than 73.71.

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

44 MR. MIZUNO: I'm not sure --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36 MODERATOR WEST: Thank you, Loren.

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

44 MODERATOR WEST: I think the answer would  
45 be yes.

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

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

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

5 MS. HAYES: Thank you.

6 MR. MIZUNO: Can I just add something?

7 MODERATOR WEST: Please.

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

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

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

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

29 MODERATOR WEST: Thank you, Geary.

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

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

38 MODERATOR WEST: Correct.

39 MR. HARRIS: All right.

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

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

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1 Thank you.

2 MODERATOR WEST: Thank you. Please.

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

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

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

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

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

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

27 MODERATOR WEST: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19                   Yet another question under this section  
20 26.80, if a licensee pays for a split specimen to be  
21 analyzed at a particular HHS certified laboratory and  
22 utilizes that laboratory only for split specimen re-  
23 analysis, does this obligate the licensee to perform  
24 an annual audit of that HHS certified laboratory?

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

33                   Would there be any further questions on  
34 this particular section?

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

47                   I'd like to hear an explanation.

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

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

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

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

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

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

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

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

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

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

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

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

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

20 MODERATOR WEST: I understand.

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

25 MODERATOR WEST: Correct.

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

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

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

37 MODERATOR WEST: I think part of the  
38 rationale--

39 MR. MIZUNO: Can I provide at least one?

40 MODERATOR WEST: Please.

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

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

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

12 If an employee chose X Laboratory, okay,  
13 not -- and if we required an audit requirement on a  
14 12-month basis, you'd have to -- you would know ahead  
15 of time that that laboratory is going to be chosen by  
16 the employee, so the only way you could comply with  
17 that possibly is like I said, either audit all of the  
18 potential things or assure yourself that there was  
19 some other licensee that had audited that lab so that  
20 you ultimately ended up with some patchwork to assure  
21 yourself that everyone had been audited and that just  
22 wasn't a reasonable thing to impose upon the licensee.  
23 And so that's the reason why.

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

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

42 MODERATOR WEST: Please.

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

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

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

3 MODERATOR WEST: Thank you for the  
4 suggestion.

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

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

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

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

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

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

37 MODERATOR WEST: I see.

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

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

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

47 MODERATOR WEST: How would you --

48 MR. MIZUNO: Is that licensee personnel?

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

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

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

9 MS. HAYES: Backshift.

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

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

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

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

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

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

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

37 MODERATOR WEST: Please, Loren.

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

45 AUDIENCE MEMBER: Eight hours won't cover  
46 that.

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

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

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

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

18 MODERATOR WEST: Thank you.

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

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

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

43 MS. TECHAV: Okay, thank you.

44 MODERATOR WEST: Certainly.

45 MS. HAYES: Lori Hayes, Progress Energy.

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

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

4 MS. HAYES: Thank you, Garmon.

5 MODERATOR WEST: And give you some further  
6 clarification.

7 Thank you. Ted?

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

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

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

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

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

48 And I also don't discount the value of

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

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

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

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

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

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

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

48 MODERATOR WEST: Please.

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

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

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

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

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

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

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

40 AUDIENCE MEMBER: Daily.

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

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

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

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

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

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

35 MODERATOR WEST: Please.

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

41 MODERATOR WEST: Correct.

42 MR. ENKEBOLL: Thank you.

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

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

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1 (Whereupon, at 12:02 p.m., the workshop  
2 was recessed, to reconvene at 1:00 p.m., Wednesday,  
3 March 21, 2001.)  
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1 particularly the redline and strikeout version of the  
2 rule changes, when those come up.

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

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

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

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

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

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

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

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

11 And under 2.3, preventing subversion of  
12 testing, we have Fitness-for-duty personnel must be  
13 tested by -- and this gets back to the independence  
14 notion of trying to achieve that in testing the  
15 Fitness-for-duty personnel, it comes up in Section  
16 2.3(b).

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

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

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

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

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

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

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

7 MR. BRAZIL: Garmon, excuse me.

8 MODERATOR WEST: Certainly.

9 MR. BRAZIL: Previously slide, if you  
10 would.

11 MODERATOR WEST: Sure.

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

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

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

27 MODERATOR WEST: Go ahead.

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

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

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

40 MR. BRAZIL: Exactly.

41 MS. DURBIN: Right.

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

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

49 MR. BRAZIL: Okay.

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

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

9 MS. DURBIN: Thank you.

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

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

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

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

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

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

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

43 (Laughter.)

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

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

7 MR. DiPIETRO: Thanks.

8 MODERATOR WEST: Certainly.

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

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

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

22 MODERATOR WEST: Any thoughts?

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

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

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

43 MR. MIZUNO: Okay.

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

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

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

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

13 (Laughter.)

14 -- would this be okay? Hypothetically.

15 MS. TECHAV: Those work.

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

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

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

34 MR. MIZUNO: Is that correct?

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

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

48 MS. TECHAV: So where does the cycle end?

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

3 MS. TECHAV: Okay.

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

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

18 MR. MIZUNO: But that's still --

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

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

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

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

27 MS. TECHAV: Absolutely.

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

30 MS. TECHAV: Absolutely.

31 MS. DURBIN: Yes.

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

42 [Sound interruption.]

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

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

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

9 MODERATOR WEST: Thank you for your  
10 comment. Yes?

11 MR. HARRIS: Neil Harris, TXU Electric.  
12 I'd like to digress for a moment to  
13 2.1(b). This gets into going back to testing. It  
14 says licensees may test for any illegal drug or any  
15 other substance suspected of having been abused.

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

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

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

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

35 But we are not designating what drugs, if  
36 any, that you have to test for, nor are we  
37 establishing what those cutoffs will be, but having  
38 said that, I will say that you -- any testing that you  
39 do under that and if you take -- if you follow actions  
40 under the Fitness-for-duty program, everything would  
41 have to be subject to the same requirements in terms  
42 of the trustworthiness of the test and the audits and  
43 --

44 MR. HARRIS: I understand.

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

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

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

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

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

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

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

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

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

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

37 MODERATOR WEST: Thank you for the  
38 question.

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

41 MODERATOR WEST: Yes.

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

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

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

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

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

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

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

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

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

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

41 MS. TECHAV: I understand.

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

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

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

14                   MODERATOR WEST: Sure.

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

20                   What is the expectation of completely  
21 audit?

22                   MR. EARNEST: Good question.

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

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

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

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

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

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

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1 MR. BUSH: No, Bruce, you're right on.

2 MR. EARNEST: Okay.

3 MR. BUSH: The intent was to indicate that  
4 the Fitness-for-duty program has a number of  
5 subelements, if you will. And that over a 36-month  
6 period we expected all of those elements to be looked  
7 at, that the audit to be complete.

8 MODERATOR WEST: Thank you.

9 MS. TECHAV: And then I just need to make  
10 one more comment and I really don't need a response,  
11 I just wanted to make a comment. On 26.27(a)(6)(i-  
12 ii), (7), when it talks about suitable inquiries. I  
13 guess it's basically (7) when it talks about suitable  
14 inquiries on reinstatements?

15 MODERATOR WEST: Yes.

16 MS. TECHAV: We did a study within the  
17 industry on how many reinstatements were completed  
18 within a year and we came up with about 16,000 that  
19 were completed and this was only five or six different  
20 utilities that we pulled. We only had two that we  
21 would have denied, based on the information on a  
22 reinstatement from a suitable inquiry information, so  
23 I just wanted that -- those types of statistics out  
24 there, so you guys could evaluate that along with  
25 everything else that you're doing with that.

26 MODERATOR WEST: Thank you.

27 MS. DURBIN: If I can make a quick  
28 response. Anyone else who has data of this kind that  
29 would be relevant and would like to provide it to  
30 Garmon via the website, it would be highly  
31 appreciated.

32 MR. EARNEST: Yes, one of the things that  
33 I've been doing while I've been sitting here for about  
34 a day and a half now is making up my own list of  
35 questions which I intend to give to Garmon and to put  
36 through the program because you're looking at how do  
37 I implement this? I'm looking at this how do I  
38 regulate it? How do I inspect it? What am I expected  
39 to come back from your site with? How do I know if  
40 you're doing it right?

41 And unless I can answer that, I have to  
42 answer the same questions that you're asking for the  
43 simple reason that if I don't understand it, I can't  
44 give you a fair review. So one of the questions about  
45 this that -- it kind of struck me and I'd like your  
46 help on it. And one of the changes that you're  
47 talking about here was to allow you if a person had  
48 not been tested, had been tested at another plant in  
49 the last few days and these have gone from there to

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

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

17 AUDIENCE: No.

18 MR. EARNEST: All right. Now, I want to  
19 make sure, he has not been out from under a program  
20 less than 30 days. What about over 30 days, but under  
21 60, you're giving it to him?

22 AUDIENCE: Yes.

23 MR. EARNEST: Everybody is giving it to  
24 him?

25 MR. SMITH: No, everyone is not.

26 MR. EARNEST: I'm sorry.

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

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

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

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

46 MR. SMITH: Anybody understand his  
47 question at all?

48 (Laughter.)

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

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

10 MR. EARNEST: If a random --

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

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

15 MR. FITZSIMMONS: Yes.

16 AUDIENCE: Yes.

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

19 AUDIENCE: Yes.

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

22 AUDIENCE: Sixty days.

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

25 AUDIENCE: Right.

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

28 That answers my question. Thank you very  
29 much.

30 MS. DURBIN: Now I want to ask some  
31 questions because I'm not sure of what Bruce's  
32 questions meant. So I just want to make sure that  
33 I've got it clear. Barring people who have had a test  
34 within the last 60 days, those people are -- we're  
35 just not going to think about those. How many of you  
36 are testing someone who comes to your site within 30  
37 days of leaving another site? They're moving within  
38 30 days. So you're testing everyone who comes to your  
39 site as long as they haven't had a test within the  
40 last 60 days?

41 AUDIENCE: Right.

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

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

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1 MR. SMITH: Take the test out. Now who's  
2 doing the test in 30 days and who's doing the test at  
3 60 days, eliminate the random.

4 MS. DURBIN: Did I say random?

5 MR. SMITH: How many people are using the  
6 30-day cutoff?

7 Okay, how many people are using the  
8 60-day cutoff? Thank you.

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

11 MR. SMITH: One guy back there, two guys.  
12 (Laughter.)

13 MS. DURBIN: If they've had no test within  
14 60 days?

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

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

21 AUDIENCE: Yes.

22 MODERATOR WEST: Thank you for that.

23 MR. MORIARTY: John Moriarty from Vermont  
24 Yankee.

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

32 MR. EARNEST: Exactly.

33 MR. MORIARTY: And we're all at the  
34 30-day -- most of us at the 30-day point. But just a  
35 little history there.

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

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

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

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

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

12 (Off the record.)

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

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

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

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

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

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

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

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

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

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

21 I've got a question.

22 MODERATOR WEST: Sure.

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

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

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

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

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

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

48 MR. FITZSIMMONS: Rich Fitzsimmons, DTE  
49 Energy.

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

4 MODERATOR WEST: I see.

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

8 MODERATOR WEST: That ties in --

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

14 MODERATOR WEST: Sure.

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

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

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

23 AUDIENCE: Yes.

24 MODERATOR WEST: Thank you. Loren?

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

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

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

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

49 AUDIENCE: We throw it away.

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

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

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

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

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

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

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

19 MR. EARNEST: Trust me, I know.

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

24 MS. TECHAV: And something that must be  
25 brought out is that bringing up this whole issue is  
26 back in 1996, the words in there said that the  
27 specimens must be combined. That's been removed since  
28 1996.

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

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

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

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

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

45 Our response is as follows. The  
46 individual's oral temperature is taken at the  
47 individual's request if the specimen submitted is  
48 outside the acceptable temperature range of 90.5 to  
49 99.8 degrees Fahrenheit or another range, another more

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

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

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

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

29 Yes?

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

32 MODERATOR WEST: NO problem.

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

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

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

49 MODERATOR WEST: Right.

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

10 MR. EARNEST: That was never changed  
11 anyway.

12 MR. BRAZIL: Correct.

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

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

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

23 MR. BUSH: Yes.

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

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

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

37 MR. BRAZIL: No.

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

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

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

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

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

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

12 MR. BRAZIL: No, it shouldn't.

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

15 MR. BRAZIL: Please do. Thank you.

16 MODERATOR WEST: Thank you.

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

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

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

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

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

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

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

14           Ted?

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

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

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

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

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

5 MODERATOR WEST: Thank you for that  
6 clarification.

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

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

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

27 MODERATOR WEST: Yes.

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

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

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

39 (Laughter.)

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

45 MR. BRAZIL: Keep going.

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

49 MR. BRAZIL: Sure.

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1 MR. BUSH: Okay. What's wrong with that?

2 MR. BRAZIL: Where's the third container?

3 MR. BUSH: You have a split specimen, you  
4 have the specimen that's going to the lab and you have  
5 the specimen that you're going to do your on-site  
6 testing on.

7 You're not going to take the specimen  
8 after the individual's walked off and start pouring,  
9 opening it up and pouring things around and all that  
10 kind of stuff. You've ruined the chain of custody.

11 MR. BRAZIL: Your technician is already  
12 subject to a higher standard and --

13 MR. BUSH: It doesn't make any difference.  
14 You're going to go to court and argue that he opened  
15 up this bottle and then we sent it on to the lab for  
16 testing?

17 MR. BRAZIL: First of all, there's no  
18 requirement to split, correct?

19 MR. BUSH: No.

20 MR. BRAZIL: It may be split at the  
21 licensee's discretion.

22 MR. BUSH: Correct.

23 MR. BRAZIL: I just tried to do what you  
24 just described which is to have a bottle that I'm  
25 going to use on-site, a second bottle that I'm going  
26 to send off if it is determined that that first bottle  
27 is positive on-site. I was informed that that was  
28 splitting specimens. I had a primary and a split.

29 MR. BUSH: No. A split specimen is the --  
30 a way of looking at it is that it is the specimen that  
31 is "owned" -- quotes around owned -- by the donor in  
32 case he questions the results from the lab. He can  
33 then say I want to test my split.

34 MODERATOR WEST: And the HHS is owned by  
35 the licensee. Do you have any further comments?

36 MR. BUSH: In other words, you have a  
37 retest of the specimen you sent to the lab. It's the  
38 licensee's specimen. The split specimen, as the rule  
39 is written, is the specimen that belongs to the  
40 individual. The individual decides whether he wants  
41 to challenge the test result. Okay?

42 On top of that, you have the specimen, the  
43 aliquot to be correct, that you're going to use for  
44 your on-site testing. What I'm saying is the rule is  
45 structure and good forensic practices, the individual  
46 is there when each of those specimen bottles are  
47 labeled and initialed. So if there's any challenge at  
48 any time in the future, you can go right to it and say

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

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

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

10 (Laughter.)

11 MODERATOR WEST: Please, do you have a  
12 comment?

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

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

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

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

35 MODERATOR WEST: Before you seal it?

36 MR. BOISMENU: Before -- correct.

37 MODERATOR WEST: My response would be yes.

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

40 MR. EARNEST: Courageous stand.

41 MS. PATSY: Rebecca Patsy, ConEdison.

42 MODERATOR WEST: Please.

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

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

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

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

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

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

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

23 MODERATOR WEST: Well, again --

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

27 MODERATOR WEST: As opposed to the  
28 individual?

29 MS. PATSY: Correct.

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

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

40 MS. PATSY: Other than the technician?

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

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

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

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

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

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

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

27 MODERATOR WEST: Okay, please.

28 MR. BUSH: I'm leaving.

29 (Laughter.)

30 MODERATOR WEST: That's related.

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

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

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

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

48 MS. BURKETT: Go ahead.

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

17 MODERATOR WEST: Are you at 2.4?

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

19 (Pause.)

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

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

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

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

31 MODERATOR WEST: Okay.

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

40 Are you with me so far?

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

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

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

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

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

11 MODERATOR WEST: That's a good point.

12 MS. DURBIN: But --

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

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

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

29 MODERATOR WEST: That's very well stated.

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

34 MR. BRAZIL: Absolutely.

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

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

41 MODERATOR WEST: Sure.

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

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

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1 We as an industry --

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

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

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

19 MODERATOR WEST: Was it transcribed?

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

22 MODERATOR WEST: Your comment is note.

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

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

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

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

43 MODERATOR WEST: Thank you for your  
44 comment.

45 MR. EARNEST: Thank you, Loren.

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

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1 Please.

2 MS. LANOUILLE: Susan Lanouette from North  
3 Atlantic.

4 I just need to go back to 2.4(g)(11). I  
5 just want to clarify, we do not do splits. We do one  
6 sample. In here, you're telling us that a partial  
7 specimen less than 30 milliliters should be retained  
8 and sent with any subsequent selected specimen or  
9 specimens? And further down, you're also telling us  
10 that each specimen must be sent separately for  
11 analysis?

12 Can you explain that?

13 MODERATOR WEST: So you're saying --

14 MS. LANOUILLE: What are you telling me?

15 MR. MIZUNO: They want to know why we  
16 changed our mind with respect to combining partial  
17 samples, which was in the proposed rule and then we  
18 changed our mind and now said do not combine partials  
19 and now we're keeping them separate --

20 MODERATOR WEST: Is that close to what  
21 you're asking or not?

22 MS. LANOUILLE: Are you talking to him or  
23 to me?

24 MODERATOR WEST: I was talking to you but  
25 with respect to what he just characterized. Was that  
26 your question, what he just mentioned?

27 MR. MIZUNO: I mean the rule says I have  
28 to -- I think you're complaining or you're asking what  
29 is the basis for -- as I understand it, your question  
30 is what is the NRC's basis for requiring that each  
31 partial specimen that does not meet the minimum  
32 amount, less than 30 milliliters be (1) retained and  
33 (2) labeled separately, and (3) sent off to the lab  
34 for quote testing, even though, in fact, it may be in  
35 a level too small to even be tested by that lab.

36 I think that's what I --

37 MODERATOR WEST: Why not just get rid of  
38 that --

39 MS. LANOUILLE: Right, you're saying we  
40 have to send it separately.

41 MS. DURBIN: What you're asking is can it  
42 be in the same container?

43 MS. LANOUILLE: Can it be in the same bag  
44 with the same COC or does it have to be separate COC  
45 for each single specimen?

46 MODERATOR WEST: I don't think it has to  
47 be separately, no.

48 MS. LANOUILLE: Then how do I label it  
49 because I only two labels, one for primary and one for

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1 split. How am I going to label it and have that  
2 individual sign it?  
3 I'm going to have to have more labels.  
4 MODERATOR WEST: Does anyone have any  
5 thoughts on that?  
6 MS. TAYLOR: The custody is supposed to be  
7 referring to a particular specimen that's going on.  
8 If you're going to do it separately --  
9 MODERATOR WEST: To maintain the chain of  
10 custody.  
11 MS. LANOUILLE: And if you send them all  
12 separately, how do you notify the lab that that's all  
13 from one person and how do they determine that it's  
14 all from one person?  
15 MODERATOR WEST: Can we pause here just a  
16 moment?  
17 (Pause.)  
18 MODERATOR WEST: I'm sorry, could you  
19 repeat your question again, please?  
20 MS. LANOUILLE: The question here is  
21 partial specimens.  
22 MODERATOR WEST: Yes.  
23 MS. LANOUILLE: I have less than 30 mls.  
24 that I've collected. I have to collect another  
25 partial to get that 30 mls.  
26 MODERATOR WEST: To come up to the 30 mls,  
27 okay.  
28 MS. LANOUILLE: But you're also saying  
29 that I cannot combine them.  
30 MODERATOR WEST: Yes, we're clearly saying  
31 that.  
32 MS. LANOUILLE: I have to -- let's say I  
33 have 15 mls. I have to send that 15 mls. separately  
34 with the other 15 mls. that I collect separately.  
35 AUDIENCE: No.  
36 MODERATOR WEST: No wait, let me pause  
37 here. You collect 15 mls. You don't have the minimum  
38 of 30.  
39 MS. LANOUILLE: Right.  
40 MODERATOR WEST: So you collect another 15  
41 mls.  
42 MS. LANOUILLE: Right.  
43 MODERATOR WEST: And you're assuming that  
44 you have to send them separately?  
45 MS. LANOUILLE: Right, because that's what  
46 you're saying here.  
47 MR. BUSH: Separately means don't combine  
48 them. It doesn't mean you can't put them in the same  
49 container.

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1 MS. LANOUILLE: Right, but how can I put  
2 them in the same bag with the same COC if there's not  
3 enough labels --

4 MODERATOR WEST: But why wouldn't you just  
5 take each one individually and send them off?

6 MS. LANOUILLE: And how am I going to  
7 label that? I'm going to put in my computer that I  
8 have three different specimens for one person, so I  
9 have three random separate tests? Uh-uh. I have one  
10 test. One specimen or actually one person, but three  
11 specimens?

12 MODERATOR WEST: I guess unless someone at  
13 the table or Loren has some further insights on that,  
14 we'll have to take that one up to give you some  
15 further guidance on that.

16 Let me make sure I understand the question  
17 before you leave, please. You have potentially two  
18 different specimens, each are less than the 30 minimum  
19 and you can't ship them both together.

20 MS. LANOUILLE: Right. Because I only  
21 have one label that says primary.

22 MODERATOR WEST: Because of your label.

23 MS. LANOUILLE: Right. So how do I label  
24 the second specimen?

25 MODERATOR WEST: We'll take that one as an  
26 action item.

27 Do you have anything on that, Ted?

28 MS. DURBIN: Does your question also  
29 include how you deal with chain of custody?

30 MS. LANOUILLE: Yes.

31 MODERATOR WEST: It's related, certainly,  
32 yes.

33 MR. SHULTS: This issue isn't without  
34 precedence. And in fact, under the current DOT  
35 regulations, there's an analogous situation and you  
36 know what it is or most of you know what it is.  
37 That's when you collect the specimen that's cold and  
38 it doesn't meet the temperature. Now under their  
39 regulations they say that you're supposed to capture  
40 that and send it in and collect a new specimen.

41 Now the only way I can conceptualize that  
42 is that really is capturing a separate urine specimen,  
43 it's a separate piece of evidence with its own chain  
44 of custody and if you do a split, it's split. If you  
45 don't do a split, it's not split. Under DOT, it's  
46 supposed to be split. Now the challenge in the DOT  
47 program as many of you can already anticipate is what  
48 oftentimes happens it that cold specimen is guess

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1 what, negative, you know? And you get this negative  
2 report that comes in.

3 The MRO says negative and the guy is off  
4 flying an airplane. And then 3 days later a revolting  
5 development happens, you get another specimen with the  
6 same name on it, this time it's positive. So the way  
7 in which DOT's regulated companies deal with that is  
8 on the chain of custody for the first specimen they  
9 note that this is the first of two specimens that are  
10 going to be coming.

11 So you use that notation piece on the  
12 chain of custody. But this procedure is a little bit  
13 different. This is a different type of thing because  
14 now we're going to be capturing possibly two, three,  
15 four specimens and we're going to be doing some type  
16 of analysis on those specimens and we're going to have  
17 another set of complexities.

18 What happens if specimen 2 is positive for  
19 nitrite and specimen 3 is positive for cocaine and  
20 none of them have B bottles? So I think what probably  
21 would be worthwhile in looking at this is to look at  
22 it holistically in terms of again looking what the HHS  
23 is doing in this area and sort of giving sort of a  
24 protocol on how to deal with this and also to address,  
25 I think, what was also getting bungled up a little bit  
26 earlier is a distinction between the chain of custody  
27 issues and the integrity of the evidence in terms of  
28 what standard practices are for how on-site tests are  
29 done. Those are sort of separate issues.

30 They go essentially to the admissability  
31 and integrity of it, but they're two separate types of  
32 issues. But it is going to require a lot more  
33 infrastructure in how you manage your specimens and  
34 how you manage those -- with the laboratory. As you  
35 well know, when these laboratories start getting these  
36 specimens that are linked together, they will also  
37 have to develop the software to track it in-house and  
38 also have an understanding of how to report that to  
39 you.

40 MODERATOR WEST: Certainly that's relevant  
41 to the fact that we do indeed have a set of questions  
42 that we need to do some follow-up on that are relevant  
43 to talking to HHS and perhaps we can get some useful  
44 insights here.

45 Please?

46 MS. LANOUILLE: And to complicate it  
47 further, if you are doing on-site testing, you are  
48 supposed to first fulfill the A and then the B and

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1 then the C which is the on-site testing, that sheet  
2 could be a very different sample. So you may be  
3 on-site testing a diluted sample than what you just  
4 sent down. You'd have to wait for everything to come  
5 back anyway.

6 If you sent a sample, the first sample  
7 down, that was say 15 mls.

8 MODERATOR WEST: Okay.

9 MS. LANOUILLE: And then you wanted to  
10 -- you couldn't on-site test at all, you would lose  
11 that. Because even if you did receive a quantity  
12 enough to fulfill the other split and on-site,  
13 couldn't do anything with that result until that first  
14 sample is still out there.

15 So you might lose a lot of your ability to  
16 get your quick results with the on-site test.

17 MODERATOR WEST: Thank you for that  
18 comment. Yes?

19 MR. BUCHER: I'm Richard Bucher from  
20 Bensinger, DuPont. I have a question, really a  
21 clarification. For the initial collection for any  
22 test, what is the minimum quantity that the rule  
23 requires be collected, period? If I collect only 25  
24 milliliters on the first collection, what happens to  
25 that specimen?

26 MODERATOR WEST: I think the answer to the  
27 minimum question is 30.

28 MR. BUCHER: And by implication this gets  
29 thrown?

30 MODERATOR WEST: No, not at all. I think  
31 I addressed that on a previous slide. First of all,  
32 unlike the current rule, we would not say in the new  
33 rule that anything could be destroyed. That's one  
34 point.

35 In the new rule, the minimum would be 30  
36 and if you get 25, then you're still seeking that  
37 minimum of 30 through yet another collection. So the  
38 definition of specimen is whatever aggregate urine I'm  
39 able to provide. Is that correct? I don't understand  
40 it, so I'm just trying to understand --

41 MODERATOR WEST: Whatever single  
42 collection --

43 MR. BUCHER: Will you please go to 2.4(g)(11) --

44 MODERATOR WEST: Okay.

45 MR. BUCHER: If I read this right it says  
46 the predetermined quantity for any particular specimen  
47 -- now you just said that's a single void.

48 MR. MIZUNO: That's right.

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1 MR. BUCHER: Must include at least 30  
2 milliliters. What if I don't get 30 milliliters. I  
3 haven't made the requirement.

4 MR. MIZUNO: That's right. You haven't  
5 made the requirement.

6 MR. BUCHER: So now what do I do?

7 MR. MIZUNO: You go down, continue down  
8 and it says it's considered then to be a partial  
9 specimen, less than 30 milliliters. It must be  
10 retained. It must be kept in a separate container.  
11 You have to --

12 MODERATOR WEST: And with any subsequent  
13 collected specimen.

14 MR. MIZUNO: That's right. That partial  
15 specimen has to be inspected, sealed, labeled and so  
16 forth --

17 MODERATOR WEST: And sent on to the lab.

18 MR. MIZUNO: Sent to the lab.

19 MS. LANOUILLE: I think what he's asking  
20 is let's go back to the 15 mls. that I've collected.

21 MODERATOR WEST: Okay.

22 MR. MIZUNO: Okay.

23 MS. LANOUILLE: Do I now have to wait and  
24 collect another 15 mls. to equal 30 or do I have to  
25 collect 30 mls.?

26 MR. MIZUNO: You have to collect an  
27 additional 30. Forget about that 15. That 15 is a  
28 partial specimen. You have to collect 30.

29 MS. LANOUILLE: So no matter what, I have  
30 to have 30 mls. in one container?

31 MR. MIZUNO: That's correct. For one  
32 void.

33 MS. LANOUILLE: No matter if it looks like  
34 water or not? You're going to dilute it.

35 MR. MIZUNO: You have a question about  
36 dilution, I guess, is further down in 11 where it says  
37 individual may be given a reasonable amount of liquid,  
38 but normally 8 ounces every 30 minutes, but not to  
39 succeed a maximum of 24 ounces. That's to address the  
40 question about that, about dilution.

41 Yeah, it ultimately still comes down, you  
42 need to collect 30 milliliters in order to have a full  
43 specimen.

44 MODERATOR WEST: We have another comment,  
45 please?

46 MR. PRIEBE: Just further clarification,  
47 please. Mike Priebe, Palo Verde.

48 I do not have as much experience on this  
49 as most people here, but I'm told we have people that

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1 just have a great deal of trouble providing that  
2 amount. I did hear somebody up at the table say  
3 earlier well, if you have documented medical reason or  
4 whatever, that might help with a problem like this,  
5 but if we have somebody who is in for the first time  
6 and we don't have any documented medical condition on  
7 this person and they give 15 and they wait and wait  
8 and two hours later they still have not given a single  
9 specimen of 30, and two hours later they still have  
10 not, at what point do we say what? Do we keep them  
11 overnight, do we keep them for the week? Do we keep  
12 them -- do we just tell them go away, you don't have  
13 a badge anymore?

14 (Laughter.)

15 Honestly, I'm not trying to be facetious.  
16 I really don't know.

17 MR. MIZUNO: That's a good question and  
18 under the final rule it says that to anticipate that  
19 situation, the last sentence of 11 says if the  
20 individual fails for any reason to provide a quantity  
21 of urine sufficient to fulfill all analysis and re-  
22 analysis requirements, the collection site person  
23 shall contact appropriate authority and I guess a  
24 minimum first up the chain and then presumably that  
25 person will contact the NRC to obtain guidance on the  
26 action to be taken.

27 I didn't say you were required to contact  
28 the NRC, but I'm saying that person contacts the next  
29 person up the chain and determines what it is.

30 MR. PRIEBE: At my site they're going to  
31 contact me and I have no clue what to tell them, so  
32 I'm really looking for some advice. So when they  
33 contact me I'll say --

34 MR. MIZUNO: Do you have any suggestions?

35 MR. PRIEBE: Do I? No.

36 MR. MIZUNO: Contact MRO. Do you have any  
37 suggestions as to what our guidance would say as to  
38 what would be an appropriate course of action in that  
39 situation? I mean that's -- we're looking for that.

40 MODERATOR WEST: Please.

41 MS. TAYLOR: Garmon, for this particular  
42 thing, when you all are doing your NUREG in question  
43 and answers, can you clarify how -- she brought up,  
44 like for example, if this is a random test and I end  
45 up sending like four or five specimens off and I'm  
46 going to get four or five results, can you clarify in  
47 there how we report this during our reporting period?  
48 Because like right now, I have a system that I count  
49 randoms, but I'm going to receive five different

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1 results for one test. Do I count that as one test?  
2 Or like if four come back negative and one comes back  
3 positive, do I count that as five different -- do you  
4 see what I'm saying?

5 MODERATOR WEST: I understand exactly.

6 MS. TAYLOR: Could you clarify that for  
7 us, please?

8 MODERATOR WEST: I would also suggest for  
9 -- obviously, we're not giving you specific guidance  
10 in the rule on the question of what do you do. While  
11 I appreciate Geary's point, we say that you should  
12 contact your management, but it doesn't tell you  
13 precisely where you end up. I would suggest also that  
14 this one, in addition to us just thinking about it a  
15 little bit more for any additional thoughts we might  
16 have, might be yet another one that might be HHS has  
17 some guidance on.

18 I think that takes us to 2.5. We probably  
19 have about enough remaining to get through perhaps  
20 within the next hour. Would you like to have a short  
21 break now?

22 Let's reconvene in about 10 minutes, say  
23 a quarter after.

24 (Off the record.)

25 MODERATOR WEST: The next section is 2.5  
26 and in this particular section we didn't have any  
27 particular questions. I guess the way that I would  
28 propose dealing with this, I'll just have you refer to  
29 the redline and strikeout version and see if there's  
30 any particular aspect of it, that you'd have any  
31 specific comments or questions about.

32 Most of the beginning portion of it, up  
33 through Section 7 and even to some extent 7(b) is  
34 largely editorial type changes. And then under (b),  
35 under 7(b) test validation, we've added certifying  
36 scientists as defined in Section 1.2 of the HHS  
37 Guidelines and some additional language there in that  
38 section and then some additional changes under (d),  
39 (e) and (f), the files, for example, the laboratory  
40 personnel files shall include, and there's some  
41 specifics on that. Back to (e), there's some  
42 additional language there on training, a laboratory's  
43 urine drug testing program shall make available  
44 continuing education programs to meet the needs of  
45 laboratory personnel.

46 I'll go on to Section 2.6. And under this  
47 one, again, if you take a look at the redline and  
48 strikeout, we have some added language with respect to  
49 day to day management of operations. Any licensing

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1 testing facility shall have an individual to be  
2 responsible for day to day operations and to supervise  
3 the testing of technicians. And the further addition,  
4 these individuals shall have at least a bachelor's  
5 degree in the chemical or biological science, medical  
6 technology or equivalent. He or she shall have  
7 training and experience in the theory of practice of  
8 the procedures used in the licensing, testing  
9 facility. Little more specifics there.

10 And then under 2.7, largely changes with  
11 regard -- conforming type changes with regard to the  
12 terminology for the chain of custody. That particular  
13 form.

14 And then under 2.7(a) -- actually, it's  
15 (b)(2)(c) under the short-term refrigerated shortage,  
16 specimens that do not receive screening testing and  
17 for appropriate or confirmatory test, there was some  
18 additional language there.

19 And then moving forward to subsection (e),  
20 there's certainly quite a bit that's been added with  
21 respect to greater emphasis on specimen validity. And  
22 you can see all the details of that.

23 Then in Section 2.8 --

24 MS. DURBIN: We had a pre-submitted  
25 question on 2.7.

26 MODERATOR WEST: I'll address the  
27 question. Section 2.7. What qualifications would a  
28 staff person need to review and sign negative test  
29 results?

30 I think we've had some discussion of this  
31 in the past. The MRO must review and sign negative  
32 test results as noted earlier. A staff can receive  
33 test results and prepare them for MRO review as well  
34 as scheduling interviews. The MRO should determine the  
35 need for an interview.

36 And then further under 2.7, the rule on  
37 split specimens states in part, the chain of custody  
38 and testing procedures to which the split specimen is  
39 subject must be the same as those used to test the  
40 primary specimen. However, HHS guidelines for  
41 retesting of split specimens prohibit rescreening by  
42 immunoassay, except for dilution information.  
43 Therefore, is it acceptable for split specimens to be  
44 tested by GC/MS only for purposes of substantiating  
45 the original result?

46 And the answer there is no. And we  
47 further note that screening by immunoassay is  
48 necessary for dilution information, but a negative  
49 screening in this case does not negate the GC/MS. I

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1 think this is one of the ones that I had alluded to  
2 earlier where we have a set that we intend to have  
3 some follow-up discussions with HHS.

4 MR. HARRIS: Neil Harris, TXU Electric.  
5 Right here we talk about using GC/MS for testing.  
6 However, back a few pages on page 28, we struck  
7 basically the use, actual use of the word or term  
8 GC/MS. That's under -- let's see, future revisions  
9 where it begins "in order to adapt a rule for changes  
10 involving disciplines relating to substance abuse" we  
11 strike out the words "at this time gas chromatography  
12 and mass spec is the only authorized confirmatory  
13 method." We have stricken those words. I'm wondering  
14 why they're reappearing.

15 MS. DURBIN: They reappear somewhere else,  
16 I believe. I can't find it for you this minute.

17 MR. HARRIS: I'm just wondering why we're  
18 seeing a dichotomy here within the document.

19 MODERATOR WEST: That's just a function of  
20 how this redline and strikeout --

21 MR. HARRIS: Okay.

22 MS. DURBIN: But we'll look for it when we  
23 get your question on the transcript.

24 MR. HARRIS: Another item here is when we  
25 talk about shipping. We say that we will cool to 6  
26 degrees Centigrade or 43 degrees Fahrenheit.

27 MODERATOR WEST: What's your reference  
28 point for that?

29 MR. HARRIS: It's back a few pages, I  
30 can't -- then we get to where we're talking about  
31 "then the sample must not be raised to a temperature  
32 any greater than 6 degrees" or I think it's 42.7  
33 degrees. In other words, you have a disparity between  
34 your degrees in Fahrenheit in this and at the same  
35 time you give no leeway on a divergence of the  
36 temperature. You must cool down to 6 degrees and you  
37 must not raise above 6 degrees. So where do you get  
38 any type of capability of having a plus or minus on  
39 this?

40 I know it sounds like of trite. However,  
41 as being a supervisor of a laboratory for several  
42 years and writing multiple procedures for our own  
43 company, I know that a lot of times you have to have  
44 a range that you can work within and by cooling down  
45 to one temperature and saying that's absolute and then  
46 saying you cannot get above that, if I go in and audit  
47 your system and I find out that your temperature  
48 control is not absolute, then there's a potential for  
49 a hit on that. That's just a comment.

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1 MODERATOR WEST: Okay, thank you for your  
2 comment.

3 Now the next question under 2.7, the  
4 laboratory shall retain the original custody and  
5 control form and must send only to the MRO certified  
6 true copies of the original custody and control form  
7 and the test report. Does this mean that HHS  
8 laboratories must send the certified true copies of  
9 the custody and control form to the licensee on  
10 negative drug tests?

11 And the answer here is yes, with this  
12 explanation. The rule hasn't changed with regard to  
13 the requirement to send custody and control forms on  
14 negative test results, only that the laboratory shall  
15 retain the original.

16 An additional question. HHS laboratories  
17 use two types of negative screening, control  
18 specimens, a drug-free control and a -25 percent of  
19 the cut-off negative control. Appendix A 2.7(e)(4)  
20 states in part, "the responses of questionable donor  
21 specimens must be compared to the acceptable range of  
22 negative screening control responses. Those specimens  
23 that have responses that are greater than the negative  
24 control responses must be subject to confirmation  
25 testing by GC/MS at the laboratory's limit of  
26 detection, LOD."

27 The question is, which negative screening  
28 control is expected to be utilized in this case?

29 And the answer that we provide, the drug-  
30 free control should be used in order to identify any  
31 detectable drugs in these questionable specimens.  
32 However, we will also discuss this particular item  
33 with HHS, just to ensure that it's a reasonable  
34 approach.

35 Another question under this section,  
36 confirmatory tests for amphetamines should be reported  
37 as amphetamine and methamphetamine. However, Appendix  
38 A 2.7(g)(5) states specimens that have a positive  
39 GC/MS result for amphetamines must be tested for d and  
40 l isomers. The question is would it not be more  
41 appropriate to state that specimens that have a  
42 positive test for methamphetamine must be tested for  
43 d and l isomers?

44 Our comment here is that, in response, is  
45 that believe the wording is actually correct.  
46 However, again, we'll also take this one up with HHS  
47 just as a confirmation.

48 And the next question has two parts to it.  
49 Why is there an extra day allowed for l and d isomer

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1 testing, but not for 6 a.m. testing? The licensee is  
2 the -- second item -- the licensee is supposed to  
3 promptly notify the NRC in the case of a false  
4 positive test result. What is the definition of  
5 promptly in this case?

6 On the first one, we didn't necessarily  
7 believe it was an implementation question, but we  
8 crafted a response, nevertheless. There's been no  
9 change in the requirements for the laboratory to  
10 submit testing results for 6 a.m. The NRC followed  
11 the HHS technical advisory of March 11, 1991 in  
12 developing the requirements for l and d isomer  
13 testing.

14 And then with regard to the second item,  
15 this is an obviously existing requirement and no  
16 problems have been caused by the very few false  
17 positive results to date. Contacting the NRC FFD  
18 program manager within a day or two of the result has  
19 been acceptable. Follow-up with contact on  
20 information provided has been useful as has the  
21 written report made within 30 days in accordance with  
22 Appendix A, 2.8(f).

23 That was the last question we received in  
24 that section. Before going to the next section 2.8  
25 are there any comments or questions on 2.7?

26 And here at 2.8 deals with quality  
27 control, quality assurance and quality control. And  
28 I'd ask you to turn to your redline and strikeout  
29 version.

30 MS. TECHAV: In reference to 2.7(d), the  
31 very last sentence says "the MRO shall report any  
32 adulteration or dilution evidence excluding hydration  
33 resulting from an acceptable reason to management  
34 immediately." Does that mean that they don't have to  
35 talk to the donor prior to this and are they declaring  
36 the test something?

37 MODERATOR WEST: I'm sorry, this is under  
38 2.7?

39 MS. TECHAV: 2.7(d). The last sentence.  
40 I guess my question is does this mean the MRO does not  
41 speak to the donor and would this be considered an  
42 immediate violation?

43 MS. DURBIN: I would say that's a very  
44 useful question. My kind of thought on it which is  
45 not binding in any way on anyone is that the intent  
46 here is if it's not a questionable specimen, if it's  
47 totally, if it's adulterated or so dilute that it  
48 couldn't possibly be a normal urine specimen and we  
49 have ranges specified for that in the specimen

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1 validity, then there would be an immediate report. If  
2 it's a questionable specimen, then it goes through the  
3 testing procedure that's specified for specimens that  
4 are questionable and then if the MRO determines that  
5 there is no detectable evidence, then it wouldn't be  
6 reported if they do determine that it was a violation.

7 Loren Bush seems to have additional  
8 comment on this.

9 MS. TECHAV: You snuck up on me.

10 MR. BUSH: This particular change was  
11 designed to provide management some flexibility to  
12 take action if they so desire to in the interest of  
13 public safety. In other words, you have this mess in  
14 your hand and you haven't gone through the legal  
15 process of assuring yourself that it is, in fact, what  
16 you are quite sure that it is, but NRC management was  
17 concerned that you have, in hand, evidence that  
18 somebody may be impaired, may be a threat to public  
19 health and safety and all that sort of thing.  
20 Management should be afforded the opportunity to shine  
21 and take whatever action they need to protect public  
22 health and safety, so that's what this is all about.

23 MODERATOR WEST: Thank you, Loren.

24 MR. MIZUNO: Did he address the part about

25 --

26 MS. TECHAV: What are we going to do?

27 MR. MIZUNO: No notice to the individual?

28 MODERATOR WEST: Did you have any thoughts  
29 on that, Loren?

30 MR. MIZUNO: And while Loren is going  
31 there, I would just point out that my view is that  
32 26.28 is a relevant requirement for notice to the  
33 individual and that my initial cut is that 2.7(d) does  
34 not address specifically the issue of whether notice  
35 to the individual is necessary at that point. I  
36 think what definitely controls is 26.28.

37 MR. BUSH: Thank you, Geary.

38 MODERATOR WEST: Thank you, Geary.

39 MR. SHULTS: Ted Shults, again. Back when  
40 this rule was conceptualized, there was no recognition  
41 of a need to have MRO oversight over specimen, what's  
42 called now specimen validity, adulterated or  
43 substituted specimens. And for those of you who have  
44 any dealings with DOT know that under their provided  
45 rule change at the end of this year, they've now asked  
46 for Medical Review Officers to oversee this process.  
47 At the same time, I think Loren's point is well taken,  
48 that under this program I can certainly see it  
49 acceptable to have a person removed from duty.

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1           Now the reason I mention this is that this  
2 issue is still in play and that you need to be aware  
3 that there's been a great deal of controversy over the  
4 substituted specimen standard under DHHS and it's  
5 interesting to point out that one of the complaints  
6 that the unions have made concerning the way in which  
7 specimens were handled under the DOT program was that  
8 there was insufficient due process, that there was no  
9 oversight over -- and the idea that since management's  
10 sanctions were often more severe for adulterated  
11 specimens or substituted specimens, that that just  
12 didn't pass muster and in fact, so DOT responded by  
13 requiring the MRO to review that.

14           Now I should say that even given that  
15 consideration, there has now been a challenge, a legal  
16 challenge in the Ninth Circuit by the Delta union  
17 challenging DOT's regulations, again, being a  
18 violation of due process, not to have MRO over -- that  
19 even with MRO oversight, that somehow or another these  
20 rules are defective. So just be aware that that's  
21 currently out there.

22           From my perspective, your program is  
23 functionally different in the sense that DOT does not  
24 provide for an appeal process where you do and I think  
25 that it may be very appropriate that you may have that  
26 sort of oversight and due process through the appeals  
27 process and the MRO could be involved in terms of not  
28 being the decision maker in that, but also developing  
29 up the data that whoever is making that decision would  
30 be able to look at.

31           But anyway, I just wanted to share that  
32 sort of background with you.

33           MODERATOR WEST: Thank you. I appreciate  
34 that. Now under Section 2.8, quality assurance and  
35 quality control, some editorial type changes in the  
36 beginning portion of it. There is some addition there  
37 in Section b with respect to the results reported by  
38 the certified laboratory must be evaluated and  
39 appropriate corrective actions taken.  
40 And several shalls to musts for sure.

41           And some additional changes under (d),  
42 actually it's (e), subitem (ii), specifying during the  
43 initial 90-day period of any contract with an HHS  
44 certified laboratory, not included in rewritten or  
45 renewed contracts. And the minimum, well, first of  
46 all the 50 percent has gone to 20 percent with respect  
47 to the total number of specimens submitted, up to a  
48 maximum now from 50 samples to 100 samples or 30 blind  
49 performance test specimens whichever is greater,

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1 following the additional 90-day period, a minimum of  
2 3 percent of specimens and from a maximum of 250 to 25  
3 or 10 blind performance test specimens, whichever is  
4 greater must be submitted per quarter.

5 And further, licensees should make an  
6 attempt to submit blind performance test specimens  
7 during the initial 90-day period and per quarter,  
8 thereafter, at a frequency that corresponds with the  
9 submission of frequencies for other specimens so that  
10 they're not all stacked towards the end. And then  
11 further, under item 3, it's gone from 80 to 50 percent  
12 of the blind performance test specimens must be blank.  
13 And then in addition, 10 percent of the positive blind  
14 specimens must be appropriated adulterated or diluted  
15 and spiked between 60 percent and 80 percent of the  
16 screening cutoff values established in 2.7(f).

17 Then there's some additional language  
18 under (f)(i).

19 MS. DURBIN: I just have a question. Is  
20 anyone having difficulty getting -- has anyone tried  
21 to get adulterated specimens that were spiked at these  
22 levels and if so, is anyone having difficulty getting  
23 those blind performance test specimens?

24 MS. TAYLOR: I just found out yesterday  
25 because I've been trying to get those for a year and  
26 a half and I talked to Nancy yesterday and asked her  
27 who said in the rule that it was easy to get these and  
28 I found that in the comment section it said the  
29 toxicologist said there should be no reason why people  
30 cannot provide these. It wasn't -- so you know,  
31 anyway, I found out yesterday, I don't know who you  
32 all used.

33 We use you all solely, but our person has  
34 indicated they will provide these blinds at such time  
35 this regulation is out for implementation. But up  
36 until now I have not been able to get anybody to  
37 provide them for me because we started testing for  
38 nitrites like a year and a half ago and we've been  
39 trying to get blinds ever since to do it and we  
40 haven't been able to up until now.

41 MS. DURBIN: Thank you. I knew that  
42 question was pending and I wanted to make sure it was  
43 in the record, but now we have an answer. Thank you.

44 MODERATOR WEST: Thank you for the update.  
45 Then under (f)(1), the added language there with  
46 respect to testing errors or unsatisfactory  
47 performance discovered in blind performance testing.  
48 And then it ends with some additional editorial-type  
49 changes.

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1 Under 2.9, reporting and review of  
2 results, there's some additional language in  
3 subsection (b) regarding the MRO shall not be an  
4 employee or agent or have any financial interest in a  
5 laboratory or contracted operator of an on-site  
6 testing facility whose drug test results the MRO is  
7 reviewing for the licensee. Similar to other  
8 agencies, some additional language with respect to  
9 conflict of interest.

10 And then towards the middle of that  
11 section, the MRO is also responsible for identifying  
12 issues associated with the collection and testing of  
13 specimens and advising and assisting management in the  
14 planning and oversight of the overall FFD program.

15 Subitem (c) is an addition with regard to  
16 the medical officer verification of FFD policy  
17 violations.

18 And then just the highlights, if you will,  
19 some additional language on presumptive positive  
20 screening test results is not to be reported as except  
21 as provided in 26.24(d).

22 I can probably skip over to subsection  
23 (f). And there's additional language there under --  
24 concerning the MRO shall further evaluate the result  
25 and medical explanation to determine if there's a  
26 potential risk to public health and safety of the  
27 individual being impaired on duty from the substance  
28 or from the medical condition. If the MRO determines  
29 that such a risk exists, he or she shall conduct a  
30 medical determination of fitness and then it goes in  
31 through a list under (g) of the various forms of  
32 medical determination of fitness.

33 I won't go through all of those, but just  
34 to bring them to your attention.

35 Then under Section 3.1, I just have a  
36 couple more to conclude with, largely deleting  
37 portions of that current requirement and then lastly  
38 the use of HHS-certified laboratories. And that's  
39 been modified to some degree, only with respect to  
40 addresses and that sort of thing.

41 And then at the end of that section  
42 there's been an addition there, under subsection (b)  
43 as well as (c) has been added. Because the HHS  
44 national laboratories certification process does not  
45 cover practices outside the HHS guidelines such as  
46 using more stringent cutoff levels than set forth in  
47 the HHS guidelines or testing for additional  
48 substances, licensees and their contractors that  
49 choose to use practices outside the HHS guidelines

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1 must take measures that are consistent with this part  
2 to assure that the reported test results are valid and  
3 defensible. And then lastly, all contracts related to  
4 this part between licensees and their contractors and  
5 laboratories must require implementation for all  
6 obligations of this appendix applicable to HHS  
7 certified laboratories.

8 Well, that ends the two very intense days  
9 we've had and I sincerely -- I'm sorry, go ahead, and  
10 I know Mr. Enkeboll would like to make some final  
11 comments and I have some final comments myself, but  
12 please, go right ahead.

13 MS. KOPP: I'd like to address 2.7(j), the  
14 retesting of specimens. I have a question relative to  
15 an adulterated sample and split specimen.  
16

17 It says because some metabolites  
18 deteriorate or are lost during freezing and storage,  
19 etcetera, etcetera, quantification for a retest is not  
20 subject to a specific cutoff requirement, but must  
21 provide data sufficient to confirm the presence of a  
22 drug or metabolite.

23 Then we go on to say for the retesting of  
24 specimens that have been determined to have been  
25 adulterated or diluted the retest need only  
26 substantiate the information that the MRO used to make  
27 the initial determination.

28 Do we as a utility -- in the past, we have  
29 not offered a split specimen to the employee with an  
30 adulterated sample, only because we have found that  
31 the split has come back as a negative and did not  
32 prove an adulterant from the beginning. So it's kind  
33 of a touchy area and can we as a utility sanction the  
34 fact that if it comes back initially on the aliquot  
35 and the initial testing that it proved to be an  
36 adulterant, do we have to offer a split sample as part  
37 of the appeal?

38 MODERATOR WEST: I think the general  
39 answer and correct me if I'm wrong, Geary, the general  
40 answer to that is that the split specimen is at the  
41 discretion of the licensee.

42 Do you disagree?

43 MR. MIZUNO: No, we don't require --

44 MODERATOR WEST: That's my point.

45 MR. MIZUNO: Okay, I thought you were  
46 saying once you collected, whether it's actually going  
47 to be tested or not is at the option of the --

48 MS. KOPP: You see, at the utility we do  
49 offer, we do take a split and we do offer that split.

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1 MR. MIZUNO: Right, but I believe whether  
2 the split gets tested, I believe is the option of the  
3 individual. I do not believe that -- I have to go  
4 back and look at it again, but I don't think the  
5 licensee can on his own volition --

6 MODERATOR WEST: Loren, are you going to  
7 help us out?

8 MR. BUSH: First of all, the collection or  
9 splitting a split sample away from the primary  
10 specimen is the discretion of the licensee. It's not  
11 required to split specimens.

12 If you do split specimens, then the  
13 individual has the option when he gets the test  
14 results back of using that specimen to challenge the  
15 results.

16 MR. MIZUNO: Correct.

17 MR. BUSH: The MRO is the principal person  
18 who decides whether or not the test results are  
19 questionable. It could be because of the data from  
20 the lab. It could be from his interview. He can  
21 decide whether or not he wants to retest the sample.  
22 That's what we're talking about here, the retesting of  
23 the specimen -- the MRO can make a decision that  
24 there's no need to retest.

25 MS. KOPP: Thank you.

26 MODERATOR WEST: Thank you for that  
27 clarification, Loren. Would you like to go next?

28 MR. HARRIS: Yes, please. Neil Harris,  
29 TXU Electric.

30 Two questions, in one of the sections here  
31 we talk about day to day management of operation of  
32 the testing facility. It says the individuals who are  
33 in control of these facilities shall have a bachelor's  
34 degree in chemical or biological sciences, etcetera,  
35 or the equivalent. Now what are we using to measure  
36 the "or equivalent" statement in here?

37 MODERATOR WEST: We haven't specified that  
38 in any other document that I have been able to  
39 identify, certainly not in 13.85. The question has  
40 come up and I think that would be certainly a good one  
41 for us to give some additional clarification on in the  
42 NUREG document.

43 MR. HARRIS: Thank you. The other  
44 question is on page 50 concerning records, is there  
45 retention at the laboratories. It says that the  
46 licensee's testing laboratory or facility shall  
47 maintain records for a minimum of two years. We  
48 require records of audits or records of positives to  
49 be kept from anywhere between 3 and 5 years, yet we

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1 only require the laboratories to require their records  
2 to be maintained for 2 years. We feel this is  
3 adequate document control. That's just a statement.  
4 Thank you.

5 MODERATOR WEST: Thank you for the  
6 comment. Please.

7 MS. TECHAV: Okay, 2.9(c)(1), added that  
8 the MRO shall give the individual an opportunity to  
9 discuss the test results or other occurrence, any type  
10 of program violation with him or her. So if somebody  
11 refuses the test, they have to be afforded the  
12 opportunity to talk to the MRO. And then also,  
13 somebody who violates like the 5-hour rule, they also  
14 have to be afforded the opportunity to talk to the  
15 MRO? Section 2.9(c)(1).

16 MODERATOR WEST: It's page 57. I'll just  
17 read the portion again.

18 Before making a final decision to verify  
19 a laboratory confirmed positive test result, and  
20 additional language, of the occurrence that would  
21 constitute an FFD policy violation with the associated  
22 example, attempted subversion, the MRO shall give the  
23 individual an opportunity discuss the test result or  
24 other occurrence with him or her. And I believe you  
25 gave some --

26 MS. TECHAV: So somebody who refuses to  
27 test and somebody that violates like the 5-hour rule  
28 should be afforded the opportunity to talk to the MRO  
29 or must be?

30 MODERATOR WEST: I believe the answer to  
31 that in terms of someone that's refusing to test would  
32 be yes, given that -- under the new rule, it's my  
33 recollection that that's a violation of the licensee's  
34 Fitness-for-duty policy.

35 MS. TECHAV: Yes, it is.

36 MODERATOR WEST: So I think the answer on  
37 that one would be yes.

38 MR. MIZUNO: I concur.

39 MS. TECHAV: Okay, then 2.9(c)(ii).

40 MODERATOR WEST: Okay, your question?

41 MS. TECHAV: And for the 5-hour rule, did  
42 you say yes to both?

43 MODERATOR WEST: No, I didn't say yes to  
44 the 5-hour rule. Could you tell us a little bit about  
45 that?

46 MS. TECHAV: Somebody who admits to  
47 drinking 5 hours prior to their assigned work time.  
48 You have a for cause test and they're positive, any  
49 type of violation like that?

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1 MODERATOR WEST: I think the answer to  
2 that one would also be yes. Would you agree, Geary?  
3 Given that they're supposed to abstain 5 hours prior  
4 to working on a shift.

5 We'll give you an initial yes on that one  
6 as well.

7 MR. FITZSIMMONS: I'd like some  
8 clarification on an individual who refuses to test.  
9 The individual gets up and walks out, leaves the  
10 facility. How do we get him to the MRO if he's not  
11 even going to test? If the individual leaves, he  
12 doesn't have the opportunity -- he's not going to talk  
13 to the MRO. Does that mean we do not constitute that  
14 as a failure to test or a  
15 Fitness-for-duty violation?

16 MODERATOR WEST: I think you would -- if  
17 I hear your question correctly, I think you would  
18 clearly count that as a violation of the licensee's  
19 Fitness-for-duty policy.

20 MR. FITZSIMMONS: Okay, but you just  
21 previously said that an individual who refuses a test  
22 must go and talk to the MRO. Isn't that what I heard.

23 MR. SMITH: Afforded the opportunity.

24 MODERATOR WEST: No, afforded the  
25 opportunity.

26 MR. FITZSIMMONS: Okay, so if he refuses  
27 that, okay. All right, thank you.

28 MODERATOR WEST: I think also the aspect  
29 of affording the opportunity is covered in a question  
30 in NUREG 1385 as well.

31 While I'm thinking of this, I think it  
32 would perhaps be appropriate to consider a revision 1  
33 perhaps to NUREG 1385. It's clear that there's  
34 certain information there that continues to be  
35 relevant to the new rule and my further thinking on  
36 this, not that I've given a whole lot of thought to  
37 it, but it would essentially deal with an issue of not  
38 having two different documents that you'd have to go  
39 to. You'd essentially have the Rev. 1 that would  
40 supersede the other one, cleanly, but yet at the same  
41 time roll over any relevant information.

42 Yes?

43 MS. TECHAV: Okay, 2.9(c)(2)(ii). Page  
44 58.

45 MODERATOR WEST: Yes.

46 MS. TECHAV: It talks about prior to  
47 making a final decision. The MRO, after making all  
48 reasonable efforts has been unable to contact the

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1 individual within 14 days under which the MRO receives  
2 notice of the lab, confirmed positive test results.

3 Does this mean that the full 14 days need  
4 to pass before declaring a violation?

5 MODERATOR WEST: I think here again if I  
6 recall accurately, I think aspects of this may be  
7 covered in NUREG 13.85.

8 Does anyone at the table have any --

9 MR. MIZUNO: Okay, I just want to  
10 understand this; (c)(2) says MRO may verify a  
11 laboratory confirmed positive test result or otherwise  
12 make a determination of an FFD policy violation  
13 without having discussed the test result in these  
14 three circumstances. So yes, if you want to take  
15 advantage of (c)(2)(ii) and that provision only, you  
16 do have to wait under (c)(2)(ii) for 14 days to pass  
17 and make reasonable attempts to contact. But if you  
18 choose to go down some other route in order to -- for  
19 the MRO to declare a Fitness-for-duty violation, you  
20 don't have to wait 14 days.

21 MS. TECHAV: So the licensee can set  
22 different expectations, proceduralize-type?

23 MODERATOR WEST: Different than what?

24 MR. MIZUNO: So long as you --

25 MS. TECHAV: That's what he just said that  
26 we can --

27 MR. MIZUNO: So long as you -- if you  
28 choose to do some other way of attempting to contact  
29 the person and provide them the opportunity under  
30 either (1) or (3). I mean for example, if you have a  
31 situation, okay, of confirmed positive test result and  
32 then you contact the individual and they expressly  
33 decline the opportunity to discuss it, you can make  
34 your -- once you hang up that phone, you can make that  
35 determination that there is an FFD policy violation at  
36 that moment, because you're doing it under (c)(2)(i).

37 If you haven't been able to contact them,  
38 however, and you don't have (3), okay, I assume (3)  
39 doesn't apply, yes, then you do have to wait for 14  
40 days to pass before you can declare the FFD policy  
41 violation.

42 MS. DURBIN: Okay, I think I can say  
43 something about what we expected here. If the  
44 individual is working on your site, the MRO should be  
45 able to contact them very rapidly and so this two week  
46 was someone who's left the site, isn't working for  
47 you, you can't get a hold of them, they don't get back  
48 to you in two weeks. You haven't been able to get a

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1 hold of them. You can declare a confirmed and report  
2 it to other licensees as a confirmed.

3 MR. MIZUNO: Right, (3) is the one that  
4 talks about the -- Roman 3 is the one where the guy is  
5 on site. If he's on site and you've documented  
6 contact and we can argue about whether the contact is  
7 actually you have to talk to him as opposed to leaving  
8 him a notice in his locker, for example, and  
9 instructed him, if that notice says contact the MRO  
10 within 5 days and 5 days go by, you haven't heard from  
11 that person, okay.

12 MS. DURBIN: As I said, we're assuming  
13 that MRO, if they're working at the plant, that the  
14 MRO can contact them in a much shorter period, so it's  
15 -- these were for circumstances of difference absence  
16 categories and the 2 weeks was, as I said,  
17 specifically for somebody who has left the site. You  
18 can't get a hold of them and it was so that you're not  
19 stuck with an unconfirmed positive test result because  
20 -- or laboratory confirmed positive test result and  
21 you don't know what to say when they -- you can  
22 confirm it, it's a violation and they do have the  
23 right to appeal it and reopen.

24 MR. SHULTS: Can I make a comment about  
25 that before your next question? Because these again  
26 are rules that are derived from DOT's practices with  
27 the 5-day and the 14-day rule. They have changed that  
28 and reduced it in their new rule to being 5 days and  
29 72 hours. But even with that, to some transportation  
30 concerns, it's been problematic.

31 For example, the concept of having  
32 somebody who is in your -- performing safety sensitive  
33 functions who knows they're positive and has been told  
34 to contact the MRO, it's just a sense of great  
35 uneasiness that an airline would have, for example,  
36 somebody out there who had 5 days to contact the MRO.

37 So the point I'd like to make is that what  
38 a lot of employers have done is they haven't vitiated  
39 their own management responsibilities. In other  
40 words, many employers will say to that individual who  
41 is in the DOT program call the MRO in two hours or  
42 else. And they can do that. Now it's not conforming  
43 with this regulation, but you don't -- don't forget  
44 you have your own sort of management prerogative in  
45 this area. And many -- that's exactly how a lot of  
46 DOT companies deal with that. They'll basically give  
47 them notice that they have to contact -- and if they  
48 don't do it, it's basically in subordination and  
49 they're removed from duty based upon insubordination.

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1 MS. TECHAV: We cannot take any action on  
2 a presump. positive. We'll get a violation for doing  
3 just that.

4 MS. DURBIN: It's a laboratory confirmed  
5 positive test result, not a presump.

6 MS. TECHAV: But without them talking to  
7 the donor, we cannot take any action.

8 MR. MIZUNO: But he's not taking action on  
9 the basis of the laboratory test I think is his point.

10 MR. SHULTS: Right, exactly.

11 MR. MIZUNO: He's taking the basis on the  
12 subordination which is a non-FFD issue.

13 MR. SHULTS: Right, exactly. It's  
14 basically a directive that you're giving to contact  
15 the MRO. That's -- and if they fail to do that, it's  
16 the failure to follow that directive that's the  
17 violation that you are removing him for. Again, I  
18 understand how this has all gotten convoluted, but  
19 think it through.

20 MS. TECHAV: Well, and then 29(c)(2)(iii)  
21 kind of goes hand in hand with the previous one  
22 because there was an addition added that a licensee  
23 representative has successfully made documented  
24 contact with the individual and instructed him or her  
25 to contact the MRO and more than five days have passed  
26 since the date of that individual's contact. Since we  
27 can't take any action on uncovered positive, this  
28 allows the individual to continue to working in the  
29 plant for 5 days.

30 If we've got documented that they were  
31 told to contact the MRO, now we're going to have to  
32 sit there and say okay, did he call? Did he call?  
33 Did he call? Did he call? And administratively, make  
34 sure that that is happening and for five days he could  
35 be working in our plant with unsafe conditions.

36 MS. DURBIN: That wasn't the intent of  
37 this change, so we can look at that.

38 MODERATOR WEST: I was thinking if you --  
39 I acknowledge what you were saying. It certainly  
40 wasn't the intent, but if you had some --

41 MS. TECHAV: I just want it documented so  
42 we can look at that.

43 MR. MIZUNO: I wouldn't say that. See, I  
44 have to go back and look at it. I think you have some  
45 independent authority to remove a person immediately  
46 on the basis of current information that shows they're  
47 unfit for duty, okay?

48 The problem is that a confirmed positive  
49 that occurred testing five, whatever days ago, no

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1 longer provides you a basis for saying that they are  
2 at that point in time unfit for duty, but that  
3 authority to immediately remove somebody on a current  
4 basis for believing that they are unfit for duty  
5 exists, okay? So you always have the authority and  
6 indeed the responsibility to assure yourself that  
7 every person who comes on site, every time he comes on  
8 site and enters that protected area, that he is fit  
9 for duty. And if you have any -- if you have  
10 reasonable belief that he is not, you may immediately  
11 prevent that person from entering --

12 MODERATOR WEST: Through other parts of  
13 the regulation.

14 MR. MIZUNO: Yes, yes. The only thing  
15 we're dealing with here is when you have the positive  
16 HHS lab test.

17 MODERATOR WEST: Thank you.

18 MS. TECHAV: Okay, and 2.9(c)(3). It was  
19 added that the MRO can reopen a case that the  
20 individual can present to the MRO information  
21 documenting reasons why they did not contact him or  
22 her? I mean there's no time frame specified here, so  
23 a year later somebody comes back and gives them the  
24 information? We may have a reversal possibly and so  
25 how do we report that and document that? Well, we can  
26 document that, but how to report that?

27 MODERATOR WEST: The time frame for the  
28 MRO having that discretion?

29 MS. TECHAV: Well, in 2.9(c)(3) it says  
30 that the MRO can reopen the case if the person can  
31 give them information documenting reasons why they  
32 didn't contact the MRO.

33 So they didn't contact the MRO initially.  
34 The MRO declared it a positive test and now the guy is  
35 coming back and saying well, hey, I was in the  
36 hospital, I was unconscious, I was in a coma, I was  
37 whatever a year later and we had already had a  
38 positive test and now it's going to come back and be  
39 possibly a negative test?

40 MODERATOR WEST: The individual wouldn't  
41 still be in the employ of the MRO, excuse me, the  
42 licensee?

43 MS. TECHAV: Who knows? It doesn't  
44 matter. I just wanted some guidance on how to deal  
45 with that reporting.

46 MODERATOR WEST: We can take that one as  
47 an action item as well. Thank you for the question.  
48 We'll take a question or comment over there.

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1 MR. BUCHER: This is just an issue of  
2 intent, 29(c)(1), the MRO has established that indeed  
3 there was an occurrence of violation and then the MRO  
4 to immediately notify the EAP and licensee management  
5 official. What is the intent of notifying the EAP  
6 consequent to the establishment of a violation?

7 MODERATOR WEST: Well, I guess -- is there  
8 something about this in terms of the new rule? I mean  
9 that's essentially what's in the current rule.

10 MR. BUCHER: I'm asking what is the intent  
11 of contacting the EAP at that point? If you've  
12 established the violation through the MRO, the MRO  
13 would more than likely notify management to take  
14 appropriate action. What's the intent of notifying  
15 EAP? And I realize that there's not a change, but I'm  
16 asking the intent question.

17 MODERATOR WEST: Does anyone at the table  
18 have any insight on that?

19 Is it possibly that the individual --  
20 would you assume here that the individual is involved  
21 in some EAP program?

22 MR. BUCHER: That assumption is not  
23 merited.

24 MR. MIZUNO: Is the question why is there  
25 a requirement under (c)(1) to notify the EAP  
26 immediately or to notify the EAP at all?

27 Before Loren goes, let me just say --

28 MR. BUCHER: The point is you've got an  
29 FFD violation that's been established by the MRO.

30 MODERATOR WEST: I hear what you're  
31 saying.

32 MR. BUCHER: What is the EAP going to do  
33 that in a sense management would not dictate to the  
34 EAP and management, in turn, would take the  
35 appropriate action. If it's second violation, why  
36 notice via EAP, the person may have been terminated.

37 MS. DURBIN: I think it says, isn't this  
38 after it says "as provided by the licensee's policy?"  
39 I think -- so if the policy requires that you talk to  
40 the EAP, then you talk to the EAP. I guess.

41 MR. BUCHER: I don't read it that way.  
42 Let me hear from Loren then.

43 MODERATOR WEST: I think that's a  
44 reasonable

45 --

46 MR. BUSH: We wanted to make sure that the  
47 EAP was earning its money.

48 (Laughter.)

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1           Actually, I think there's an assumption on  
2 our part that as described elsewhere in the rule in  
3 many locations that people who've tested positive have  
4 been sent part of their chain of actions to include  
5 being referred to EAP for counseling and follow-up  
6 treatment and all that sort of thing. There's a  
7 general assumption that there's not going to be too  
8 many second positives, so we don't write the rule to  
9 address those infrequent incidents. We wrote it  
10 address the more frequently occurring thing. It  
11 shouldn't be a problem, I wouldn't think. I would  
12 think the EAP would want to know there's one less  
13 person that they will have coming in for counseling.

14           (Laughter.)

15           MODERATOR WEST: Thank you, Loren. Yes?

16           MR. BOISMENU: Brett Boismenu, Nine Mile  
17 Point Nuclear.

18           Maybe there's a disconnect here and this  
19 has to do with the reporting of the results from the  
20 MRO. If you look at the strikeout page on page 14 it  
21 says "should the MRO review not be completed within 14  
22 days of the collection of the specimen" and then when  
23 you go over to page 58 it says "14 days from the date  
24 of which the MRO received results."

25           Are they talking about the same thing?

26           MODERATOR WEST: And you're referring in  
27 14 on page 14, under (f), should the MRO's review not  
28 be completed within 14 days of the collection of a  
29 specimen, licensee management must be advised of  
30 available test results, the status of the review, the  
31 reasons for the delay, so that one is saying --

32           MR. BOISMENU: They need to know within 14  
33 days from collection.

34           MODERATOR WEST: So what's the -- is your  
35 question what's the reference point there?

36           MR. BOISMENU: Well, there's a disconnect.  
37 It's almost like they need to know within 14 days from  
38 collection here. As you go, on page 58, it says the  
39 MRO can take an additional two weeks from when he  
40 receives the results. Am I not reading it right, or  
41 is there a disconnect?

42           MS. DURBIN: Actually, I think this is  
43 useful to the earlier question. On page 14,  
44 regardless of whether it's been a confirmed positive  
45 test result, it says that you can notify licensee  
46 management after 14 days of the status which might be,  
47 we have a laboratory confirmed positive test result,  
48 but we haven't been able to contact the individual.  
49 So that's the 14 days from the date of the test.

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1           The other one is 14 days after you've  
2           tried to contact the individual, if they haven't  
3           gotten back to you, then you've declared a confirmed  
4           positive test and it's done.

5           The first one is you notify management of  
6           the status at 14 days and the status may be that it's  
7           not yet confirmed because you have not yet contacted  
8           the individual. So what this is saying is that after  
9           14 days you have to tell management what's going on,  
10          even if you haven't been able to contact the  
11          individual.

12          MR. MIZUNO: To put it another way, on  
13          page 14, the 14-day limit there was intended to assure  
14          that the MRO just doesn't sit around and management  
15          doesn't lose sight of what's going on. It kind of is  
16          a ticker that says MRO, I mean basically it's an MRO  
17          saying gee, if I have to tell my management that I'm  
18          14 days on this, I better make sure that I've done  
19          everything possible to get this thing cleared out or  
20          else I have some valid reason for holding on it. But  
21          that really is separate than from the 14 days which is  
22          on page 58 and as I recall that was just arrived from  
23          the HHS guidelines as to a due process concern. It  
24          has nothing to do, whereas on F, on page 14, that's  
25          more an internal --

26          MR. BOISMENU: A status report?

27          MR. MIZUNO: A status report -- really, it  
28          was intended to assure that the process, internal  
29          process within the licensee proceed in the most  
30          expeditious fashion and that the MRO be required to  
31          explain why there is any delay beyond 14 days.

32          MODERATOR WEST: Does that answer your  
33          question? Thank you.

34          I wish to thank you, not only for the many  
35          insights, inputs, additional questions that you've  
36          given us, but also for your patience over the last  
37          couple of days.

38          I'd just like to take a few minutes to  
39          make some closing remarks and then we'll get Mr.  
40          Enkeboll a chance to also make some closing remarks.  
41          I think it's clear that beyond the questions that  
42          you've submitted to us in advance, there's certainly  
43          some additional ones that we need to be entertaining  
44          and working on as well and I might add that will  
45          certainly also allow you even if there are questions  
46          downstream of the workshop to provide any additional  
47          ones that come up and the way to do that would be I  
48          think the preferred way on my end at least would be to  
49          do it through the Fitness-for-duty web page and some

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1 of you have asked me how do you get to the Fitness-  
2 for-duty web page.

3 If you are familiar with the external web  
4 page for the NRC, if you take that path and I can  
5 bring you the exact address tomorrow, what you would  
6 do would be to click on the external web page and  
7 then, in turn, you'll see the various icons. You  
8 select the ones, the one for the reactor icon and  
9 then, in turn, you'll have various -- an alphabetical  
10 listing, including the Fitness-for-duty web page.  
11 That's one route.

12 On that web page, you'd have the option of  
13 either the Fitness-for-duty mailbox which is one of  
14 the standard features up at the top or you'd have a  
15 comment box that's provided there under the question  
16 and answers or comment section. So that would be one  
17 possibility. Or you could just send it, even if you  
18 weren't on the web page, you could just send it  
19 directly to the Fitness-for-duty at nrc.gov. And  
20 coming to that particular mailbox certainly helps to  
21 sort of sort out my incoming, my other type of  
22 incoming e-mails versus the ones that are specific to  
23 your questions.

24 But I think generally speaking what we  
25 would propose to do would be to, as I've mentioned,  
26 throughout the workshop to ultimately have a NUREG  
27 type document that will capture the generic type  
28 questions and answers, but we would certainly start  
29 off with trying to capture all of them from the  
30 transcript. It takes about 7 days for us to get the  
31 transcript and we would expect to go through that  
32 transcript and identify all of your questions. And  
33 then make an additional cut on what the questions are  
34 available to you, so you can take a look at those to  
35 make sure we captured the questions properly.

36 And then there would be perhaps several  
37 methods that we could perhaps use for both the  
38 questions and the answers that we could have you to  
39 take a look at before we eventually publish the final  
40 NUREG and with the input of my management and  
41 certainly the Commission relative to the  
42 implementation date of the final rule, the staff  
43 recommendation at least would be to try to get the  
44 NUREG question and answer type document issued prior  
45 to the implementation and understand clearly what  
46 implementation means on your end when it actually goes  
47 in the Federal Register as has been explained.

48 Beyond that, I think big picture of what  
49 we're considering is collecting hopefully the totality

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1 of what you've told us today, not simply the questions  
2 and the answers, focusing on that, but also some of  
3 your concerns about the rule itself and here again,  
4 one of the benefits of the transcription, it allows us  
5 to be able to go back and do that in some systematic  
6 way. But that will provide us with a means to brief  
7 management.

8 And by that I mean to make it known up the  
9 management chain. We would also propose to brief the  
10 Commission with respect to the technical assistance  
11 with regard to your concerns about the rule such that  
12 hopefully I'm conveying that it's not simply  
13 restricted to the questions and answers that you've  
14 raised, but some of the broader concerns you have  
15 about costs and so on.

16 So that's the overall plan and certainly  
17 there are some details of scheduling and so forth that  
18 we need to work out a little bit better. And again,  
19 I thank you for your taking the time to spend a couple  
20 of days and even an additional day, tomorrow, with us.

21 I'll let Mr. Enkeboll have an opportunity.  
22 After he finishes, I'll make a few brief comments on  
23 tomorrow.

24 Please.

25 MR. ENKEBOLL: Rich Enkeboll, NEI. On  
26 behalf of the Nuclear Energy Institute, we thank you  
27 for the opportunity to discuss our concerns with the  
28 new Fitness-for-duty rule. We think this should have  
29 been done a long time ago.

30 The industry Fitness-for-duty Task Force  
31 meets tomorrow at NEI to evaluate how to challenge the  
32 premise that since the Commission has approved the  
33 rule that it is a done deal. It will delay access.  
34 It will overturn 10 years of a process that has been  
35 working. It has been five years working without  
36 stakeholder evaluation, interaction. The rule is not  
37 risk-informed. It is not performance-based and not in  
38 concert with the direction the Agency is going in the  
39 other areas like regulatory oversight process. We  
40 will work directly with the Commission for those  
41 concerns.

42 That said, the industry will work with the  
43 staff as appropriate to provide comments for  
44 consideration in the impending NUREG or other  
45 clarification document. We would prefer that this be  
46 interactive, face-to-face, to avoid misunderstandings.

47 Any other comments from the industry?

48 MODERATOR WEST: Thank you for your  
49 comments. With respect to tomorrow, certainly a much

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1 shorter day, we will get started here at the same area  
2 at 9 o'clock. We're scheduled to go until 10:30,  
3 however, we do, in fact, have the room for longer than  
4 that, just to emphasize the fact we're not going to  
5 get kicked out at 10:30. And the topic is separate  
6 from this larger rulemaking effort is a proposed  
7 amendment to Part 26 that would essentially amend Part  
8 26 with regard to the scope of random testing and  
9 would redefine it simply in terms of random testing  
10 relative, instead of the protected area, would  
11 redefine it in terms of the vital area.

12 I just throw that out to give you sort of  
13 an overview of it and what we will do is hand out the  
14 handouts with respect to -- and this essentially tells  
15 you in a nutshell where the rulemaking effort is. We  
16 would provide you a copy of the rulemaking plan which  
17 is SECY 00-0022 and I think the way to view this is  
18 that it's an attempt, similar to this particular  
19 workshop over the last two days, but much earlier in  
20 the process if you will, to get your comments. We'll  
21 have to treat them as public comments relative to the  
22 proposed rule.

23 We're not quite there yet with regard to  
24 the proposed rule, but this would be viewed as a  
25 preliminary effort to get stakeholders' views on and  
26 we'll have to couch it in terms of the rulemaking  
27 plan, rather than -- because we can't talk from a  
28 predecisional perspective with regard to the proposed  
29 rule, but we thought since you were here, principally  
30 for the larger role it would certainly be advantageous  
31 to provide the opportunity to even give some limited  
32 time to consideration of the proposed amendment. So  
33 on that note unless anyone else has any from the table  
34 or elsewhere has additional closing remarks, I thank  
35 you again and look forward to seeing you tomorrow.

36 (Whereupon, at 4:23 p.m., the workshop was  
37 recessed to reconvene tomorrow, Thursday, March 22,  
38 2001 at 9:00 a.m.)  
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